| Recruitment <br> Status | Condition | Intervention | Phase | $\begin{aligned} & \text { Study } \\ & \text { type } \end{aligned}$ | Study design | Target size | Primary outcome | Secondary outcome | Date enrollement |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| Recruiting | Gastric | Drug: | Phase | Interve | Allocation: | 60 | The 1-year |  | 01/04/2021 |
|  | Cancer | tirelizumab;D | 2 | ntional | Non- |  | DFS rate |  |  |
|  |  | rug: |  |  | Randomize |  |  |  |  |
|  |  | chemotherap |  |  | d. |  |  |  |  |
|  |  | $y$ with |  |  | Intervention |  |  |  |  |
|  |  | oxaliplatin + |  |  | model: |  |  |  |  |
|  |  | heroda |  |  | Parallel |  |  |  |  |
|  |  |  |  |  | Assignment. |  |  |  |  |
|  |  |  |  |  | Primary |  |  |  |  |
|  |  |  |  |  | purpose: |  |  |  |  |
|  |  |  |  |  | Treatment. |  |  |  |  |
|  |  |  |  |  | Masking: |  |  |  |  |
|  |  |  |  |  | None (Open |  |  |  |  |
|  |  |  |  |  | Label). |  |  |  |  |


| Not | gastric | patient | Diagn | Cause | Case study | patient | Progress | Free | 29/03/2023 |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| Recruiting | cancer | group:immu | ostic | /Relati |  | group: | Survival;Disease control |  |  |
|  |  | notherapy; | New | ve |  | 50; | rate;adverse |  |  |
|  |  |  | Techni | factors |  |  | events;Lymph | hocyte |  |
|  |  |  | que | study |  |  | subpopulatio | ns and |  |
|  |  |  | Clincal |  |  |  | cytokine level |  |  |
|  |  |  | Study |  |  |  |  |  |  |
| Recruiting | Esophagus | Drug: | Phase | Interve | Allocation: | 32 | Rate of | Rate of | 01/08/2023 |
|  | Adenocarci noma | Durvalumab; | 2 | ntional | N/A. |  | clinical | cCR/pCR |  |
|  |  | Drug: |  |  | Intervention |  | and | (long term |  |
|  |  | FLOT;Drug: |  |  | model: |  | pathologic | follow |  |
|  |  | mFOLFOX- |  |  | Single |  | al | up);Subgro |  |
|  |  | 6;Radiation: |  |  | Group |  | complete | up analysis |  |
|  |  | Radiotherapy |  |  | Assignment. |  | response | of |  |
|  |  |  |  |  | Primary |  | (cCR/pCR | cCR/pCR; |  |
|  |  |  |  |  | purpose: |  | ) | Rate of |  |
|  |  |  |  |  | Treatment. |  |  | salvage |  |


|  |  |  |  |  | Masking: |  |  | surgery;M |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  |  |  |  |  | None (Open |  |  | ortality;De |  |
|  |  |  |  |  | Label). |  |  | terminatio |  |
|  |  |  |  |  |  |  |  | n of the sites of |  |
|  |  |  |  |  |  |  |  | tumor |  |
|  |  |  |  |  |  |  |  | relapse;Saf ety |  |
|  |  |  |  |  |  |  |  | Endpoints |  |
| Recruiting | Immunothe | Drug: | Phase |  | Allocation: | 130 | Pathologic | Major | 10/05/2023 |
|  | rapy | Tislelizumab; | 2/Phas | ntional | Randomize |  | al | pathologic |  |
|  | Gastrict | Drug: | e 3 |  | d. |  | complete | al |  |
|  | Cancer | apatinib;Dru |  |  | Intervention |  | response | response;O |  |
|  |  | g : |  |  | model: |  |  | bjective |  |
|  |  | oxaliplatin;Dr |  |  | Parallel |  |  | Response |  |
|  |  | ug: S-1 |  |  | Assignment. |  |  | Rate (ORR) |  |
|  |  |  |  |  | Primary |  |  |  |  |



|  |  |  |  |  |  |  |  | S);R0 |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  |  |  |  |  |  |  |  | resection |  |
|  |  |  |  |  |  |  |  | rate;Adver |  |
|  |  |  |  |  |  |  |  | se events |  |
| Not | Advanced | Drug: | Phase | Interve | Allocation: | 59 | Objective | Progressio | 01/11/2022 |
| recruiting | Gastric or | Serplulimab; | 2 | ntional | N/A. |  | response | n -free |  |
|  | Gastroesoph | Drug: |  |  | Intervention |  | rate (ORR) | survival |  |
|  | ageal | Lenvatinib;D |  |  | model: |  |  | (PFS);Over |  |
|  | Junction | rug: |  |  | Single |  |  | all survival |  |
|  | Adenocarci | Paclitaxel |  |  | Group |  |  | (OS);Disea |  |
|  | noma |  |  |  | Assignment. |  |  | se Control |  |
|  |  |  |  |  | Primary |  |  | Rate |  |
|  |  |  |  |  | purpose: |  |  | (DCR);Dur |  |
|  |  |  |  |  | Treatment. |  |  | ation of |  |
|  |  |  |  |  | Masking: |  |  | Overall |  |
|  |  |  |  |  | None (Open |  |  | Response |  |
|  |  |  |  |  | Label). |  |  | (DOR);Safe |  |


|  |  |  |  |  |  |  |  | ty and |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  |  |  |  |  |  |  |  | tolerability |  |
|  |  |  |  |  |  |  |  | based on |  |
|  |  |  |  |  |  |  |  | incidence |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  | treatment- |  |
|  |  |  |  |  |  |  |  | emergent |  |
|  |  |  |  |  |  |  |  | adverse |  |
|  |  |  |  |  |  |  |  | events as |  |
|  |  |  |  |  |  |  |  | assessed |  |
|  |  |  |  |  |  |  |  | by CTCAE |  |
| Recruiting | Immunothe | Drug: | Phase | Interve | Allocation: | 200 | Pathologic | Major | 01/09/2022 |
|  | rapy;Gastric | Terelizumab; | 2 | ntional | Non- |  | al | pathologic |  |
|  | Cancer;Rect | Drug: |  |  | Randomize |  | complete | response |  |
|  | al | CapeOx;Drug |  |  | d. |  | response;O | (MPR);Ove |  |
|  | Cancer; Che | : |  |  | Intervention |  | RR | rall |  |
|  | motherapy | Trastuzumab; |  |  | model: |  | (objective | survival |  |


|  | Effect;Radio | Radiation: |  |  | Parallel |  | response | (OS);Disea |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  | therapy | Radiotherapy |  |  | Assignment. |  | rate) per | se-free |  |
|  |  |  |  |  | Primary |  | RECIST 1.1 | survival |  |
|  |  |  |  |  | purpose: |  |  | (DFS);R0 |  |
|  |  |  |  |  | Treatment. |  |  | resection |  |
|  |  |  |  |  | Masking: |  |  | rate |  |
|  |  |  |  |  | None (Open |  |  |  |  |
|  |  |  |  |  | Label). |  |  |  |  |
| Not |  |  | Phase | Interve | Allocation: | 141 |  |  | 25/08/2022 |
| recruiting |  |  | 2 | ntional | Randomize |  |  |  |  |
|  |  |  |  |  | d. |  |  |  |  |
|  |  |  |  |  | Intervention |  |  |  |  |
|  |  |  |  |  | model: |  |  |  |  |
|  |  |  |  |  | Parallel |  |  |  |  |
|  |  |  |  |  | Assignment. |  |  |  |  |
|  |  |  |  |  | Primary |  |  |  |  |
|  |  |  |  |  | purpose: |  |  |  |  |


|  |  |  |  |  | Treatment. |  |  |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  |  |  |  |  | Masking: |  |  |  |  |
|  |  |  |  |  | None (Open |  |  |  |  |
|  |  |  |  |  | Label). |  |  |  |  |
| Not | Gastric | Gold | Diagn | Diagn | Diagnostic | Target | Objective | Objective | 11/06/2022 |
| Recruiting | cancer | Standard:The | ostic | ostic | test for | conditi | response | response |  |
|  |  | effect of | New | test | accuracy | on:286; | rate after | rate after |  |
|  |  | immunothera | Techni |  |  | Difficu | the second | fourth |  |
|  |  | py and | que |  |  | lt | treatment | treatment |  |
|  |  | chemotherap | Clincal |  |  | conditi | period; | period;Pat |  |
|  |  | $y \quad$ by | Study |  |  | on:0 |  | hological |  |
|  |  | abdominal |  |  |  |  |  | complete |  |
|  |  | enhanced CT |  |  |  |  |  | response |  |
|  |  | (according to |  |  |  |  |  | rate;3 year |  |
|  |  | RECIST V1.1 |  |  |  |  |  | overall |  |
|  |  | standard);Ind |  |  |  |  |  | survival |  |
|  |  | ex |  |  |  |  |  | rate;3 year |  |


|  | test:The\&\#32; |  |  |  | disease- |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  | effect\&\#32;of |  |  |  | free |  |
|  | \&\#32;immun |  |  |  | survival |  |
|  | otherapy\&\#3 |  |  |  | rate;Diseas |  |
|  | 2;and\&\#32;ch |  |  |  | e control |  |
|  | emotherapy \& |  |  |  | rate;3 year |  |
|  | \#32;by\&\#32; |  |  |  | progess- |  |
|  | protein\&\#32; |  |  |  | free |  |
|  | profiling; |  |  |  | survival |  |
|  |  |  |  |  | rate; |  |
| Recruiting | Unresectable Gastric Cancer | Observ | 100 | Surgical |  | 01/06/2022 |
|  |  | ational |  | conversion | resection |  |
|  |  |  |  |  | rate;Major |  |
|  |  |  |  |  | pathologic |  |
|  |  |  |  |  | al response |  |
|  |  |  |  |  | (MPR);Ove |  |
|  |  |  |  |  | rall |  |



| Advanced | including | Randomize | CTC;Incidence rate of |
| :---: | :---: | :---: | :---: |
| Gastric | blood and | d. | ctDNA deletion, |
| Cancer | tissue | Intervention | amplification, insertion |
|  | collection;Pro | model: | and other types of |
|  | cedure: CTC | Parallel | variation evaluated by |
|  | detection;Pro | Assignment. | next generation |
|  | cedure: | Primary | sequence(NGS).;Proport |
|  | ctDNA | purpose: | ions of lymphocytes, |
|  | detection;Pro | Screening. | stromal cells, tumor cells |
|  | cedure: 10 脳 | Masking: | in tumor tissue assessed |
|  | genomics | None (Open | by single cell |
|  | single cell | Label). | transcriptome |
|  | RNA |  | sequence.;Incidence rate |
|  | sequence;Pro |  | of gene deletion |
|  | cedure: |  | amplification, insertion |
|  | Whole exon sequence;Pro |  | and other types of variation of tumor |


| Recruiting | Immunothe rapy;Gastric t Cancer | cedure: <br> Proteomics <br> detection | Phase <br> 2 | Interve ntional | Allocation:N/A. | 40 | evaluated by whole exon sequence(WES).;Tumor associated proteins expression level of tumor |  | 31/10/2021 |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  |  |  |  |  |  |  |  |  |  |
|  |  | Drug: |  |  |  |  | Total/mod | Objective |  |
|  |  | Tislelizumab; |  |  |  |  | erate | Response |  |
|  |  | Drug: |  |  | Intervention |  | tumor | Rate |  |
|  |  | Apatinib |  |  | model: |  | regression | (ORR);Ove |  |
|  |  | Mesylate;Dru |  |  | Single |  | rate under |  |  |
|  |  | g : |  |  | Group |  | pathology | survival |  |
|  |  | oxaliplatin;Dr |  |  | Assignment. |  |  | (OS) |  |
|  |  | ug: Tegafur |  |  | Primary |  |  |  |  |
|  |  |  |  |  | purpose: |  |  |  |  |
|  |  |  |  |  | Treatment. |  |  |  |  |
|  |  |  |  |  | Masking: |  |  |  |  |


| Recruiting |  |  |  | Interve ntional | None (Open Label). | 31 | Objective <br> Response | Progressio <br> n -free | 15/02/2022 |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  | Gastric | Drug: | Phase |  | Allocation: |  |  |  |  |
|  | Cancer; Che | Sintilimab | 2 |  | N/A. |  |  |  |  |
|  | motherapy;I | 200 mg, |  |  | Intervention |  | Rate (ORR) | Survival |  |
|  | mmunother | intravenously |  |  | model: |  |  | (PFS);Dise |  |
|  | apy | (IV) every 3 |  |  | Single |  |  | ase Control |  |
|  |  | weeks(Q3W) |  |  | Group |  |  | Rate |  |
|  |  |  |  |  | Assignment. |  |  | (DCR);Dur |  |
|  |  |  |  |  | Primary |  |  | ation of |  |
|  |  |  |  |  | purpose: |  |  | Response |  |
|  |  |  |  |  | Treatment. |  |  | (DoR);Adv |  |
|  |  |  |  |  | Masking: |  |  | erse events |  |
|  |  |  |  |  | None (Open |  |  | (AEs) |  |
|  |  |  |  |  | Label). |  |  |  |  |



|  | carcinoma; | group:Liquid |  |  |  | ns or |  |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  | Advanced | biopsy or |  |  |  | no |  |  |  |
|  | gastric | puncture |  |  |  | super- |  |  |  |
|  | cancer | biopsy; |  |  |  | progre |  |  |  |
|  |  |  |  |  |  | ssion <br> group: |  |  |  |
| Not | gastric | case | 0 | Observ | Sequential | 100; case | 68Ga-FAPI | PET/CT | 01/12/2021 |
| Recruiting | cancer | series:Nil; |  | ational |  | series: | related para | meters, PFS, |  |
|  |  |  |  | study |  | 20; | OS; |  |  |
| Recruiting | Advanced | Drug: | Phase | Interve | Allocation: | 115 | Recommen | Pharmaco | 27/08/2021 |
|  | Solid | MDNA11 | 1/Phas | ntional | N/A. |  | ded Dose | kinetic |  |
|  | Tumor;Unre | Monotherapy | e 2 |  | Intervention |  | for | characteris |  |
|  | sectable | ;Drug: |  |  | model: |  | Expansion | tics on |  |
|  | Solid | Combination |  |  | Sequential |  | (RDE) for | MDNA11 - |  |
|  | Tumor;Clea | (MDNA11 + |  |  | Assignment. |  | MDNA11;I | Cmax |  |
|  | r Cell Renal |  |  |  | Primary |  | ncidence of | $(\mathrm{ug} / \mathrm{mL}) ; \mathrm{P}$ |  |


| Cell | pembrolizum | purpose: | Treatment | harmacoki |
| :---: | :---: | :---: | :---: | :---: |
| Carcinoma; | $\mathrm{ab})$ | Treatment. | Related | netic |
| Triple |  | Masking: | Adverse | characteris |
| Negative |  | None (Open | Events | tics on |
| Breast |  | Label). | (TRAEs);In | MDNA11 |
| Cancer;Non |  |  | cidence of | Tmax |
| -Small Cell |  |  | Treatment | (h);Pharma |
| Lung |  |  | Emergent | cokinetic |
| Cancer |  |  | Adverse | characteris |
| Squamous; |  |  | Events | tics on |
| Non-Small |  |  | (TEAEs) | MDNA11 |
| Cell Lung |  |  |  | AUClast |
| Cancer Non- |  |  |  | (h.ug/mL); |
| squamous;C |  |  |  | Pharmaco |
| olorectal |  |  |  | dynamic |
| Cancer |  |  |  | effects of |
| (MSI- |  |  |  | MDNA11; |


| H);Gastric | Anti- |
| :--- | :--- |
| Cancer;Cerv | tumor |
| ical | activity of |
| Cancer;Basa | MDNA11 |
| $1 \quad$ Cell | (alone or in |
| Carcinoma; | combinatio |
| Bladder | n with CPI) |
| Cancer;Mer | Overall |
| kel $\quad$ Response |  |
| Carcinoma; | Rate |
| Squamous | (ORR);Ant |
| Cell | i-tumor |
| Carcinoma | activity of |
| of Head and | MDNA11 |
| Neck;Cutan | (alone or in |
| eous | combinatio |
| Squamous | n with CPI) |

## Cell

Carcinoma;
Pleural
Mesothelio
ma;Esophag
eal
Cancer;Hep
atocellular
Carcinoma;
Endometrial
Carcinoma;
Solid
Tumor;Solid
Tumor,
Adult;MSI-
H Solid
Malignant

- Disease

Control
Rate
(DCR);Ant
i-tumor
activity of
MDNA11
(alone or in
combinatio
n with CPI)

Progressio
n Free
Survival
(PFS)

Tumor;Canc
er With A
High Tumor
Mutational
Burden;Epit
helial
Ovarian
Carcinoma;
Primary
Peritoneal
Cancer;Gast
roesophage
al Junction
(GEJ)
Cancer;Acra
1
Melanoma;

|  | Mucosal |  |  |  |  |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  | Melanoma; |  |  |  |  |  |  |
|  | Cutaneous |  |  |  |  |  |  |
|  | Melanoma; |  |  |  |  |  |  |
|  | DMMR |  |  |  |  |  |  |
|  | Solid |  |  |  |  |  |  |
|  | Malignant |  |  |  |  |  |  |
|  | Tumor;Fallo |  |  |  |  |  |  |
|  | pian Tube |  |  |  |  |  |  |
|  | Cancer |  |  |  |  |  |  |
| Recruiting | Advanced | Device: EV-array | Observ | 40 | EV-Score | Survival | 01/11/2018 |
|  | Gastric |  | ational |  |  | significanc |  |
|  | Adenocarci |  |  |  |  | e of EV- |  |
|  | noma;Immu |  |  |  |  | Score |  |
|  | notherapy |  |  |  |  |  |  |


| Recruiting | Esophageal <br> Cancer;Gast <br> ric Cancer | Procedure: | Observ <br> ational | 10000 | Diagnostic | Epidemiol | 27/04/2020 |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  |  | Surgery;Drug: |  |  | and | ogical |  |
|  |  | Chemotherapy, anti- |  |  | therapeuti | profiles;Ris |  |
|  |  | targeted agents and |  |  | c approach | k |  |
|  |  | immunotherapy;Radia |  |  |  | factors;Pat |  |
|  |  | tion: Radiotherapy |  |  |  | hological |  |
|  |  |  |  |  |  | features; Cl |  |
|  |  |  |  |  |  | inical and |  |
|  |  |  |  |  |  | diagnostic |  |
|  |  |  |  |  |  | approach; |  |
|  |  |  |  |  |  | Treatments |  |
|  |  |  |  |  |  | adjusted to |  |
|  |  |  |  |  |  | prognostic |  |
|  |  |  |  |  |  | variables;V |  |
|  |  |  |  |  |  | alidate and |  |
|  |  |  |  |  |  | compare |  |
|  |  |  |  |  |  | prognostic |  |


|  |  |  |  |  |  | models; Pr |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  |  |  |  |  |  | ognostic |  |
|  |  |  |  |  |  | factors;Cre |  |
|  |  |  |  |  |  | ate and |  |
|  |  |  |  |  |  | validate a |  |
|  |  |  |  |  |  | predictive |  |
|  |  |  |  |  |  | model |  |
| Not | Gastric | Drug: PD-1 inhibitor | Observational | 200 | Predictive | Predictive | 01/06/2021 |
| recruiting | Cancer;Mag |  | [Patient Registry] |  | value of | value of |  |
|  | netic |  |  |  | CT and | CT and |  |
|  | Resonance |  |  |  | MRI after | MRI after |  |
|  | Imaging;To |  |  |  | the | the |  |
|  | mography, |  |  |  | neoadjuva | neoadjuva |  |
|  | X-Ray |  |  |  | nt | nt |  |
|  | Computed; |  |  |  | treatment | treatment |  |
|  | Neoadjuvan |  |  |  | for | for |  |
|  | t |  |  |  | developing | pathologic |  |


| Immunothe | a pCR at T |  |
| :--- | :--- | :--- |
| rapy;Neoadj | surgery | staging;Pre |
| uvant |  | dictive |
| Chemothera | value of |  |
| py | CT and |  |
|  | MRI after |  |
|  | the |  |
|  | neoadjuva |  |
|  | nt |  |
|  | treatment |  |
| for |  |  |



| amino acid | amino acid |
| :--- | :--- |
| and/or | and/or |
| metabolite | metabolite |
| concentrati | concentrati |
| ons, which | ons, which |
| are useful | are useful |
| for | for |
| predicting | predicting |
| overall | progressio |
| survival in | n free |
| patients | survival in |
| treated | patients |
| with anti- | treated |
| PD-1/PL- | with anti- |
| L1 | PD-1/PL- |
| antibody | L1 |


| Recruiting | Gastric | Drug: | Phase | Interve | Allocation: | 40 | objective | progressio | 01/03/2021 |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  | Cancer;Colo | Tislelizumab; | 2 | ntional | N/A. |  | response | n -free |  |
|  | -rectal | Drug: |  |  | Intervention |  | rate | survival;ov |  |
|  | Cancer | Anlotinib |  |  | model: |  |  | erall |  |
|  |  |  |  |  | Single |  |  | survival |  |
|  |  |  |  |  | Group |  |  |  |  |
|  |  |  |  |  | Assignment. |  |  |  |  |
|  |  |  |  |  | Primary purpose: |  |  |  |  |
|  |  |  |  |  | Treatment. |  |  |  |  |
|  |  |  |  |  | Masking: |  |  |  |  |
|  |  |  |  |  | None (Open |  |  |  |  |
|  |  |  |  |  | Label). |  |  |  |  |
| Recruiting | Gastric | Drug: XELOX | Phase | Interve | Allocation: | 110 | Major | Disease- | 12/03/2021 |
|  | Cancer;Sto | or SOX;Drug: | 2 | ntional | Randomize |  | pathologic | free |  |
|  | mach | JS001+XELO |  |  | d. |  | response | survival |  |
|  | Neoplasm | X or SOX |  |  | Intervention |  | (MPR) | (DFS);Over |  |


|  |  |  |  |  | model: |  |  | all |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  |  |  |  |  | Parallel |  |  | survival(O |  |
|  |  |  |  |  | Assignment. |  |  | S);pCR;R0 |  |
|  |  |  |  |  | Primary |  |  | resection |  |
|  |  |  |  |  | purpose: |  |  | rate;Adver |  |
|  |  |  |  |  | Treatment. |  |  | se event |  |
|  |  |  |  |  | Masking: |  |  | incidence |  |
|  |  |  |  |  | Double |  |  | rate |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  | Provider, |  |  |  |  |
|  |  |  |  |  | Outcomes |  |  |  |  |
|  |  |  |  |  | Assessor). |  |  |  |  |
| Recruiting | Gastric | Drug: | Phase | Interve | Allocation: | 60 | Objective | Overall | 19/03/2021 |
|  | Adenocarci | Atezolizuma | 2 | ntional | Non- |  | response | survival; $\operatorname{Pr}$ |  |
|  | noma;Metas | $\mathrm{b}+$ |  |  | Randomize |  | rate | ogression- |  |
|  | tatic Gastric | Ipatasertib;Dr |  |  | d. |  |  |  |  |
|  | Cancer;Met | ug: |  |  | Intervention |  |  | survival;Sa |  |


|  | astatic | Atezolizuma |  |  | model: |  |  | fety, |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  | Adenocarci | b + |  |  | Parallel |  |  | treatment- |  |
|  | noma;Adva | Bevacizumab |  |  | Assignment. |  |  | related |  |
|  | nced Gastric |  |  |  | Primary |  |  | adverse |  |
|  | Carcinoma |  |  |  | purpose: |  |  | events |  |
|  |  |  |  |  | Treatment. |  |  |  |  |
|  |  |  |  |  | Masking: |  |  |  |  |
|  |  |  |  |  | None (Open |  |  |  |  |
|  |  |  |  |  | Label). |  |  |  |  |
| Recruiting |  |  | 0 |  | Single arm | 1:20; | overeall |  | 31/12/2020 |
|  | cancer | immunothera |  | ntional |  |  | survival; |  |  |
|  |  | py; |  | study |  |  |  |  |  |
| Recruiting | gastric | patients | 1 | Interve | single arm | 12 | safety | progressio | 22/02/2021 |
|  | cancer | recieve |  | ntional | study, |  |  |  |  |
|  |  | combination |  |  | open(maski |  |  | survival<b |  |
|  |  | of |  |  | ng not |  |  | $r>$ overall |  |
|  |  | immunothera |  |  | used), |  |  | survival<b |  |



Cancer;Unre
sectable
Non-Small
Cell Lung
Carcinoma;
Unresectabl
e Stage III
Non-Small
Cell Lung
Cancer;Smal
1 Cell Lung
Cancer
Extensive
Stage;Stage
IV Merkel
Cell
Carcinoma;

| purpose: | hange in Anxiety |  |
| :--- | :--- | :--- |
| Health | participant | Inventory; |
| Services | knowledge | Change in |
| Research. | , using the participant |  |
| Masking: | Immunoth anxiety, |  |
| None (Open | erapy | using the |
| Label). | Knowledg | State |
|  | e | Subscale of |
|  | Assessmen the State |  |
|  | t;Change | and Trait |
|  | in | Anxiety |
|  | participant | Inventory; |
| knowledge | Patient |  |
|  | , using the | questions |
|  | Immunoth | asked in |
|  | erapy | visit with |
|  | Knowledg | oncologist |

Stage IV
Cutaneous
Squamous
Cell
Carcinoma;
Stage IV
Basal Cell
Carcinoma;
Stage IV
Breast
Cancer;Stag
e IV
Colorectal
Cancer;Stag
e IV Gastric
Cancer;Stag
e
IV

Esophageal
Cancer;Stag
e IV
Hepatocellu
lar
Cancer;Stag
e IV Renal
Cell
Carcinoma;
Stage IV
Bladder
Cancer;Stag
e IV Head
and Neck
Squamous
Cell

## Carcinoma;

|  | Stage |  |  |  |  |  |  |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  | Cervical |  |  |  |  |  |  |  |  |
|  | Cancer; |  |  |  |  |  |  |  |  |
|  | e |  |  |  |  |  |  |  |  |
|  | Endome |  |  |  |  |  |  |  |  |
|  | Cancer; |  |  |  |  |  |  |  |  |
|  | e |  |  |  |  |  |  |  |  |
|  | Mesoth |  |  |  |  |  |  |  |  |
|  | ma;Imm |  |  |  |  |  |  |  |  |
|  | therapy |  |  |  |  |  |  |  |  |
|  | mune |  |  |  |  |  |  |  |  |
|  | Checkp |  |  |  |  |  |  |  |  |
|  | Inhibito |  |  |  |  |  |  |  |  |
| Recruiting | Gastric | experimental | 4 | Interve | Single arm | experi | ORR; | Incidence | 14/10/2020 |
|  | cancer | group: |  | ntional |  | mental |  | of adverse |  |
|  |  | Sindilimuma |  | study |  | group: |  | events and |  |
|  |  | b combined |  |  |  | 100; |  | serious |  |


|  |  | with |  |  |  |  |  |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  |  | conventional |  |  |  |  |  | events;OS; |  |
|  |  | chemotherap |  |  |  |  |  | PFS; |  |
|  |  | y; |  |  |  |  |  |  |  |
| Recruiting | ;Neoplasms | Drug : Study | Phase1 | Interve | Primary | 20 | safety |  | 06/01/2021 |
|  |  | subjects will |  | ntional | Purpose |  |  | response |  |
|  |  | receive |  | Study | Treatment, |  |  | rate |  |
|  |  | nivolumab |  |  | Intervention |  |  |  |  |
|  |  | 240 mg |  |  | Model |  |  |  |  |
|  |  | intravenously |  |  | Single |  |  |  |  |
|  |  | (IV) and |  |  | Group, |  |  |  |  |
|  |  | OTSGC-A24 |  |  | Blinding/M |  |  |  |  |
|  |  | consisted of 1 |  |  | asking |  |  |  |  |
|  |  | 碌 mol (~1 |  |  | Open, |  |  |  |  |
|  |  | mg ) of |  |  | Allocation : |  |  |  |  |
|  |  | OTSGC-A24- |  |  | Non-RCT |  |  |  |  |
|  |  | Fo, OTSGC- |  |  |  |  |  |  |  |


|  |  | A24-De, |  |  |  |  |  |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  |  | OTSGC-A24- |  |  |  |  |  |  |  |
|  |  | Ki, OTSGC- |  |  |  |  |  |  |  |
|  |  | A24-VE1 and |  |  |  |  |  |  |  |
|  |  | OTSGC-A24- |  |  |  |  |  |  |  |
|  |  | Ur 1.0 碌 mol |  |  |  |  |  |  |  |
|  |  | (as API) |  |  |  |  |  |  |  |
|  |  | administered |  |  |  |  |  |  |  |
|  |  | subcutaneous |  |  |  |  |  |  |  |
|  |  | ly on Day 1 |  |  |  |  |  |  |  |
|  |  | and D15 each |  |  |  |  |  |  |  |
|  |  | 28 day cycle |  |  |  |  |  |  |  |
|  |  | (q28d) for up |  |  |  |  |  |  |  |
|  |  | to 24 months. |  |  |  |  |  |  |  |
| Not | gastric | Chimer | 44928 | interve | Randomizat | 5 | Side effect. | Clinical | 20/01/2021 |
| Recruiting | cancer. | Construction |  | ntional | ion: N/A, |  | Timepoint: | and |  |
|  | <br>Malign | Design: using |  |  | Blinding: |  | 7 days. | immune |  |


| ant neoplasm of | immunogene tic epitopes of | Not blinded, Placebo: Not | Method of measurem | response. <br> Timepoint: |
| :---: | :---: | :---: | :---: | :---: |
| stomach | MAGEA4, | used, | ent: clinical | one year. |
|  | LAGE1, and | Assignment: | measurem | Method of |
|  | NY-ESO1 | Single, | ent. | measurem |
|  | antigens, a | Purpose: |  | ent: Flow |
|  | chimeric | Treatment. |  | cytometry |
|  | molecule is |  |  | - ELISA - |
|  | prepared |  |  | Overall |
|  | which, due to |  |  | survival |
|  | the pivotal |  |  | rate |
|  | role of |  |  | Tumor- |
|  | dendritic cells |  |  | free |
|  | in inducing |  |  | survival |
|  | an immune |  |  | rate. |
|  | response, is sent into |  |  |  |

these cells in
the form of
mRNA to
stimulate the
immune
system.
Provide
gastric cancer
patients. Due
to the
overexpressio
n of selective
markers
(MAGE-A4,
LAGE1, and
NY-ESO1) in
gastric tumor
cells
compared to
normal cells,
the structural
basis of the
construct
molecule was
based on
specific
sequences of
the same
genes. Our
goal is to
identify these
proteins to
lymphocyte
cells as tumor
markers.
Since it is
difficult to
transfer the
complete
gene or
mRNA of all
three markers
to the
antigen-
supplying
cells, parts of
each protein
were selected
and
synthesized
together into
one
molecule.Con
struction of
contraceptive
mRNA by
Mmessage
Mmachin
kit:Plasmid
PGEM-4Z /
GFP / A64,
which has a
polymythine
sequence at
the end of the
transcription
region, is
used as the
target vector
for the
synthesized
construct.
Chimeric
Antigene
mRNA
amplification
is performed
using an in
vitro
transcription
reaction.Leuk
ophoresis and
isolation of
monocytes
from

## peripheral

blood:Isolatio
n of diseased
monocytes
and
lymphocytes

## from

peripheral
blood
mononuclear
cells (PBMC)
is performed
by
leukophoresi
s. After
isolation of
monocytes
and
lymphocytes
by specific
leukophoresi
s kits, the cells
were
transferred to
the laboratory
to be
converted to
DC cells in
vitro. In order
to isolate T
lymphocytes,
which are
required in
the next
stages of the
test, using the
conventional
method of
attaching
monocyte
cells to the
bottom of the
culture flask,
the
unattached
cells are the
same T
lymphocytes
that are used
for the next
steps of the

|  |  | test. |  |  |  |  |  |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  |  | Placed.Produ |  |  |  |  |  |  |  |
|  |  | ction of |  |  |  |  |  |  |  |
|  |  | dendritic |  |  |  |  |  |  |  |
|  |  | immature |  |  |  |  |  |  |  |
|  |  | cells (DC i |  |  |  |  |  |  |  |
| Not | Gastric | Experimental | 2 | Interve | Parallel | Experi | ORR;R0 | PFS;QOL; | 01/10/2020 |
| Recruiting | Cancer | group:reduce |  | ntional |  | mental | resection |  |  |
|  |  | d SOX+anti- |  | study |  | group: | rate;3 year |  |  |
|  |  | PD-1;Control |  |  |  | 30;Con | OS; |  |  |
|  |  | group:SOX; |  |  |  | trol |  |  |  |
|  |  |  |  |  |  | group: |  |  |  |
|  |  |  |  |  |  | 30; |  |  |  |
| Not | Gastric | Wnt/ | 0 | Basic | Parallel | Wnt/ - | Drug- |  | 15/09/2020 |
| Recruiting | cancer | catenin |  | Scienc |  | catenin | sensitivity; |  |  |
|  |  | pathway |  | e |  | pathw |  |  |  |
|  |  | activated and |  |  |  | ay |  |  |  |




|  |  | rimental group |  |  |  |  |  |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  |  | 2:radiotherap |  |  |  |  |  |  |  |
|  |  | y ? |  |  |  |  |  |  |  |
|  |  | chemotherap |  |  |  |  |  |  |  |
|  |  | y combined with |  |  |  |  |  |  |  |
|  |  | immunothera |  |  |  |  |  |  |  |
|  |  | py before |  |  |  |  |  |  |  |
|  |  | surgery; |  |  |  |  |  |  |  |
| Authorised | For patients | <br>Trade | Huma | Interve | Controlled: | 60 | Main | Secondary | 21/01/2021 |
|  | with | Name: | n | ntional | no<br>Ran |  | Objective: | end |  |
|  | advanced/ | Avastin<br> | pharm | clinical | domised: |  | To assess | point(s): |  |
|  | metastatic | Product | acolog | trial of | no<br>Ope |  | the efficacy | Progressio |  |
|  | gastric | Name: | y | medici | n : |  | of | n -free |  |
|  | adenocarcin | Bevacizumab | (Phase | nal | yes<br>Sing |  | personaliz | survival |  |
|  | omas in | <br>Product | I): no |  | le blind: |  | ed targeted | evaluated |  |


| progression | Code: | Therap | produc | no<br>Dou | immunoth | according |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| <br>MedD | L01XC07<br> | eutic | t | ble blind: | erapy | to iRECIST |
| RA version: | Pharmaceutic | explor |  | no<br>Paral | combinatio | criteria.<br |
| 21.1 | al Form: | atory |  | lel group: | ns in | >- Overall |
| Level: LLT | Concentrate | (Phase |  | no<br>Cros | recurrent | survival.< |
| Classificatio | and solvent | II): yes |  | over: | advanced/ | br>- |
| n code | for solution | Therap |  | no<br>Othe | metastatic | Toxicity |
| 10071114 | for | eutic |  | r: | gastric | using NCI- |
| Term: | infusion<br> | confir |  | yes<br>Oth | carcinoma | CTCAE |
| Metastatic | <br>Product | matory |  | er trial | patients, | v5.0.<br>- |
| gastric | Name: | - |  | design | assessed | Translatio |
| adenocarcin | ipatasertib | (Phase |  | description: | by the | nal |
| oma | $100 \mathrm{mg}<\mathrm{br}>\operatorname{Pr}$ | III): no |  | Umbrella<b | objective | research: |
| System | oduct Code: | Therap |  | $r>$ If | response | tumor |
| Organ | RO5532961<b | eutic |  | controlled, | rate | immune |
| Class: | $r>$ Pharmaceu | use |  | specify | (ORR). ;Sec | gene |
| 10000000486 | tical Form: |  |  | comparator, | ondary | expression |


| 4 | Film-coated | (Phase | Other | Objective: - | (inflamed, |
| :---: | :---: | :---: | :---: | :---: | :---: |
| ;Therapeutic | tablet<br><b | IV): no | Medicinial | To assess | excluded, |
| area: | r>Trade |  | Product: | other | desert), |
| Diseases [C] | Name: |  | no<br>Plac | efficacy | tumor |
| Cancer | Tecentriq<br |  | ebo: | parameters | mutational |
| [C04] | $>$ Product |  | no<br>Othe | of | load and |
|  | Name: |  | r: | personaliz | circulating |
|  | atezolizumab |  | no<br>Nu | ed targeted | DNA |
|  | <br>Product |  | mber of | immunoth | mutational |
|  | Code: |  | treatment | erapy | load, |
|  | RO5541267<b |  | arms in the | combinatio | kinetics of |
|  | r $>$ Pharmaceu |  | trial: $3<\mathrm{br}>$ | ns in | circulating |
|  | tical Form: |  |  | recurrent | hPG80, gut |
|  | Concentrate |  |  | advanced/ | microbiom |
|  | for solution |  |  | recurrent | e flora. |
|  | for |  |  | metastatic | <br>;Time |
|  | infusion<br> |  |  | gastric | point(s) of |


| <br>Product | carcinoma | evaluation |
| :---: | :---: | :---: |
| Name: | patients | of this end |
| ipatasertib | with | point: The |
| $200 \mathrm{mg}<\mathrm{br}>\mathrm{Pr}$ | survival | whole |
| oduct Code: | analyses | treatment |
| RO5532961<b | (PFS, | period or |
| r $>$ Pharmaceu | OS)<br>- | at the end |
| tical Form: | To assess | of |
| Film-coated | the safety | treatment |
| tablet<br><b | of |  |
| r> | personaliz |  |
|  | ed targeted |  |
|  | immunoth |  |
|  | erapy |  |
|  | combinatio |  |
|  | $\mathrm{ns} \quad \mathrm{in}$ |  |
|  | metastatic |  |

/advanced
gastric
carcinoma
patients,
assessed
by NCI-
CTCAE.<b
r>;Primary
end
point(s):
Objective
response
rate, using
iRECIST,
defined as
the
percentage
of patients
experienci
ng a
complete
response
or a partial
response,
as their
best tumor
responses
during the
whole
treatment
period.;Ti
mepoint(s)
of
evaluation

| Recruiting | Gastric <br> Cancer |  |  |  |  |  | of this end point: The whole treatment period. |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  |  | A: chemotherap y combined with anti-pd1 immunothera py;B:Active supportive therapy; | 0 | Interve <br> ntional <br> study | Non randomized control | $\begin{aligned} & \text { A:50;B: } \\ & 30 ; \end{aligned}$ | PFS; | $\begin{aligned} & \text { ORR;OS;Sa } \\ & \text { fety; } \end{aligned}$ | 01/06/2020 |
| Recruiting | Locally | Drug: | Phase | Interve | Allocation: | 36 | Adverse | Quantify | 19/05/2020 |
|  | Advanced | ACE1702;Dru | 1 |  | Non- |  | events, | NK cell |  |
|  | Solid | g: |  |  | Randomize |  | including | persistence |  |
|  | Tumor;Meta | Cyclophosph |  |  | d. |  | Dose | after |  |


|  | static | amide;Drug: |  |  | Intervention |  | Limiting | administer |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  | Cancer;Soli | Fludarabine |  |  | model: |  | Toxicities | ing |  |
|  | d |  |  |  | Sequential |  | (DLTs) and | ACE1702;E |  |
|  | Tumor;HER |  |  |  | Assignment. |  | Serious | valuate |  |
|  | 2-positive |  |  |  | Primary |  | Adverse | immune |  |
|  | Gastric |  |  |  | purpose: |  | Events | function |  |
|  | Cancer;HER |  |  |  | Treatment. |  | (SAEs);Pha | after |  |
|  | 2-positive |  |  |  | Masking: |  | se Ib/II | administer |  |
|  | Metastatic |  |  |  | None (Open |  | starting | ing |  |
|  | Breast |  |  |  | Label). |  | dose for | ACE1702 |  |
|  | Cancer |  |  |  |  |  | ACE1702 |  |  |
| Recruiting | Gastric | Drug: | Phase | Interve | Allocation: | 30 | objective | Progress | 10/02/2020 |
|  | Cancer;Gast | Anlotinib | 2 | ntional | N/A. |  | response | Free |  |
|  | ro- | Plus |  |  | Intervention |  | rate | Survival;O |  |
|  | oesophageal | Toripalimab |  |  | model: |  |  | verall |  |
|  | Junction |  |  |  | Single |  |  | Survival;D |  |
|  | Cancer;Imm |  |  |  | Group |  |  | eepness of |  |


|  | unotherapy; |  |  |  | Assignment. |  |  | response;D |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  | Anlotinib;T |  |  |  | Primary |  |  | isease |  |
|  | oripalimab |  |  |  | purpose: |  |  | control |  |
|  |  |  |  |  | Treatment. |  |  | rate;advers |  |
|  |  |  |  |  | Masking: |  |  | e events |  |
|  |  |  |  |  | None (Open |  |  |  |  |
|  |  |  |  |  | Label). |  |  |  |  |
| Recruiting | Esophageal | Drug: Nal- | Phase | Interve | Allocation: | 52 | Cohort 1: | Progressio | 13/07/2020 |
|  | Adenocarci | IRI;Drug: | 2 | ntional | Non- |  | Objective | $\mathrm{n} \quad$ Free |  |
|  | noma;Gastri | Oxaliplatin;D |  |  | Randomize |  | Response | Survival |  |
|  | c | rug: 5- |  |  | d. |  | Rate | (PFS);Dise |  |
|  | Adenocarci | FU;Drug: |  |  | Intervention |  | (ORR);Coh | ase Control |  |
|  | noma | Trastuzumab; |  |  | model: |  | ort 3: | Rate |  |
|  |  | Drug: |  |  | Single |  | Objective | (DCR);Pro |  |
|  |  | Pembrolizum |  |  | Group |  | Response | gression |  |
|  |  | ab;Drug: |  |  | Assignment. |  | Rate | Free |  |
|  |  | Nivolumab |  |  | Primary |  | (ORR);Coh | Survival at |  |


| purpose: | orts 2 and | 6 |
| :--- | :--- | :--- |
| Treatment. | $4:$ | months;Pr |
| Masking: | Incidence | ogression |
| None (Open | of Adverse | Free |
| Label). | Events | Survival at |
|  |  | 12 |
|  |  | months;Co |
|  |  | $3:$ |
|  |  | Incidence 1 and |
|  |  | of Adverse |
|  |  | Events;Co |
|  |  | horts 2 and |
|  | $4:$ Overall |  |
|  |  | Response |
|  |  | Rate |


| Not | Advanced | Genetic: Allogeneic | Observ | 20 | Overall | 11/06/2019 |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| recruiting | Solid | natural killer (NK) cell | ational |  | Survival |  |
|  | Tumor;Lym |  |  |  | (OS) post- |  |
|  | phoma;Gast |  |  |  | Infusion |  |
|  | ric |  |  |  |  |  |
|  | Cancer;Colo |  |  |  |  |  |
|  | rectal |  |  |  |  |  |
|  | Cancer; Hea |  |  |  |  |  |
|  | d and Neck |  |  |  |  |  |
|  | Cancer;Squa |  |  |  |  |  |
|  | mous Cell |  |  |  |  |  |
|  | Carcinoma; |  |  |  |  |  |
|  | EGFR |  |  |  |  |  |
|  | Positive |  |  |  |  |  |
|  | Solid |  |  |  |  |  |
|  | Tumor;HER |  |  |  |  |  |
|  | 2-positive |  |  |  |  |  |

## Breast

Cancer;Hep
atocellular
Carcinoma;
Small-cell
Lung
Cancer;Rena
1 Cell
Carcinoma;
Pancreas
Cancer;Mela
noma;NSCL
C;Urothelial
Carcinoma;
Cervical
Cancer;Micr
osatellite

|  | Instability; |  |  |  |  |  |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  | Merkel Cell |  |  |  |  |  |  |  |
|  | Carcinoma |  |  |  |  |  |  |  |
| Recruiting | Gastric | Drug: | Phase | Interve | Allocation: | 58 | Cohort 1: | Cohort 1: 01/12/2020 |
|  | Cancer;Gast | Pembrolizum | 2 | ntional | Randomize |  | Evaluate | Compare |
|  | roEsophage | ab |  |  | d. |  | the best | BORR |
|  | al | Monotherapy |  |  | Intervention |  | overall | between |
|  | Cancer;Ade | ;Drug: |  |  | model: |  | response | Arm A and |
|  | nocarcinom | Ramuciruma |  |  | Sequential |  | rate | Arm |
|  | a | b;Drug: |  |  | Assignment. |  | (BORR) by | B.;Cohort |
|  |  | Paclitaxel |  |  | Primary |  | pooling | 1: Evaluate |
|  |  |  |  |  | purpose: |  | Arm A and | duration of |
|  |  |  |  |  | Treatment. |  | Arm | response |
|  |  |  |  |  | Masking: |  | B;Cohort 2: | between |
|  |  |  |  |  | None (Open |  | Evaluate | Arm A and |
|  |  |  |  |  | Label). |  | Progressio | B.;Cohort |
|  |  |  |  |  |  |  | n free | 1: Evaluate |


| survival | irPFS |
| :--- | :--- |
| (PFS) $\quad$ of | between |
| Ramuciru | Arm A and |
| mab | B.;Cohort |
| (RAM) | 1: Evaluate |
| plus | overall |
| Paclitaxel | survival |
| plus | (OS) |
| Pembroliz | between |
| umab | Arm A and |
| (PEM) | B.;Cohort |
|  | 1: |
|  | Compare |
|  | progressio |
|  | $n$ |
|  | survival |
|  | [PFS] |


|  |  |  |  |  |  |  |  | between |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  |  |  |  |  |  |  |  | Arm A vs |  |
|  |  |  |  |  |  |  |  | Arm |  |
|  |  |  |  |  |  |  |  | B;Assess |  |
|  |  |  |  |  |  |  |  | the |  |
|  |  |  |  |  |  |  |  | frequency |  |
|  |  |  |  |  |  |  |  | and |  |
|  |  |  |  |  |  |  |  | severity of |  |
|  |  |  |  |  |  |  |  | adverse |  |
|  |  |  |  |  |  |  |  |  |  |
| Not | Gastric | PSK(-) | Not |  | Parallel | 800 | Five year | Overall | 01/02/1987 |
| Recruiting | cancer | <br>PSK(+): | selecte | ntional | Randomize |  | overall | survival |  |
|  |  | <br>PSK was |  |  |  |  | survival | according |  |
|  |  | administered |  |  |  |  |  | to HLA |  |
|  |  | orally from 14 |  |  |  |  | gastrectom | antigens. |  |
|  |  | days after |  |  |  |  | y |  |  |
|  |  | gastrectomy |  |  |  |  | according |  |  |

```
at a dose of
to the
3.0g/day and
at least at a
dose of over
270g.
Fluoropyrimi
dine prodru
(5-FU
150mg/day
or FT
(600mg/day
or HCFU
400mg/day)
was
administered
orally from 14
days after
```

gastrectomy
over 1 year.
MMC was
injected
intravenously
20 mg
intraoperativ
ely and/or 10
mg on
postoperative
day $\quad 1$.
<br>CEA(-)A
PR(-)
<br>CEA(-)A
PR(+)
$<$ br>CEA(+)
APR(-)
<br>CEA(+)
APR(+)
<br>T1:
Gastrectomy
alone or
Gastrectomy
$+\quad$ PSK
<br>T2-4:
Gastrectomy
$+\mathrm{MMC}+\mathrm{F}+$
PSK
Not
recruiting

| Gastric | Drug: | Phase | Interve | Allocation: 21 | Rate of | Determina 26/09/2019 |
| :--- | :--- | :--- | :--- | :--- | :--- | :--- | :--- | :--- |
| Cancer;Ade | Nivolumab;D 2 | ntional | Randomize | pathologic | tion of |  |


| stric | rug: | Assignment. | of Curative |
| :--- | :--- | :--- | :--- |
| Junction | Docetaxel;Dr | Primary | (R0) |
|  | ug: 5- | purpose: | resection |
|  | Fluorouracil | Treatment. | rate;Assess |
|  | (5-FU);Drug: | Masking: | ment of |
|  | Folic acid | None (Open | disease- |
|  | (FA) |  | free |
|  |  |  | survival |
|  |  | rate;Assess |  |
|  |  | ment of |  |
|  |  | Survival |  |
|  |  | rate;Evalu |  |
|  |  | ation of |  |
|  |  | number of |  |
|  |  | patients |  |

events
grade 1
through
grade 5
adverse
events
(AEs),
graded
according
to NCI
CTCAE
Version
5.0.;Assess
ment of
perioperati
ve
morbidity;

|  |  |  |  |  |  |  |  | Assessmen |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  |  |  |  |  |  |  |  | $t$ of |  |
|  |  |  |  |  |  |  |  | perioperati |  |
|  |  |  |  |  |  |  |  | ve |  |
|  |  |  |  |  |  |  |  | mortality; T |  |
|  |  |  |  |  |  |  |  | ime to |  |
|  |  |  |  |  |  |  |  | relapse;Pat |  |
|  |  |  |  |  |  |  |  | ient- |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  | outcome |  |
|  |  |  |  |  |  |  |  | (PRO) |  |
| Recruiting | Localized | Drug: | Phase | Interve | Allocation: | 32 | Complete | Disease- | 23/10/2019 |
|  | Oesogastric | Nivolumab | 2 | ntional | N/A. |  |  |  |  |
|  | Adenocarci | 10 |  |  | Intervention |  | al response | survival |  |
|  | mona;MSI | MG/ML;Dru |  |  | model: |  | (cPRR) rate | (DFS);Over |  |
|  | and or | g : |  |  | Single |  |  | all Survival |  |
|  | dMMR | Ipilimumab |  |  | Group |  |  | (OS);Num |  |


| 200 MG in 40 | Assignment. | ber of |
| :---: | :---: | :---: |
| ML Injection | Primary | participant |
|  | purpose: | s with |
|  | Treatment. | treatment- |
|  | Masking: | related |
|  | None (Open | adverse |
|  | Label). | events;Ana |
|  |  | lyze MSI |
|  |  | status;Qua |
|  |  | ntification |
|  |  | of antigen- |
|  |  | specific |
|  |  | CD4+ T |
|  |  | cells as |
|  |  | biomarker |
|  |  | of anti- |
|  |  | PD1/PDL1 |


|  |  |  |  |  | immunoth |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  |  |  |  |  | erapy in |  |
|  |  |  |  |  | dMMR |  |
|  |  |  |  |  | tumors;Nu |  |
|  |  |  |  |  | mber of |  |
|  |  |  |  |  | Species of |  |
|  |  |  |  |  | bacteria |  |
|  |  |  |  |  | and yeast |  |
|  |  |  |  |  | compositio |  |
|  |  |  |  |  | n |  |
| Recruiting | Stomach Neoplasms | Observ | 200 | the | The | 01/02/2019 |
|  |  | ational |  | proportion | proportion |  |
|  |  |  |  | s of | of ctDNA |  |
|  |  |  |  | patients | content |  |
|  |  |  |  | with | decreased |  |
|  |  |  |  | positive | in patients |  |
|  |  |  |  | serum | with good |  |



| Authorised | oeso-gastric | <br> |  | Interve | <br> | 32 | Main | <br> | 13/06/2019 |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  | adenocarcin | Trade Name: |  | ntional | Controlled: |  | Objective: | Secondary |  |
|  | oma <br> | OPDIVO<br> | Huma | clinical | no<br> |  | To | end |  |
|  |  | Product | n | trial of | Randomised |  | evaluate | point(s): - |  |
|  | MedDRA | Name: | pharm | medici | no<br> |  | the rate of | DFS,<br> |  |
|  | version: 20.0 | nivolumab<b | acolog | nal | Open: |  | complete | - OS and |  |
|  |  | r> | y | produc | yes<br> |  | pathologic | safety |  |
|  | Level: PT | Pharmaceutic | (Phase | t | Single blind: |  | response | (NCI |  |
|  |  | al Form: | I): no |  | no<br> |  | rate (cPRR) | CTCAE |  |
|  | Classificatio | Solution for |  |  | Double |  | with | v5.0), <br> |  |
|  | n code | infusion<br> | Therap |  | blind: |  | nivolumab | IHC |  |
|  | 10001150 | INN or | eutic |  | no<br> |  | and | evaluation |  |
|  |  | Proposed | explor |  | Parallel |  | ipilimuma | of MMR |  |
|  | Term: | INN: | atory |  | group: |  | b | proteins |  |
|  | Adenocarci | NIVOLUMA | (Phase |  | no<br> |  | combinatio | followed |  |
|  | noma | B<br> | II): yes |  | Cross over: |  | $n \quad$ in | by tumor |  |
|  | gastric | Other |  |  | no<br> |  | patients | BRAF |  |


|  | descriptive | Therap | Other: | with MSI | analysis |
| :---: | :---: | :---: | :---: | :---: | :---: |
| System | name: | eutic | no<br> | and/or | (germline |
| Organ | NIVOLUMA | confir | If | dMMR | mutation) |
| Class: | B<br> | matory | controlled, | localized | and/or |
| 10029104 | Concentratio | - | specify | oeso- | MLH1 |
| Neoplasms | n unit: | (Phase | comparator, | gastric | promoter |
| benign, | $\mathrm{mg} / \mathrm{ml}$ | III): no | Other | cancer;Pri | hypermeth |
| malignant | milligram(s)/ |  | Medicinial | mary end | ylation |
| and | millilitre<br> | Therap | Product: | point(s): | analysis |
| unspecified | Concentratio | eutic | no<br> | Complete | (somatic |
| (incl cysts | $n \quad$ type: |  | Placebo: | pathologic | mutation) |
| and polyps) | equal<br> | (Phase | no<br> | al response | when |
|  | Concentratio | IV): no | Other: | rate | MLH1 |
| ;Therapeutic | n number: 10- |  | no<br> | (cPRR); Ti | protein is |
| area: | <br><br> |  | Number of | mepoint(s) | absent |
| Diseases [C] | Trade Name: |  | treatment | of | (Lynch |
|  | YERVOY<br |  |  | evaluation | versus |


| $-\quad$ Cancer | $>$ |
| :--- | :--- |
| [C04] | Product |
|  | Name: |
|  | ipilimumab< |
|  | br> |
|  | Pharmaceutic |
|  | al Form: |
|  | Solution for |
|  | infusion<br> |
|  | INN $\quad$ or |
|  | Proposed |
|  | INN: |
|  | IPILIMUMA |
|  | B<br> |
|  | Other |
|  | descriptive |
|  | name. |


| arms in the <br> trial: $1<b r>$ | of this end point: | sporadic <br> cases |
| :---: | :---: | :---: |
|  | cPRR will | testing), <b |
|  | be defined | r> |
|  | as | - PD-1 and |
|  | complete | PD-L1 |
|  | tumor | expression |
|  | disappeara | evaluation |
|  | nce of | (CPS in |
|  | tumor in | addition to |
|  | the low | TPS), (PD- |
|  | esophagus |  |
|  | or the | expression |
|  | stomach | cut-off |
|  | (from 1/3 | $=1 \%$ or |
|  | inferior of | $=5 \%),<\mathrm{br}>$ |
|  | the | CD3, |


| IPILIMUMA | oesophagu | CD8, |
| :---: | :---: | :---: |
| B<br> | to | FOXP3 |
| Concentratio | pylorus) | expression |
| n unit: | after- | evaluation, |
| $\mathrm{mg} / \mathrm{ml}$ | surgery | <br> |
| milligram(s)/ | examinatio | - Blood |
| millilitre<br> | n ; <br> | samples |
| Concentratio | Secondary | Evaluation |
| n type: | Objective: - | of the |
| equal<br> | To assess | potential |
| Concentratio | disease- | role of |
| n number: 5- | free | immune |
| <br><br> | survival | checkpoint |
|  | (DFS), <br> | inhibitors: |
|  | - To assess | PD-1, PD- |
|  | overall | L1, PD-L2, |
|  | survival | CTLA-4, |


| (OS),<br> | TIM-3, |
| :---: | :---: |
| To | LAG-3, |
| evaluate | GAL9, and |
| the safety | IDO using |
| (National | nanostring |
| Cancer | technology |
| Institute | and IHC as |
| Common | predictive |
| Terminolo | markers of |
| gy Criteria | patients |
| for | 鉄?respons |
| Adverse | e to |
| Events | treatment, |
| [NCI | <br> |
| CTCAE] | blood |
| v5.0), <br> | samples |
| To | ctDNA |


| evaluate | evolution |
| :--- | :--- |
| the efficacy | during |
| of | treatment, |
| nivolumab | MSI status |
| and | and CD4+ |
| ipilimuma | T cells in |
| b regimen | blood,<br> |
| according | - |
| to selected | Microbiota |
| tumor - | analysis.<b |
| biomarker | r> |
| s:<br> | ;<br> |
| 鉄 ?MMR | Timepoint( |
| proteins | s) |
| status | evaluation |
| (Lynch | of this end |
| versus | point: |


| sporadic), $<$ | DFS is |
| :--- | :--- |
| br> | defined as |
| 鉄 ?BRAF | the time |
| gene | from the |
| mutational | date of |
| status | starting |
| and/or | treatment |
| MLH1 | to local |
| gene | recurrence |
| epigenetic | and/or |
| status,<br | metastases |
| $>$ | or death |
| 鉄 ?PD-1 | irrespectiv |
| and PD-L1 | and |
| expression | censored at |
| (combined | the date of |
| positive |  |


| score [CPS] | last |
| :---: | :---: |
| in addition | contact.<br |
| to tumor | > |
| proportion | - OS is |
| score | defined as |
| [TPS]), | time |
| (=1\% and | between |
| =5\% | the date of |
| versus no | the first |
| expression | dose |
| ),<br> | study |
| 鈥 ?CD3+, | treatment |
| CD8+, and | and the |
| FOXP3 | death |
| (expressio | date.<br> |
| n versus no | - AEs : at |
| expression | every visit |


| ), <br> | during |
| :---: | :---: |
| To | treatment |
| evaluate | and at 3 |
| whetherP | months |
| D-L1, PD- | after |
| L2, PD-1, (- | treatment |
| 4, TIM-3, | ends(NCI- |
| LAG-3, | CTCAE |
| GAL9, | version |
| IDO, | 5.0)<br> |
| expression | MSI |
| could be | and/or |
| predictive | dMMR |
| of patients | had to be |
| 欽?respons | confirmed |
| e to these | with an |
| molecules, | archival or |


| <br> | fresh |
| :--- | :--- |
| $-\quad$ Blood | tumor |
| assessment | FFPET |
| for ctDNA, | block from |
| MSI status, | the |
| and CD4+ | primary |
| T | tumor |
| cells,<br> | obtained at |
| $-\quad$ To | the time of |
| investigate | the initial |
| whether | diagnosis< |
| the gut | br> |
| microbiota | - Blood |
| compositio | Samples : |
| n | is |
| at baseline, |  |


| and | neoadjuva |
| :--- | :--- |
| efficacy of | nt |
| nivolumab | treatment, |
| and/or | at C1D1 |
| ipilimuma | after |
| b | surgery, |
| treatment. | and at the |
| <br> | end of |
|  | treatment |
|  | visit<br> |
|  | Fecal |
|  | sample: At |
|  | baseline |
|  | and $\quad 12$ |


| Recruiting | Gastric | Drug： | Phase | Interve | Allocation： | 30 | Pathologic | objective | 01／04／2019 |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  | Cancer | SHR1210；Dru | 2 | ntional | Non－ |  | al | response |  |
|  |  | g： |  |  | Randomize |  | remission | rate（ORR） |  |
|  |  | Apatinib；Dru |  |  | d． |  | rate（PRR） | of PD－1 |  |
|  |  | g：S1；Drug： |  |  | Intervention |  | rate of PD－ | antibody |  |
|  |  | Oxaliplatin |  |  | model： |  | 1 antibody | monothera |  |
|  |  |  |  |  | Single |  | monothera | py or in |  |
|  |  |  |  |  | Group |  | py or in | combinatio |  |
|  |  |  |  |  | Assignment． |  | combinatio | n with |  |
|  |  |  |  |  | Primary |  | n with | anti－ |  |
|  |  |  |  |  | purpose： |  | anti－ | angiogenes |  |
|  |  |  |  |  | Treatment． |  | angiogenes | is |  |
|  |  |  |  |  | Masking： |  | is | VEGFR2－ |  |
|  |  |  |  |  | None（Open |  | VEGFR2－ | TKI |  |
|  |  |  |  |  | Label）． |  | TKI | apatinib |  |
|  |  |  |  |  |  |  | apatinib | 卤 S1 卤 |  |
|  |  |  |  |  |  |  | 卤 S1 卤 | Oxaliplatin |  |


| Oxaliplatin | in |
| :--- | :--- |
| in | neoadjuva |
| neoadjuva | nt |
| nt | (preoperati |
| (preoperati | ve) |
| ve) | treatment |
| treatment | of |
| of | resectable |
| resectable | locally |
| locally | advanced |
| advanced | gastric |
| gastric | cancer.;pro |
| cancer.;Im | gression |
| munothera | free |
| py-related | survival |
| biomarker | (PFS)of |
| s | PD-1 |

anti-
angiogenes
is
VEGFR2-
TKI
apatinib
卤 S1 卤

Oxaliplatin
in
neoadjuva
nt
(preoperati
treatment
of
resectable
locally
advanced
gastric
cancer.;ove
rall
survival
(OS) of PD-
1 antibody
monothera
py or in
combinatio
n with
anti-
angiogenes
is
VEGFR2-
TKI
apatinib
卤 S1 卤
Oxaliplatin
in
neoadjuva
nt
(preoperati
ve)
treatment
of
resectable
locally
advanced
gastric
cancer.;saf
ety as
measured
by the rate
of adverse
events
(AEs),
laboratory
abnormalit
ies, dose
adjustment
discontinu
ation of
administra
tion, early

|  |  |  |  |  |  |  |  | discontinu ation of the study drug, and delay to surgery.;R 0 resection rate |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| Not recruiting | Esophageal <br> Cancer:Bilia | Drug: DKN01;Drug: | Phase 2 | Interve ntional | Allocation: <br> Randomize | 0 | Objective response | Best overall | 01/12/2019 |
|  | ry Tract | Atezolizuma |  |  | d. |  | rate | response |  |
|  | Cancer;Gast | b;Drug: |  |  | Intervention |  |  | distributio |  |
|  | roEsophage | Paclitaxel |  |  | model: |  |  | n;Immune |  |
|  | al |  |  |  | Parallel |  |  | objective |  |
|  | Cancer; Hep |  |  |  | Assignment. |  |  | response |  |
|  | atobiliary |  |  |  | Primary |  |  | rate |  |
|  | Neoplasm |  |  |  | purpose: |  |  | according |  |


| Treatment. | to |
| :--- | :--- |
| Masking: | iRECIST;D |
| None (Open | uration of |
| Label). | response |
|  | using |
|  | RECIST 1.1 |
|  | and |
|  | iRECIST;Pr |
|  | ogression |
|  | free |
|  | survival |
|  | according |
|  | to RECIST |
|  | 1.1 |
|  | iRECIST;O and |
|  | ccurrence |
|  | of adverse |



| Authorised | Advanced | <br> |  | Interve | <br> | 94 | Main | <br> | 27/11/2018 |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  | gastric or | Product |  | ntional | Controlled: |  | Objective: - | Secondary |  |
|  | gastro- | Name: | Huma | clinical | yes<br> |  | Percentage | end |  |
|  | oesophageal | MEDI4736<b | n | trial of | Randomised |  | of patients | point(s): |  |
|  | junction | r> | pharm | medici | : yes<br> |  | alive and | Progressio |  |
|  | adenocarcin | Product | acolog | nal | Open: |  | without | n free |  |
|  | oma <br> | Code: | y | produc | yes<br> |  | progressio | survival |  |
|  |  | MEDI4736<b | (Phase | t | Single blind: |  | n at 4 | (PFS) |  |
|  | MedDRA | r> | I): no |  | no<br> |  | months of | median:<b |  |


| version: 20.0 | Pharmaceutic |  | Double | FOLFIRI | r> |
| :---: | :---: | :---: | :---: | :---: | :---: |
|  | al Form: | Therap | blind: | plus | Is defined |
| Level: LLT | Concentrate | eutic | no<br> | durvaluma | as the time |
|  | for solution | explor | Parallel | b versus | between |
| Classificatio | for | atory | group: | FOLFIRI | date of |
| n code | infusion<br> | (Phase | no<br> | plus | randomiza |
| 10042080 | INN or | II): yes | Cross over: | durvaluma | tion and |
|  | Proposed |  | no<br> | b plus | date of the |
| Term: | INN: | Therap | Other: | tremelimu | first |
| Stomach | DURVALUM | eutic | no<br> | mab in | radiologica |
| cancer | AB<br> | confir | If | patients | 1 |
|  | CAS | matory | controlled, | with | progressio |
| System | Number: | - | specify | advanced- | n |
| Organ | 1428935-60- | (Phase | comparator, | stage | (according |
| Class: | 7<br> | III): no | Other | gastric or | to RECIST |
| 10000000486 | Current |  | Medicinial | gastro- | 1.1) or |
| 4 | Sponsor code: | Therap | Product: | oesophage | death |


|  | MEDI4736<b | eutic | yes<br> | al junction (from any |
| :--- | :--- | :--- | :--- | :--- | :--- |
| <br> | r> | use | Placebo: | adenocarci cause), |


| System | Product | point(s): | Is defined |
| :---: | :---: | :---: | :---: |
| Organ | Code: | The | as the time |
| Class: | MEDI1123<b | primary | between |
| 10000000486 | r> | endpoint is | date of |
| 4 | Pharmaceutic | the | randomiza |
|  | al Form: | percentage | tion and |
| ;Therapeutic | Concentrate | of patients | date of |
| area: | for solution | alive and | death |
| Diseases [C] | for | without | (from any |
| - Cancer | infusion<br> | radiologica | cause). |
| [C04] | INN or | 1 | Patients |
|  | Proposed | progressio | alive will |
|  | INN: | n | be |
|  | TREMELIMU | (according | censored at |
|  | MAB<br> | to RECIST | date of last |
|  | CAS | 1.1) at 4 | news.<br> |
|  | Number: | months | <br> |


| 745013-59- | after | Time to |
| :---: | :---: | :---: |
| 6<br> | randomiza | progressio |
| Current | tion | n |
| Sponsor code: | according | (TTP):<br> |
| MEDI1123<b | to | Is defined |
| r> | investigato | as the time |
| Other | r. ;Timepoi | between |
| descriptive | $\mathrm{nt}(\mathrm{s}) \quad$ of | date of |
| name: | evaluation | randomiza |
| MEDI1123<b | of this end | tion and |
| r> | point: 4 | the date of |
| Concentratio | months | first |
| n unit: | after the | radiologica |
| $\mathrm{mg} / \mathrm{ml}$ | last patient | 1 |
| milligram(s)/ | inclusion; < | progressio |
| millilitre<br> | br> | n |
| Concentratio | Secondary | (according |

n type:
equal<br>
Concentratio
n number: 20-
<br><br>

| Objective: - | to RECIST |
| :---: | :---: |
| Percentage | v1.1). |
| of patients | Patients |
| alive and | without |
| without | progressio |
| progressio | $n$ will be |
| n at 4 | censored at |
| months | date of last |
| according | news or |
| to | date of |
| centralized | death. The |
| review<br | death will |
| > |  |
| Overall | considered |
| survival | as an |
| (OS)<br> | event.<br> |
| - Time to | <br |


| strategy | Best |
| :--- | :--- |
| failure<br | Objective |
| $>$ | Response |
| - Safety | rate |
| profile<br | (BRR):<br |
| $>$ | $>$ |
| - Quality of | Is defined |
| life | as |
| (QoL)<br> | complete |
| - Time to | or partial |
| progressio | response at |
| $\mathrm{n} \quad$ (TTP), | the best |
| progressio | response |
| n-free | evaluation |
| survival | during the |
| (median | treatment |
| PFS), best | according |


| objective | to RECIST |
| :--- | :--- |
| response | v1.1.<br>< |
| rate (BRR) | br> |
| and | Disease |
| disease | control |
| control | rate (DCR) |
| rate (DCR) | at each |
| according | timepoint: |
| to the | <br> |
| investigato | Is defined |
| r and | as |
| centralized | complete |
| review | or partial |
| (according | response |
| RECIST | or stable |
| V1.1 and | disease at |
| iRECIST | the best |

\(\left.\begin{array}{ll}criteria)<b \& response <br>
r> \& evaluation <br>
- \& Efficacy <br>
endpoints \& according <br>

to RECIST\end{array}\right\}\)| (OS, PFS, | v1.1.<br>< |
| :--- | :--- |
| TTP, BRR | br> |
| and DCR) | Time to |
| according | strategy |
| to the | failure:<br |
| expression | $>$ |
| of PD-L1 | Is defined |
| and others | as the time |
| biomarker | between |
| s (see | randomiza |
| biological | tion date |
| study)<br | and date of |
| $>$ |  |

the date of
first
radiologica
1
progressio
$n$ in the
FOLFIRI +
durvaluma
b arm or
date of the
second
radiologica
1
progressio
n after re-
introductio
$n \quad$ of
tremelimu
mab in the
FOLFIRI
plus
durvaluma
b plus
tremelimu
mab arm
or date of
definitive
discontinu
ation.<br>
In case a
treatment
is stopped
for toxicity
reason but
re-
introduced
later for
progressio
n , then this
progressio
n will not
be
considered
for this
endpoint.<
br><br>
Safety
profile<br
$>$
Toxicities
will be
graded
according
to the NCI-
CTCAE
v4.0
classificati
ons.<br><
br>
Quality of
life
(QoL)<br>
Is
evaluated
using
EORTC

## Centralize

evaluation
of PD-L1
expression
<br>
All efficacy
endpoints
(OS, PFS,
TTP, BRR
and DCR)

```
will be
evaluated
according
to the
expression
of PD-
L1.<br><b
r>
Centralize
d
radiologica
l
assessment
s of
RECIST
v1.1
response
```

response
according
Seymour et
al. criteria
(22). For
exploratio
n,
secondary
endpoints
(OS, PFS,
TTP, BRR
and DCR)
will be
analysed
according

|  |  |  |  |  |  |  |  |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  |  |  |  |  |  |  |  | centralized |  |
|  |  |  |  |  |  |  |  | review.<br |  |
|  |  |  |  |  |  |  |  | > |  |
|  |  |  |  |  |  |  |  | ;Timepoint |  |
|  |  |  |  |  |  |  |  | (s) of |  |
|  |  |  |  |  |  |  |  | evaluation |  |
|  |  |  |  |  |  |  |  | of this end |  |
|  |  |  |  |  |  |  |  | point: One |  |
|  |  |  |  |  |  |  |  | year after |  |
|  |  |  |  |  |  |  |  | the last |  |
|  |  |  |  |  |  |  |  | patient |  |
|  |  |  |  |  |  |  |  | inclusion |  |
| Not | Peritoneal | Biological: | Phase | Interve | Allocation: | 18 | Safety of | Progressio | 13/09/2018 |
| recruiting | Carcinomat | anti-CEA | 1 | ntional | N/A. |  | Intraperito | n-Free |  |
|  | osis;Periton | CAR-T cells |  |  | Intervention |  | neal CAR- | Survival;O |  |
|  | eal |  |  |  | model: |  | T Cell | verall |  |


| Metastases; | Single | Infusions | Survival;B |
| :--- | :--- | :--- | :--- |
| Colorectal | Group | as | owel |
| Cancer;Gast | Assignment. | Measured | Obstructio |
| ric | Primary | by | n Free |
| Cancer;Brea | purpose: | Number of | Survival;C |
| st | Treatment. | Participant hanges in |  |
| Cancer;Panc | Masking: | s withQuality of |  |
| reas | None (Open | Adverse | Life;Respo |
| Cancer;Carc | Label). | Events | nse by the |
| inoembryon |  |  | Peritoneal |
| ic Antigen |  |  | Carcinoma |
|  |  |  | tosis Index |
|  |  |  | (PCI);Radi |
|  |  |  | ographic |


|  |  |  |  |  |  |  |  | MRI;Radio <br> graphic <br> treatment <br> response <br> by <br> PET;Serolo <br> gic <br> response <br> rates |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| Not | Gastric | Biological: | Phase | Interve | Allocation: | 274 | BICR- | Objective | 16/10/2018 |
| recruiting | Cancer;Canc | BMS- | 2 | ntional | Randomize |  | Assessed | Response |  |
|  | er of the | 986213;Biolog |  |  | d. |  | Objective | Rate |  |
|  | Stomach;Es | ical: |  |  | Intervention |  | Response | (ORR);Dur |  |
|  | ophagogastr | Nivolumab;D |  |  | model: |  | Rate (ORR) | ation of |  |
|  | ic Junction | rug: |  |  | Parallel |  | in | Response |  |
|  |  | XELOX;Drug: |  |  | Assignment. |  | Randomiz | (DOR);Ove |  |
|  |  |  |  |  | Primary |  | ed LAG-3 |  |  |


| FOLFOX;Dru | purpose: | Positive | Survival |
| :---: | :---: | :---: | :---: |
| g : SOX | Treatment. | ( $>=1 \quad \%$ ) | (OS);Progr |
|  | Masking: | Participant | ession-Free |
|  | None (Open | s | Survival |
|  | Label). |  | (PFS);Num |
|  |  |  | ber of |
|  |  |  | Participant |
|  |  |  | s With |
|  |  |  | Adverse |
|  |  |  | Events |
|  |  |  | (AEs); Nu |
|  |  |  | mber of |
|  |  |  | Deaths;Nu |
|  |  |  | mber of |
|  |  |  | Participant |
|  |  |  | s With |
|  |  |  | Laboratory |


|  |  |  |  |  |  |  |  | Abnormali |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  |  |  |  |  |  |  |  | ties in |  |
|  |  |  |  |  |  |  |  | Specific |  |
|  |  |  |  |  |  |  |  | Liver |  |
|  |  |  |  |  |  |  |  | Tests;Num |  |
|  |  |  |  |  |  |  |  | ber of |  |
|  |  |  |  |  |  |  |  | Participant |  |
|  |  |  |  |  |  |  |  | s With |  |
|  |  |  |  |  |  |  |  | Laboratory |  |
|  |  |  |  |  |  |  |  | Abnormali |  |
|  |  |  |  |  |  |  |  | ties in |  |
|  |  |  |  |  |  |  |  | Specific |  |
|  |  |  |  |  |  |  |  | Thyroid |  |
|  |  |  |  |  |  |  |  | Tests |  |
| Recruiting | B-cell Acute | Biological: | Phase | Interve | Allocation: | 73 | Number of | Clinical | 01/03/2018 |
|  | Lymphoblas | CAR-T cell | 1/Phas | ntional | N/A. |  | Participant | response; C |  |
|  | tic |  | e 2 |  | Intervention |  | s With |  |  |

Leukemia;L immunothera
ymphoma; py
Myeloid
Leukemia;M
ultiple
Myeloma;H
epatoma;Ga
stric
Cancer;Panc
reatic
Cancer;Mes
othelioma; C
olorectal
Cancer;Esop
hagus
Cancer;Lun
g
model:
Single
Group
Assignment.
Primary
purpose:
Treatment.
Masking:
None (Open
Label).

Adverse AR-T cells
Events testing
evaluated
with NCI
CTC AE,
version 4.0

Cancer;Glio
ma;Melano
ma;Synovial
Sarcoma;Ov
arian
Cancer;Rena
1 Carcinoma

| Not | Metastatic | Other: Immuno | therapy | Observ |  | 50 | Survival |  | 04/07/2018 |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| recruiting | Gastric | responders/no | - | ational |  |  |  |  |  |
|  | Cancer | responders |  |  |  |  |  |  |  |
| Authorised | Histological | <br>Trade | Huma | Interve | Controlled: | 44 | Main | Secondary | 23/05/2019 |
|  | ly | Name: | n | ntional | yes |  | Objective: | end |  |
|  | confirmed, | OPDIVO 庐 | pharm | clinical | Randomised |  | Primary | point(s): |  |
|  | resectable | ( $100 \mathrm{mg} / 10 \mathrm{ml}$ | acolog | trial of | : yes |  | endpoint is | 欽 ? Patholo |  |
|  | advanced | )<br>Pharma | y | medici | Open: yes |  | the rate of | gical |  |
|  | gastric | ceutical | (Phase | nal | Single blind: |  | pathologic | response |  |
|  | cancer GC | Form: | I): no |  | no |  | al | rate |  |



| Organ | Concentratio | （Phase | treatment | $15 \%$ is | $1.1<$ br＞ |
| :---: | :---: | :---: | :---: | :---: | :---: |
| Class： | n type： | IV）：no | arms in the | expected | 欽 ？Overall |
| 10029104 | equal＜br＞Co |  | trial： 2 | serves as | survival |
| Neoplasms | ncentration |  |  | historical | rate at 3 |
| benign， | number：10－ |  |  | control， | years＜br＞ |
| malignant | ＜br＞＜br＞Pro |  |  | which | 鈥 ？Safety |
| and | duct Name： |  |  | could be |  |
| unspecified | Relatlimab＜b |  |  | achieved | and |
| （incl cysts | $r>$ Product |  |  | with the | tolerability |
| and polyps） | Code：BMS－ |  |  | standard | ＜br＞ |
|  | 986016＜br＞P |  |  | FLOT | 欽？Periope |
| ＜br＞MedD | harmaceutica |  |  | chemother | rative |
| RA version： | 1 Form： |  |  | apy based | morbidity |
| 21.0 | Solution for |  |  | on the | and |
| Level：LLT | solution for |  |  | results of | mortality |
| Classificatio | infusion＜br＞I |  |  | the FLOT4 | ＜br＞ |
| n code | NN or |  |  | trial．An | 鈥？Feasibil |


| 10030151 | Proposed |
| :--- | :--- |
| Term: | INN: |
| Oesophagea | Relatlimab<b |
| l cancer | r>Other |
| System | descriptive |
| Organ | name: |
| Class: | RELATLIMA |
| 10029104 | B<br>Concen |
| Neoplasms | tration unit: |
| benign, | mg/ml |
| malignant | milligram(s)/ |
| and | millilitre<br> |
| unspecified | Concentratio |
| (incl cysts | $\mathrm{n} \quad$ type: |
| and polyps) | equal<br>Co |
|  | ncentration |
| <br>MedD | number: 10- |


| increase to | ity of |
| :--- | :--- |
| $35 \% \quad$ in | perioperati |
| Arm B or D | ve |
| is assumed | immunoth |
| to be | erapy and |
| clinically | immunoch |
| relevant. ;S | emotherap |
| econdary | y, |
| Objective: | completen |
| 鍁 | ess of pre- |
| etermina | and |
| tion of | postoperat |
| pathologic | ive therapy |
| al response | <br> |
| rate | 鉄 ?Patient |
| (complete | reported |
| or subtotal | outcomes |


| RA version： 21.0 | $<$ br $><$ br $>$ Tra de $\quad$ Name： |
| :---: | :---: |
| Level：LLT | Fluorouracil－ |
| Classificatio | GRY 庐 50 |
| n code |  |
| 10056267 | roduct Name： |
| Term： | 5－ |
| Gastroesoph ageal cancer | Fluorouracil＜ br>Pharmace |
| System | utical Form： |
| Organ | Concentrate |
| Class： | for solution |
| 10029104 | for |
| Neoplasms | infusion＜br＞I |
| benign， | NN or |
| malignant | Proposed |
| and | INN： |


| response | assessed |
| :---: | :---: |
| $\mathrm{pCR} / \mathrm{pSR}$ ） | by Quality |
| according | of Life |
| to the | questionna |
| Becker | ire＜br＞ |
| criteria＜br | 欽 ？Transla |
| 鈥 | tional |
| urative | endpoints： |
| （R0） | tumor |
| resection | sample， |
| rate＜br＞鈥 | flow |
| ssessmen | cytometry， |
| $t$ of | microbiom |
| disease－ | e analysis |
| free | of gastric |
| Survival | fluid and |
| （DFS）rate | stool＜br＞； |


| unspecified | Fluorouracil< | at 3 years | Timepoint( |
| :---: | :---: | :---: | :---: |
| (incl cysts | br>Other | per | s) of |
| and polyps) | descriptive | Response | evaluation |
| ;Therapeutic | name: 5- | Evaluation | of this end |
| area: | Fluorouracil< | Criteria In | point: |
| Diseases [C] | br>Concentra | Solid | Evaluation |
| - Cancer | tion unit: | Tumors | s will be |
| [C04] | $\mathrm{mg} / \mathrm{ml}$ | (RECIST) | done after |
|  | milligram(s)/ | $1.1<\mathrm{br}>$ 鈥 | reaching |
|  | millilitre<br> | valuation | the |
|  | Concentratio | of overall | correspon |
|  | $n \quad$ type: | survival | ding end |
|  | equal<br $>$ Co | (OS) rate at | points. |
|  | ncentration | 3 |  |
|  | number: 50- | years<br> |  |
|  | <br><br>Tra | 鈥 |  |
|  | de Name: |  |  |


| Leucovorin | t of safety |
| :--- | :--- |
| 10 | and |
| $\mathrm{mg} / \mathrm{ml}<$ br>P | tolerability |
| harmaceutica | <br> 鉄 |
| $1 \quad$ Form: | erioperat |
| Concentrate | ive |
| for solution | morbidity |
| for | and |
| infusion<br>I | mortality |
| NN | <br> 鈥 |
| Proposed | easibility |
| INN: | of |
| CALCIUM | perioperati |
| FOLINATE< | ve |
| br>Other | immunoth |
| descriptive | erapy and |
| name: Folic | immunoch |


| acid＜br＞Con | emotherap |
| :--- | :--- |
| centration | y， |
| unit： $\mathrm{mg} / \mathrm{ml}$ | completen |
| milligram（s）／ | ess of pre－ |
| millilitre＜br＞ | and |
| Concentratio | postoperat |
| n type： | ive |
| equal＜br＞Co | therapy＜br |
| ncentration | $>$ 鈥 atient |
| number：10－ | reported |
| ＜br＞＜br＞Tra | Quality of |
| de Name： | Life＜br＞鈥 |
| Docetaxel－ | ranslatio |
| ratiopharm 庐 | nal |
| 20 | endpoints |
| mg／ml＜br＞P | for |
| harmaceutica | investigati |


| l Form: | on of |
| :--- | :--- |
| Concentrate | immunom |
| for solution | odulatory |
| for | agents |
| infusion<br>I | alone and |
| NN | in |
| Proposed | combinatio |
| INN: | n with |
| Docetaxel<br | cytotoxic |
| $>$ ather | agents:<br |
| descriptive | ePrimary |
| name: | point(s): |
| DOCETAXEL | Primary |
| TRIHYDRAT | endpoint is |
| E<br>Concen | the rate of |
| tration unit: | pCR as |
| mg/ml |  |


| milligram(s)/ | determine |
| :--- | :--- |
| millilitre<br> | d by |
| Concentratio | pathologic |
| n type: | al |
| equal<br>Co | examinatio |
| ncentration | n of the |
| number: 20- | resected |
| <br><br>Tra | tumor |
| de Name: | following |
| ELOXATIN | preoperati |
| 庐 | ve |
| mg/ml<br>P | systemic |
| harmaceutica | therapy. |
| $1 \quad$ Form: | $<$ br><br>; |
| Concentrate | Timepoint( |
| for solution | s) of |
| for | evaluation |


| infusion<br>I | of this end |
| :--- | :--- |
| NN or | point: |
| Proposed | Pathologic |
| INN: | al |
| OXALIPLATI | examinatio |
| N<br>CAS | n of the |
| Number: | resected |
| $61825-94-$ | tumor. |
| 3<br>Concen |  |
| tration unit: |  |
| mg/ml |  |
| milligram(s)/ |  |
| millilitre<br> |  |
| Concentratio |  |
| n |  |
| equal<br>Co |  |
| ncentration |  |


| Not | Advanced non-small-cell | Not | Observ | Not selected | 200 | Primary | Secondary | 16/05/2018 |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| Recruiting | lung cancer and advanced | applica | ational | Not selected |  | outcomes: | outcomes: |  |
|  | gastric cancer which are | ble |  |  |  | Subclinical | (1) |  |
|  | indications for anti-cytotoxic |  |  |  |  | or | clinically |  |
|  | T-lymphocyte-associated |  |  |  |  | smolderin | apparent |  |
|  | antigen-4, anti-programmed |  |  |  |  | g cardiac | acute |  |
|  | death-1, and anti- |  |  |  |  | toxicity, | myocarditi |  |
|  | programmed death-ligand 1 |  |  |  |  | defined as | s; (2) acute |  |
|  | antibodies. |  |  |  |  | a | heart |  |
|  |  |  |  |  |  | composite | failure, |  |
|  |  |  |  |  |  | of BNP | cardiogeni |  |
|  |  |  |  |  |  | elevation | c shock of |  |
|  |  |  |  |  |  | up to 200 | unknown |  |
|  |  |  |  |  |  | pg/mL, | etiology, or |  |
|  |  |  |  |  |  | positive | symptoma |  |

```
troponin T, tic
elevated deteriorati
CK-MB, on in at
new-onset least one
morpholog New York
ical Heart
electrocard Associatio
iogram n
abnormalit functional
ies, or a class; (3)
reduction lethal
in the left arrhythmi
ventricular a,
ejection including
fraction of advanced
&gt;10% or
    complete
```

compared AV block,
to baseline. ventricular
tachycardi
a, or
fibrillation;
(4) cardiac
death,
new-onset
acute
coronary
syndromes
, any
coronary
revasculari
zation
procedure;
(5) other
immune-
related
adverse
events,
including
dermatolo
gical,
ophthalmo
logical,
neurologic
al,
hematologi
cal,
gastrointes
tinal,
endocrine,
genitourin


| MedDRA | Combination | (Phase | produc |  | combinatio | (AE) |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| version: 20.1 | <br> | I): no | t | Open: no | n with | <br> |
|  | Product |  |  |  | chemother | 2/ |
| Level: PT | Code: BMS- | Therap |  | Single blind: | apy with | Incidence |
|  | 986213<br> | eutic |  | no | OS of | of Serious |
| Classificatio | Pharmaceutic | explor |  |  | chemother | Adverse |
| n code | al Form: | atory |  | Double | apy alone | Events |
| 10017758 | Solution for | (Phase |  | blind: yes | in | (SAEs) |
|  | injection/inf | II): no |  |  | participant | <br> |
| Term: | usion<br> |  |  | Parallel | s with | 3/ |
| Gastric cancer | INN or | Therap |  | group: yes | unresectab | Incidence |
|  | Proposed | eutic |  |  | le, | of AEs |
|  | INN: | confir |  | Cross over: | untreated, | leading to |
| System | NIVOLUMA | matory |  | no | locally | discontinu |
| Organ | B<br> | - |  |  | advanced | ation |
| Class: | CAS | (Phase |  | Other: no | or | <br> |
| 10029104 - | Number: | III): |  |  | metastatic | 4/ |


| Neoplasms | 946414-94- | yes | If |
| :---: | :---: | :---: | :---: |
| benign, | 4<br> |  | controlled, |
| malignant | Current | Therap | specify |
| and | Sponsor code: | eutic | comparator, |
| unspecified | BMS- | use | Other |
| (incl cysts | 936558<br> | (Phase | Medicinial |
| and polyps) | Other | IV): no | Product: yes |
|  | descriptive |  |  |
| <br> | name: MDX- |  | Placebo: no |
|  | 1106, ONO- |  |  |
| MedDrA | 4538<br> |  | Other: no |
| version: 20.0 | Concentratio |  |  |
|  | n unit: |  | Number of |
| Level: LLT | $\mathrm{mg} / \mathrm{ml}$ |  | treatment |
|  | milligram(s)/ |  | arms in the |
| Classificatio | millilitre<br> |  | trial: 3 |
| $n \quad$ code | Concentratio |  |  |


| LAG-3 | Number of |  |
| :--- | :--- | :--- |
| positive | deaths |  |
| gastric | or | <br> |
| GEJ | $5 /$ |  |
| adenocarci | Incidence |  |
| noma<br> | of |  |
| - To | laboratory |  |
| compare | abnormalit |  |
| PFS | of | ies |
| BMS- |  | <br> |
| $986213 ~ i n ~$ | $6 /$ |  |
| combinatio | Objective |  |
| n with | Response |  |
| chemother | Rate (ORR) |  |
| apy with | <br> |  |
| PFS | of | $7 /$ |
| chemother | Duration |  |


| 10056267 | n type: |
| :--- | :--- |
|  | equal<br> |
| Term: | Concentratio |
| Gastroesoph | n number: 12- |
| ageal cancer | <br> |
|  | INN or |
| System | Proposed |
| Organ | INN: |
| Class: | Relatlimab<b |
| 10029104 | r> |
| Neoplasms | Current |
| benign, | Sponsor code: |
| malignant | BMS- |
| and | 986016<br> |
| unspecified | Other |
| (incl cysts | descriptive |
| and polyps) | name: anti- |


|  | LAG-3<br> | positive | years |
| :---: | :---: | :---: | :---: |
| ;Therapeutic | Concentratio | GC or GEJ | <br> |
| area: | n unit: | adenocarci | 4/ Up to 5 |
| Diseases [C] | $\mathrm{mg} / \mathrm{ml}$ | noma<br> | years |
| Cancer | milligram(s)/ | ;<br> | <br> |
| [C04] | millilitre<br> | Secondary | 5/ Up to 5 |
|  | Concentratio | Objective: - | years |
|  | n type: | To assess | <br> |
|  | equal<br> | the overall | 6/ Up to 5 |
|  | Concentratio | safety and | years |
|  | n number: 4 - | tolerability | <br> |
|  | <br> | of BMS- | 7/ Up to 5 |
|  | Pharmaceutic | 986213 in | years |
|  | al form of the | combinatio | <br> |
|  | placebo: | n with |  |
|  | Solution for | chemother |  |
|  | infusion<br> | apy with |  |


| Route of | chemother |
| :--- | :--- |
| administratio | apy alone |
| n of the | and in |
| placebo: | treated |
| Intravenous | participant |
| use<br> | s with |
| Pharmaceutic | advanced |
| al form of the | or |
| placebo: | metastatic |
| Solution for | GC or GEJ |
| infusion<br> | cancer |
| Route of | tumors; <br |
| administratio | $>$ |
| $\mathrm{n} \quad$ of the | - |
| placebo: | compare |
| Intravenous | objective |
| use<br><br> | response |


| Trade Name: | rate (ORR) |
| :---: | :---: |
| Opdivo (100 | of BMS- |
| $\mathrm{mg} / 10$ | 986213 in |
| $\mathrm{ml})<$ br> | combinatio |
| Product | n with |
| Name: | chemother |
| NIVOLUMA | apy and |
| B - 10ml vial- | with ORR |
| COMMERCI | of |
| AL<br> | chemother |
| Product | apy alone |
| Code: BMS- | in |
| 936558<br> | randomize |
| Pharmaceutic | d |
| al Form: | participant |
| Concentrate | s with |
| for solution | advanced |


| for | or |
| :--- | :--- |
| infusion<br> | metastatic |
| INN | GC or GEJ |
| Proposed | cancer, by |
| INN: | BICR and |
| NIVOLUMA | by |
| B<br> | investigato |
| CAS | r<br> |
| Number: | - |
| 946414-94- | estimate |
| $4<$ br> | Duration |
| Current | of |
| Sponsor code: | Response |
| BMS- | (DOR) of |
| 936558<br> | BMS- |
| Other | $986213 \quad$ in |
| descriptive | combinatio |


| name: MDX- | n with |
| :--- | :--- |
| 1106, ONO- | chemother |
| $4538<$ br> | apy and |
| Concentratio | with DOR |
| n unit: | of |
| $\mathrm{mg} / \mathrm{ml}$ | chemother |
| milligram(s)/ | apy alone |
| millilitre<br> | in |
| Concentratio | randomize |
| n | type: |
| equal<br> | participant |
| Concentratio | s |
| n number: $10-$ | advanced |
| <br> | or |
| Pharmaceutic | metastatic |
| al form of the | GC or GEJ |
| placebo: | cancer, by |


| Solution for | BICR and |
| :--- | :--- |
| infusion<br> | by |
| Route of | investigato |
| administratio | $\mathrm{r}<$ br> |
| n of the | $1)$ |
| placebo: | unresectab |
| Intravenous | le, |
| use<br> | untreated, |
| Pharmaceutic | locally |
| al form of the | advanced |
| placebo: | or |
| Solution for | metastatic |
| infusion<br> | $<$ br> |
| Route of | $;<b r>$ |
| administratio | Primary |
| n of the | end |
| placebo: | point(s): $1 /$ |


| Intravenous | Overall |
| :--- | :--- |
| use<br><br> | survival |
| $(\mathrm{OS})<$ br> |  |
| $2 /$ |  |
|  | Progressio |
| n $\quad$ Free |  |
| Survival |  |
| $(\mathrm{PFS})<$ br> |  |
| ;<br> |  |
| Timepoint( |  |
| s) of |  |
| evaluation |  |
| of this end |  |
| point: $1 /$ |  |
| Up to 5 |  |
| years<br> |  |


| Authorised | Advanced gastrooesop |  |  |  |  | 83 | 2/ Up to 5 years<br> |  | 24/10/2018 |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  |  | <br>Product | Huma | Interve | Controlled: |  | Main | Secondary |  |
|  |  | Name: | n | ntional | no<br>Ran |  | Objective: | end |  |
|  | hageal and | Domatinostat | pharm | clinical | domised: |  | This trial is | point(s): |  |
|  | colorectal | <br>Product | acolog | trial of | no<br>Ope |  | designed | Toxicity |  |
|  | cancer | Code: | y | medici | n : |  | to evaluate | and |  |
|  | <br>MedD | Domatinostat | (Phase | nal | no<br>Singl |  | the safety | safety<br> |  |
|  | RA version: | <br>Pharmac | I): no | produc | e blind: |  | and | Progressio |  |
|  | 20.0 | eutical Form: | Therap | t | no<br>Dou |  | efficacy of | n free |  |
|  | Level: PT | Tablet<br>IN | eutic |  | ble blind: |  | administer | survival<b |  |
|  | Classificatio | $\mathrm{N} \quad$ or | explor |  | no<br>Paral |  | ing | $r>$ Overall |  |
|  | $n \quad$ code | Proposed | atory |  | lel group: |  | Domatinos | survival<b |  |
|  | 10009944 | INN: (E)-N- | (Phase |  | no<br>Cros |  | tat a | r>Translati |  |
|  | Term: Colon | (2- | II): yes |  | s over: |  | histone | onal |  |
|  | cancer | aminophenyl | Therap |  | no<br>Othe |  | deacetylate | endpoints; |  |
|  | System | )-3-(1-(4-(1- | eutic |  | r: no<br>If |  | lysine- | Timepoint( |  |


| Organ | methyl-1H- | confir | controlled, | specific | s) of |
| :---: | :---: | :---: | :---: | :---: | :---: |
| Class: | pyrazol-4-yl)- | matory | specify | demethyla | evaluation |
| 10029104 | phenylsulfon | - | comparator, | se inhibitor | of this end |
| Neoplasms | yl)-1H- | (Phase | Other | plus | point: |
| benign, | pyrrol-3-yl)- | III): no | Medicinial | avelumab, | Toxicity |
| malignant | acrylamide | Therap | Product: | an anti- | and safety |
| and | tosylate | eutic | no<br>Plac | PD-L1 | will be |
| unspecified | (IUPAC); | use | ebo: | monoclona | assessed |
| (incl cysts | proposed | (Phase | no<br>Othe | 1 antibody | throughou |
| and polyps) | INN: | IV): no | r: no<br> | in patients | $t$ study on |
|  | domatinostat |  |  | with | an ongoing |
| <br>MedD | <br>CAS |  |  | advanced | basis<br>S |
| RA version: | Number: |  |  | bowel, | urvival |
| 20.0 | 1186222-89- |  |  | stomach or | will be |
| Level: LLT | 8<br>Current |  |  | oesophage | assessed |
| Classificatio | Sponsor code: |  |  | al | on an |
| n code | 4SC- |  |  | adenocarci | ongoing |


| 10042080 | 202<br>Othe |
| :--- | :--- |
| Term: | r descriptive |
| Stomach | name: |
| cancer | None<br>Co |
| System | ncentration |
| Organ | unit: mg |
| Class: | milligram(s)< |
| 10029104 - | br>Concentra |
| Neoplasms | tion type: |
| benign, | equal<br>Co |
| malignant | ncentration |
| and | number: |
| unspecified | 100mg per |
| (incl cysts | tablet- |
| and polyps) | $<$ br><br>Tra |
|  | de Name: |
| <br>MedD | Bavencio<br> |


| RA version: Product | Domatinos |  |
| :--- | :--- | :--- |
| 21.0 | Name: | tat in |
| Level: PT | Bavencio<br> | combinatio |
| Classificatio | Pharmaceutic | n with |
| n code | al Form: | avelumab |
| 10030137 | Concentrate | and the |
| Term: | for solution | second |
| Oesophagea | for | stage |
| l | infusion<br>I | (Phase IIB, |
| adenocarcin | NN | efficacy) |
| oma | Proposed | will assess |
| System | INN: | the efficacy |
| Organ | Avelumab<b | of this |
| Class: | r>CAS | combinatio |
| 10029104 | Number: | n therapy |
| Neoplasms | $1537032-82-$ | in |
| benign, | $8<$ br>Other | achieving |


| malignant | descriptive | radiologica |
| :--- | :--- | :--- |
| and | name: Anti- | 1 response |
| unspecified | PD- | according |
| (incl cysts | L1<br>Conce | to RECIST |
| and polyps) | ntration unit: | 1.1 |
| ;Therapeutic | mg/ml | criteria. ;Se |
| area: | milligram(s)/ | condary |
| Diseases [C] | millilitre<br> | Objective: |
| - Cancer | Concentratio | Assess |
| [C04] | n | type: |
|  | equal<br>Co | safety and |
|  | ncentration | side effects |
|  | number: 20 | of |
|  | milligram- | Domatinos |
|  | millilitre<br> | tat plus |
|  | <br>Product | avelumab |
|  | Name: | and impact |
|  |  | on survival |


| Domatinostat | and |
| :--- | :--- |
| <br>Pharmac | disease |
| eutical Form: | control in |
| Tablet<br>IN | trial |
| N or | population |
| Proposed | assess the |
| INN: (E)-N- | effect of |
| (2- | each drug |
| aminophenyl | on the |
| )-3(1-(4-(1 | cancer cells |
| methyl-1H- | in biopsies. |
| p<br>CAS | To assess |
| Number: | the effect |
| 1186222-89- | of therapy |
| $8<$ br>Current | on |
| Sponsor code: | survival. ;P |
| 4 SC- |  |


| $202<$ br>Othe | rimary end |
| :--- | :--- |
| r descriptive | point(s): |
| name: | Primary |
| None<br>Co | Objective |
| ncentration | is to assess |
| unit: mg | the efficacy |
| milligram(s)< | of the |
| br>Concentra | addition of |
| tion type: | Domatinos |
| equal<br>Co | tat $\quad$ to |
| ncentration | avelumab |
| number: | therapy in |
| $100 m g \quad$ per | patients |
| tablet- | with |
| <br><br> | previously |
|  | treated |
|  | advanced |

OGA and
CRC.
<br>Outco
me
measures:
ORR
according
to RECIST
1.1
measured
using CT
imaging.
Timepoint(
s) of
evaluation
of this
outcome
measure is
best
response at

6
months. $<\mathrm{b}$
r>;Timepoi
nt(s)
of
evaluation
of this end
point:
Primary
endpoint
of the main
study is
objective
response.
This will

|  |  |  |  |  |  |  | be assessed |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  |  |  |  |  |  |  | on CT |  |  |
|  |  |  |  |  |  |  | every 6 |  |  |
|  |  |  |  |  |  |  | weeks. |  |  |
|  |  |  |  |  |  |  | Response |  |  |
|  |  |  |  |  |  |  | will be best |  |  |
|  |  |  |  |  |  |  | response |  |  |
|  |  |  |  |  |  |  | assessed at |  |  |
|  |  |  |  |  |  |  | any |  |  |
|  |  |  |  |  |  |  | timepoint. |  |  |
| Not | Gastric and | Drug: | Phase | Interve | Allocation: | 197 | Disease | Overall | 17/07/2019 |
| recruiting | Esophagoga | Nivolumab | 2 | ntional | Randomize |  | free | survival |  |
|  |  |  |  |  |  |  | survival | (OS);Loco- |  |
|  | Junction | Ipilimumab; |  |  | Intervention |  | (DFS) | regional |  |
|  | Adenocarci | Other: |  |  | model: |  |  | failure |  |
|  | noma | chemotherap |  |  | Parallel |  |  | rates;Dista |  |
|  |  | y |  |  | Assignment. |  |  | nt failure |  |


| Primary | rates;Rate |
| :--- | :--- |
| purpose: | of adverse |
| Treatment. | events |
| Masking: | according |
| None (Open | to NCI- |
| Label). | uality of |
|  | life |
|  | assessed |
|  | with the |
|  | EORTC |
|  | Quality of |
|  | Life |
|  | Questionn |
|  | aire (QLQ- |
|  | C30) |
|  | version 3 |


| Not | Lung | Experimental | New | Observ | Case series | Experi | Tumor | recurrence | 01/03/2018 |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| Recruiting | cancer, | group:NK/N | Treatm | ational <br> study |  | mental <br> group: <br> 180; | rate.;progression-free survival;overall survival; |  |  |
|  | stomach | KT | ent |  |  |  |  |  |  |
|  | cancer, | immunothera | Measu |  |  |  |  |  |  |
|  | hepatocellul | py; | re |  |  |  |  |  |  |
|  | ar cancer, |  | Clinica |  |  |  |  |  |  |
|  | pancreatic |  | 1 Study |  |  |  |  |  |  |
|  | cancer, |  |  |  |  |  |  |  |  |
|  | colorectal |  |  |  |  |  |  |  |  |
|  | cancer, |  |  |  |  |  |  |  |  |
|  | breast |  |  |  |  |  |  |  |  |
|  | cancer |  |  |  |  |  |  |  |  |
| Not | Gastric | Biological: | Phase | Interve | Allocation: | 120 | progressio | recurrent | 01/07/2017 |
| recruiting | Cancer | activated | 2 | ntional | Non- |  | n -free | rate;overal |  |
|  |  | DCs;Procedu |  |  | Randomize |  | survival | 1 survival |  |
|  |  | re: radical |  |  | d. |  |  | rate;immu |  |
|  |  | surgery only |  |  | Intervention |  |  | ne-cells |  |


|  |  |  |  |  | model: |  |  | response;A |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  |  |  |  |  | Parallel |  |  | dverse |  |
|  |  |  |  |  | Assignment. |  |  | event rate |  |
|  |  |  |  |  | Primary |  |  |  |  |
|  |  |  |  |  | purpose: |  |  |  |  |
|  |  |  |  |  | Treatment. |  |  |  |  |
|  |  |  |  |  | Masking: |  |  |  |  |
|  |  |  |  |  | None (Open |  |  |  |  |
|  |  |  |  |  | Label). |  |  |  |  |
| Recruiting | Gastric | Drug: 5- | Phase | Interve | Allocation: | 410 | Percentage | Progressio | 13/10/2017 |
|  | Adenocarci | Fluorouracil | 1/Phas | ntional | Randomize |  | of | n-Free |  |
|  | noma or | (5-FU);Drug: | e 2 |  | d. |  | Participant | Survival |  |
|  | Gastroesoph | Leucovorin;D |  |  | Intervention |  | s With | (PFS), as |  |
|  | ageal | rug: |  |  | model: |  | Objective | Determine |  |
|  | Junction | Oxaliplatin;D |  |  | Parallel |  | Response, | d by |  |
|  | Adenocarci | rug: |  |  | Assignment. |  | as | Investigato |  |
|  | noma or | Atezolizuma |  |  | Primary |  | Determine | r |  |


| Esophageal | b;Drug: |
| :--- | :--- |
| Carcinoma | Cobimetinib; |
|  | Biological: |
|  | Ramuciruma |
|  | b;Drug: |
|  | Paclitaxel;Bio |
|  | logical: |
|  | PEGylated |
|  | recombinant |
|  | human |
|  | hyaluronidas |
|  | e |
|  | (PEGPH20);D |
|  | rug: $\quad$ BL- |
|  | $8040 ; D r u g:$ |
|  | Linagliptin;D |
|  | rug: |


| purpose: | d by | According |
| :---: | :---: | :---: |
| Treatment. | Investigato | to RECIST |
| Masking: | r | v1.1;Overa |
| None (Open | According | 11 Survival |
| Label). | to | (OS);Perce |
|  | Response | ntage of |
|  | Evaluation | Participant |
|  | Criteria in | $s$ Who Are |
|  | Solid | Alive at |
|  | Tumors | Month 6 |
|  | (RECIST) | and at |
|  | Version 1.1 | Month |
|  | (v1.1);Perc | 12;Duratio |
|  | entage of | n of |
|  | Participant | Response, |
|  | s with | as |
|  | Adverse | Determine |


| Atezolizuma | Events | d by |
| :---: | :---: | :---: |
| b;Drug: | (AEs);For | Investigato |
| Cobimetinib; | Arm 1L-A : | r |
| Drug: | Percentage | According |
| Cisplatin;Dru | of | to RECIST |
| g : | Participant | v1.1;Perce |
| Tiragolumab; | s with | ntage of |
| Drug: 5- | Serious | Participant |
| Fluorouracil | and Non- | s With |
| (5-FU) | serious | Disease |
|  | Treatment- |  |
|  | related | Determine |
|  | AEs | d by the |
|  |  | Investigato |
|  |  | $r$ per |
|  |  | RECIST |
|  |  | v1.1;Serum |

## Concentrat

ion of
Atezolizu
mab;Plasm
a
Concentrat
ion of
Cobimetini
b;Plasma
Concentrat
ion of
PEGPH20;
Plasma
Concentrat
ion of BL-
8040;Plasm
a

## Concentrat

ion of
Linagliptin
;Percentag
e of
Participant
s With
Anti-Drug
Antibody
(ADA) to
Atezolizu
mab;Perce
ntage of
Participant
s With
ADA to
PEGPH20;


| Recruiting | 1 Cell |  | None (Open |  |  |  |  | n;Tumor |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  | Carcinoma |  |  |  | Label). |  |  | Marker |  |
|  | Colon | Biological: | Phase | Interve | Intervention | 60 | Toxicity | Survival | 01/01/2017 |
|  | Cancer;Esop | CAR-T cell | 1/Phas | ntional | model: |  | profile of | time of |  |
|  | hageal | immunothera | e 2 |  | Single |  | the | anti- |  |
|  | Carcinoma; | py;Biological: |  |  | Group |  | EpCAM | EpCAM |  |
|  | Pancreatic | CAR-T cell |  |  | Assignment. |  | targeted | CAR T |  |
|  | Cancer;Pros | immunothera |  |  | Primary |  | CAR T | cells in |  |
|  | tate | py;Biological: |  |  | purpose: |  | cells with | vivo;Anti- |  |
|  | Cancer;Gast | CAR-T cell |  |  | Treatment. |  | Common | tumor |  |
|  | ric | immunothera |  |  | Masking: |  | Toxicity | efficacy of |  |
|  | Cancer;Hep | py;Biological: |  |  | None (Open |  | Criteria for | CAR-T |  |
|  | atic | CAR-T cell |  |  | Label). |  | Adverse | therapy by |  |
|  | Carcinoma; | immunothera |  |  |  |  | Effects | Response |  |
|  | Colon | py |  |  |  |  | (CTCAE) | Evaluation |  |
|  | Cancer;Esop |  |  |  |  |  | version | Criteria In |  |
|  | hageal |  |  |  |  |  | 4.0;Toxicit | Solid |  |


| Carcinoma; | y profile ofTumors <br> (RECIST) |  |
| :--- | :--- | :--- |
| Pancreatic | the | EpCAM |
| Cancer;Pros | targeted |  |
| tate | CAR T |  |
| Cancer;Gast | cells with |  |
| ric | Common |  |
| Cancer;Hep | Toxicity |  |
| atic | Criteria for |  |
| Carcinoma; | Adverse |  |
| Colon | Effects |  |
| Cancer;Esop | (CTCAE) |  |
| hageal | version |  |
| Carcinoma; | $4.0 ;$ Toxicit |  |
| Pancreatic | y profile of |  |
| Cancer;Pros | the |  |
| tate | EpCAM |  |
| Cancer;Gast |  |  |


| ric | targeted |
| :--- | :--- |
| Cancer;Hep | CAR T |
| atic | cells with |
| Carcinoma; | Common |
| Colon | Toxicity |
| Cancer;Esop | Criteria for |
| hageal | Adverse |
| Carcinoma; | Effects |
| Pancreatic | (CTCAE) |
| Cancer;Pros | version 4.0 |
| tate |  |
| Cancer;Gast |  |
| ric |  |
| Cancer;Hep |  |
| atic |  |
| Carcinoma |  |


| Recruiting | gastric <br> cancer | NRT <br> group:NRT <br> immunothera <br> py; | I+II <br> (Phase <br> I+Phas <br> e II) | Observ <br> ational <br> study | Case series | NRT <br> group: <br> 40; | mDFS;im <br> munology <br> indexes; | Serum <br> markers;sa <br> fety; | 05/12/2016 |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| Not | Gastric | Procedure: | Phase | Interve | Allocation: | 150 |  | Portability | 01/12/2016 |
| recruiting | Cancer, | neoadjuvant | 2 | ntional | Randomize |  | year | of the |  |
|  | Metastatic | chemoimmun |  |  | d, Endpoint |  | survival | systemic |  |
|  |  | otherapy |  |  | Classificatio |  |  | therapy |  |
|  |  |  |  |  | n: Efficacy |  |  | methods; |  |
|  |  |  |  |  | Study, |  |  | Mortality; |  |
|  |  |  |  |  | Intervention |  |  | Downstagi |  |
|  |  |  |  |  | Model: |  |  | ng |  |
|  |  |  |  |  | Parallel |  |  | tumor;Mor |  |
|  |  |  |  |  | Assignment, |  |  | bidity;Qua |  |
|  |  |  |  |  | Masking: |  |  | lity of life |  |
|  |  |  |  |  | Open Label, |  |  |  |  |
|  |  |  |  |  | Primary |  |  |  |  |


| Not recruiting |  |  |  |  | Purpose: <br> Treatment | 93 |  | 01/12/2014 |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  | Breast | Biological: | Phase | Interve | Allocation: |  | Adverse events graded |  |
|  | Cancer;Lun | INO- | 1 | ntional | Non- |  | in accordance with |  |
|  | g | 1400;Biologic |  |  | Randomize |  | "Common Terminology |  |
|  | Cancer;Panc | al: INO- |  |  | d. |  | Criteria for Adverse |  |
|  | reatic | 9012;Biologic |  |  | Intervention |  | Events (CTCAE)", NCI |  |
|  | Cancer; Hea | al: INO-1401 |  |  | model: |  | version 4.03;Injection |  |
|  | d and Neck |  |  |  | Single |  | site reactions including, |  |
|  | Cancer;Ova |  |  |  | Group |  | but not necessarily |  |
|  | rian |  |  |  | Assignment. |  | limited to, local skin |  |
|  | Cancer;Colo |  |  |  | Primary |  | erythema, induration, |  |
|  | Rectal |  |  |  | purpose: |  | pain and tenderness at |  |
|  | Cancer;Gast |  |  |  | Prevention. |  | administration |  |
|  | ric |  |  |  | Masking: |  | site;Changes in safety |  |
|  | Cancer;Esop |  |  |  | None (Open |  | laboratory parameters |  |
|  | hageal |  |  |  | Label). |  |  |  |


| Recruiting | Cancer;Hep <br> atoCellular |  |  |  |  | 40 |  | 01/08/2016 |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  | Carcinoma |  |  |  |  |  |  |  |
|  | Precision | Drug: | Phase | Interve | Allocation: |  |  |  | Overall |
|  | Cell | Chemotherap | 1/Phas | ntional | Randomize |  |  | survival;Progress-free |  |
|  | Immunothe | y;Biological: | e 2 |  | d, Endpoint |  | survival;Quality of |  |
|  | rapy;Chemo | Precision Cell |  |  | Classificatio |  | life;Overall |  |
|  | therapy;Ad | Immunothera |  |  | n : |  | survival;Progress-free |  |
|  | vanced | py;Drug: |  |  | Safety/Effic |  | survival;Quality of life |  |
|  | Gastric | Chemotherap |  |  | acy Study, |  |  |  |
|  | Cancer;Preci | $y$;Biological: |  |  | Intervention |  |  |  |
|  | sion Cell | Precision Cell |  |  | Model: |  |  |  |
|  | Immunothe | Immunothera |  |  | Parallel |  |  |  |
|  | rapy;Chemo | py |  |  | Assignment, |  |  |  |
|  | therapy;Ad |  |  |  | Masking: |  |  |  |
|  | vanced |  |  |  | Open Label, |  |  |  |
|  |  |  |  |  | Primary |  |  |  |


| Recruiting | Gastric |  |  |  | Purpose: | 40 | Overall survival; $\operatorname{Pr}$ ogress-free survival | Quality of 01/08/2016 |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  | Cancer |  |  |  | Treatment |  |  |  |  |
|  | Precision | Drug: | Phase | Interve | Allocation: |  |  |  |  |
|  | Cell | Chemotherap | 1/Phas | ntional | Randomize |  |  | life |  |
|  | Immunothe | y;Biological: | e 2 |  | d, Endpoint |  |  |  |  |
|  | rapy;Chemo | Precision |  |  | Classificatio |  |  |  |  |
|  | therapy;Ad | Cells |  |  | n : |  |  |  |  |
|  | vanced |  |  |  | Safety/Effic |  |  |  |  |
|  | Malignancie |  |  |  | acy Study, |  |  |  |  |
|  | s |  |  |  | Intervention |  |  |  |  |
|  |  |  |  |  | Model: |  |  |  |  |
|  |  |  |  |  | Parallel |  |  |  |  |
|  |  |  |  |  | Assignment, |  |  |  |  |
|  |  |  |  |  | Masking: |  |  |  |  |
|  |  |  |  |  | Open Label, |  |  |  |  |

Primary

|  |  |  |  |  | Purpose: <br> Treatment |  |  |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| Not | Colorectal | Biological: | Phase | Interve | Allocation: | 1 | Incidence | Persistence | 09/08/2019 |
| recruiting | Adenocarci | Adoptive | 1 | ntional | N/A. |  | of toxicity | of an |  |
|  | noma;Metas | Immunothera |  |  | Intervention |  | defined as | immune |  |
|  | tatic | py;Biological: |  |  | model: |  | grade 3 or | response |  |
|  | Cholangioca | Aldesleukin; |  |  | Single |  | 4 non- | defined by |  |
|  | rcinoma;Me | Drug: |  |  | Group |  | hematologi | level of |  |
|  | tastatic | Cyclophosph |  |  | Assignment. |  | cor grade 4 | tetramer |  |
|  | Colorectal | amide;Other: |  |  | Primary |  | hematologi | positive T |  |
|  | Carcinoma; | Laboratory |  |  | purpose: |  | c toxicity | cell |  |
|  | Metastatic | Biomarker |  |  | Treatment. |  | per | population |  |
|  | Digestive | Analysis;Biol |  |  | Masking: |  | Common | over time |  |
|  | System | ogical: |  |  | None (Open |  | Terminolo | after T cell |  |
|  | Carcinoma; | Pembrolizum |  |  | Label). |  | gy Criteria | infusion; Pe |  |
|  | Metastatic | ab |  |  |  |  | for | rsistence of |  |
|  | Esophageal |  |  |  |  |  | Adverse | an immune |  |


| Carcinoma; | Events | response |
| :--- | :--- | :--- |
| Metastatic | version 4.0 | defined by |
| Gastric | T |  |
| Carcinoma; | interferon |  |
| Metastatic | gamma |  |
| Pancreatic | release in |  |
| Adenocarci | response to |  |
| noma;Stage | selected |  |
| IV | personaliz |  |
| Colorectal | ed peptide |  |
| Cancer | antigens;P |  |
| AJCC | ersistence |  |
| v7;Stage IV | of |  |
| Esophageal | immune |  |
| Cancer | response |  |
| AJCC | defined by |  |
| v7;Stage IV | levels of |  |


| Gastric | intracellula |
| :--- | :--- |
| Cancer | r cytokine |
| AJCC | staining of |
| v7;Stage IV | T cells in |
| Pancreatic | response to |
| Cancer | stimulatio |
| AJCC 6 n | with |
| and v7;Stage | personaliz |
| IVA | ed peptide |
| Colorectal | antigens;P |
| Cancer | ersistence |
| AJCC | of |
| v7;Stage IVB | immune |
| Colorectal | response |
| Cancer | defined by |
| AJCC v7 | detection |

spreading;
Proportion
of patients
who have
received T
cell
infusion
that is alive
and
progressio
n free
(complete
response
[CR] +
partial
response
[PR] +
stable
disease)
defined
based on
response
criteria
according
to
Response
Evaluation
Criteria in
Solid
Tumors
1.1;Time to
progressio
n;Respons
e rate (CR

|  |  |  |  |  |  |  |  | + |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  |  |  |  |  |  |  |  | PR);Overal |  |
|  |  |  |  |  |  |  |  | 1 survival |  |
| Not | gastric | moxibusion | New | Interve | Parallel | moxib | White | European | 08/06/2016 |
| Recruiting | cancer | treatment | Treatm | ntional |  | usion | blood | Organizati |  |
|  |  | group:scarrin | ent | study |  | treatm | cells;lymp | on for |  |
|  |  | g | Measu |  |  | ent | hocyte;neu | Research |  |
|  |  | moxibusion; | re |  |  | group: | trophil;Plat | and |  |
|  |  | Grain | Clinica |  |  | 30;Grai | elet;CD19+ | Treatment |  |
|  |  | moxibustion | 1 Study |  |  | n | ;CD28+; ${ }^{\text {C }}$ | of Cancer |  |
|  |  | combined |  |  |  | moxib | D8+/CD28 | Quality of |  |
|  |  | with CIK |  |  |  | ustion | +;CD8+/C | Life |  |
|  |  | group:Grain |  |  |  | combi | D28-;CD3+ | Questionn |  |
|  |  | moxibustion |  |  |  | ned | ;CD3+/HL | aire; |  |
|  |  | combined |  |  |  | with | A- |  |  |
|  |  | with CIK |  |  |  | CIK | DR+;CD3+ |  |  |
|  |  | treatment; CI |  |  |  | group: | /HR- |  |  |


| K group:CIK treatment;Bla | $\begin{aligned} & \text { 30;CIK } \\ & \text { group: } \end{aligned}$ | $\begin{aligned} & \text { DR-;CD- } \\ & \text { /CD16+56 } \end{aligned}$ |
| :---: | :---: | :---: |
| nk control | 30;Blan | +;CD4+CD |
| group:Don't | k | 25+;CD4+ |
| do anything | control | /CD29+; C |
| with normal | group: | D4+/CD45 |
| people; | 30; | RA+;CD4+ |
|  |  | /CD45RO |
|  |  | +;Different |
|  |  | ial |
|  |  | expression |
|  |  | analysis of |
|  |  | genes;GO |
|  |  | and KEGG |
|  |  | function |
|  |  | notes;rng- |


|  |  |  |  |  |  |  | seq |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| Not | Gastric | Biological: | Phase | Interve | Endpoint | 36 | Progressio | Incidences | 01/03/2016 |
| recruiting | Cancer. | Autologous T | 0 | ntional | Classificatio |  | n -Free- | of adverse |  |
|  |  | cells-Based |  |  | n : |  | Survival(P | events or |  |
|  |  | Immunothera |  |  | Safety/Effic |  | FS) | serious |  |
|  |  | py |  |  | acy Study, |  |  | adverse |  |
|  |  |  |  |  | Intervention |  |  | events |  |
|  |  |  |  |  | Model: |  |  |  |  |
|  |  |  |  |  | Single |  |  |  |  |
|  |  |  |  |  | Group |  |  |  |  |
|  |  |  |  |  | Assignment, |  |  |  |  |
|  |  |  |  |  | Masking: |  |  |  |  |
|  |  |  |  |  | Open Label, |  |  |  |  |
|  |  |  |  |  | Primary |  |  |  |  |
|  |  |  |  |  | Purpose: |  |  |  |  |
|  |  |  |  |  | Treatment |  |  |  |  |


| Not recruiting | Stomach Neoplasms |  | N/A | Observ <br> ational | Observation | 250 | overall <br> survival |  | 01/03/2010 |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  |  |  |  |  | al Model: |  |  |  |  |
|  |  |  |  |  | Cohort, |  |  |  |  |
|  |  |  |  |  | Time |  |  |  |  |
|  |  |  |  |  | Perspective: |  |  |  |  |
|  |  |  |  |  | Retrospectiv |  |  |  |  |
|  |  |  |  |  | e |  |  |  |  |
| Recruiting | Liver | Biological: | Phase | Interve | Allocation: | 40 | Overall | Progress- | 01/09/2015 |
|  | Metastasis; | PIK- | 1/Phas | ntional | Randomize |  | survival | free |  |
|  | Gastric | HER2;Biologi | e 2 |  | d, Endpoint |  |  | survival;Q |  |
|  | Cancer | cal: DC- |  |  | Classificatio |  |  | uality of |  |
|  |  | PMAT |  |  | n : |  |  | life |  |
|  |  |  |  |  | Safety/Effic |  |  |  |  |
|  |  |  |  |  | acy Study, |  |  |  |  |
|  |  |  |  |  | Intervention |  |  |  |  |
|  |  |  |  |  | Model: |  |  |  |  |
|  |  |  |  |  | Parallel |  |  |  |  |


|  |  |  |  |  | Assignment, |  |  |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  |  |  |  |  | Masking: |  |  |  |  |
|  |  |  |  |  | Open Label, |  |  |  |  |
|  |  |  |  |  | Primary |  |  |  |  |
|  |  |  |  |  | Purpose: |  |  |  |  |
|  |  |  |  |  | Treatment |  |  |  |  |
| Not | Gastric | Biological: | Phase | Interve | Allocation: | 120 | Reduced | Safety, as | 01/12/2019 |
| recruiting | Cancer | CIK;Biologica | 1/Phas | ntional | Randomize |  | size of the | measured |  |
|  |  | 1: $\quad$ ?d | e 2 |  | d. |  | tumor. | by the rate |  |
|  |  | T;Biological: |  |  | Intervention |  |  | of adverse |  |
|  |  | CIK and ?d T |  |  | model: |  |  | events and |  |
|  |  |  |  |  | Parallel |  |  | serious |  |
|  |  |  |  |  | Assignment. |  |  | adverse |  |
|  |  |  |  |  | Primary |  |  | events |  |
|  |  |  |  |  | purpose: |  |  |  |  |
|  |  |  |  |  | Treatment. |  |  |  |  |
|  |  |  |  |  | Masking: |  |  |  |  |


| Recruiting | gastric <br> cancer |  |  |  | Single <br> (Investigato |  |  |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  |  |  |  |  | r). |  |  |  |  |
|  |  | Simple | II | Interve | Randomize | Simple | Progressio | The | 11/02/2015 |
|  |  | chemotherap | (Phase | ntional | d parallel | chemo | n free | disease |  |
|  |  | y | II | study | controlled | therap | survival;ov | control |  |
|  |  | group:chemo | study) |  | trial | y | erall | rate;Object |  |
|  |  | therapy ;Che |  |  |  | group: | survival;m | ive |  |
|  |  | motherapy |  |  |  | 40;Che | edian | remission |  |
|  |  | combined |  |  |  | mother | survival | rate;molec |  |
|  |  | with |  |  |  | apy | time; | ular |  |
|  |  | immunothera |  |  |  | combi |  | markers in |  |
|  |  | py |  |  |  | ned |  | serum;sub |  |
|  |  | group:Chemo |  |  |  | with |  | sets of |  |
|  |  | therapy |  |  |  | immu |  | lymphocyt |  |
|  |  | combined |  |  |  | nother |  | es in |  |
|  |  | with |  |  |  | apy |  | PBMC;reg |  |


|  |  | immunothera |  |  |  | group: |  | ulator |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  |  | py ; |  |  |  | 40; |  | cell in |  |
|  |  |  |  |  |  |  |  | PBMC;sup |  |
|  |  |  |  |  |  |  |  | pressor |  |
|  |  |  |  |  |  |  |  | cell |  |
|  |  |  |  |  |  |  |  | PBMC; |  |
| Recruiting | Breast | Biological: | Phase |  | Allocation: | 54 | Adverse | Time | 01/12/2014 |
|  | Cancer;Lun | INO- | 1 | ntional | Non- |  | events | progressio |  |
|  | g | 1400;Biologic |  |  | Randomize |  | graded in | n;Antigen |  |
|  | Cancer;Panc | al: INO-9012 |  |  | d, Endpoint |  | accordance | specific |  |
|  | reatic |  |  |  | Classificatio |  | with | cellular |  |
|  | Cancer; Hea |  |  |  | n : |  | "Common | immune |  |
|  | d and Neck |  |  |  | Safety/Effic |  | Terminolo | responses; |  |
|  | Squamous |  |  |  | acy Study, |  | gy Criteria | Antigen |  |
|  | Cell |  |  |  | Intervention |  | for | specific |  |
|  | Cancer;Ova |  |  |  | Model: |  | Adverse | ELISA;H\& |  |
|  | rian |  |  |  | Single |  | Events | E stain |  |


| Cancer;Colo | Group | (CTCAE)", | immunohi |
| :---: | :---: | :---: | :---: |
| rectal | Assignment, | NCI | stochemist |
| Cancer;Gast | Masking: | version | ry for |
| ric | Open Label, | 4.03;Injecti | CD45, |
| Cancer;Esop | Primary | on site | CD3, CD8, |
| hageal | Purpose: | reactions | FoxP3; and |
| Cancer;Hep | Treatment | including, | TCRbeta |
| atocellular |  | but not | molecular |
| Cancer |  | necessarily | analysis of |
|  |  |  | baseline/a |
|  |  |  |  |
|  |  | erythema, | tumor |
|  |  | induration, | tissue and |
|  |  | pain and | relapsed |
|  |  | tenderness | tumor |
|  |  | at | tissue, |
|  |  | administra |  |



| Not | Metastatic | Drug: OBI- Phase | Interve | Allocation: 25 | Safety and tolerability 22/12/2015 |
| :--- | :--- | :--- | :--- | :--- | :--- | :--- |
| recruiting | Gastric | 833/OBI-821 1 | ntional | Non- | assessed by adverse |


|  | astatic |  |  |  | Treatment. |  |  |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  | Cancer |  |  |  | Masking: |  |  |  |  |
|  |  |  |  |  | None (Open |  |  |  |  |
|  |  |  |  |  | Label). |  |  |  |  |
| Not | Gastric | Biological: | Phase | Interve | Allocation: | 63 | Progressio | Overall | 01/02/2013 |
| recruiting | Cancer | DC- | 1/Phas | ntional | Non- |  | $\mathrm{n} \quad$ free | survival;R |  |
|  |  | CIK;Drug: S- |  |  | Randomize |  | survival(P | esponse |  |
|  |  | 1;Drug: |  |  | d. |  | FS) | rate;Adver |  |
|  |  | Cisplatin |  |  | Intervention |  |  | se |  |
|  |  |  |  |  | model: |  |  | Events;Qu |  |
|  |  |  |  |  | Parallel |  |  | ality of life |  |
|  |  |  |  |  | Assignment. |  |  |  |  |
|  |  |  |  |  | Primary |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  | Treatment. |  |  |  |  |
|  |  |  |  |  | Masking: |  |  |  |  |



| Not | Peritoneal | Investigation Phase | Interve | Phase II 40 |
| :--- | :--- | :--- | :--- | :--- | :--- |
| Recruiting | carcinomato | al medicinal II | ntional | intervention |


| 1. Decrease | $1 . \quad$ Safety $01 / 10 / 2011$ |
| :--- | :--- |
| of the | parameters |
| incidence | :<br>1.1. |
| of | The need |
| clinically | to |
| significant | discontinu |
| malignant | e |
| ascites<br | catumaxo |
| $>2$. | mab |
| Decrease | infusion<b |
| of the | r>1.2. |
| Incidence | Frequency, |
| of | relationshi |
| intestinal | p and |
| obstructio | intensity of |
| n with the | clinically |
| need of | relevant |

: Laparoscopy
or
laparotomy
and exact
staging of
peritoneal
carcinomatosi
s will be
mandatory
Implantation
of an i.p.-port
or a catheter-
device will be
performed.
Patients with
laparoscopy
can be treated

| surgical | grade III |
| :--- | :--- |
| interventio | and IV |
| n | or |
| parenteral | adverse |
| nutrition< | $>2$. |
| br>3. | Immunolo |
| Decrease | gical |
| of the | monitoring |
| incidence | : $<$ br>2.1. |
| of ECOG | Induction |
| deteriorati | of anti- |
| on<br>4. | tumour |
| Decrease | response< |
| of the | br>2.2. |
| incidence | Quality |
| of | and |
| death<br> | quantity of |

interventio and IV
parenteral events<br
nutrition $<>2$.
br>3. Immunolo
Decrease gical
of the monitoring
incidence : <br>2.1.
of ECOG Induction
deteriorati of anti-
on<br>4. tumour
Decrease response<
of the $\mathrm{br}>2.2$.
incidence Quality
death<br> quantity of

| with the first | 5. Every | epithelial |
| :---: | :---: | :---: |
| dose of | parameter | cell |
| catumaxoma | will be | adhesion |
| $b$ after 3 days. | analysed | molecule |
| Patients with | separately | (EpCAM)- |
| tumor | in | expression |
| debulking | compariso | < br>2.3. |
| surgery or | n to | Disseminat |
| major | historical | ed tumour |
| resection | controls | cells and |
| (anterior |  | tumour |
| rectum |  | stem cells |
| resection, |  | within the |
| gastrectomy) |  | peripheral |
| can also be |  | blood |
| included. In |  | during |
| this case, |  | therapy<br |


| treatment | $>2.4$. Anti- |
| :--- | :--- |
| starts at least | EpCAM |
| 10 days after | and anti- |
| surgery. | HER2/neu |
| Further | humoral |
| criteria for | immune |
| treatment | response< |
| include | br>2.5. |
| complete | vascular |
| enteral | endothelial |
| nutrition and | growth |
| no | factor |
| postoperative | (VEGF)- |
| problems (i.e. | level |
| anastomotic | during |
| leakage, | therapy<br |
| abscess | $>2.6$. |


| formation | Induction |
| :---: | :---: |
| etc.). The 1st | of human |
| cycle of | anti-mouse |
| catumaxoma | antibodies |
| $b \quad$ is | (HAMA) < |
| completed by | br>2.7. |
| 10-20-50-200 | Systemic |
| 碌g on day 0- | levels of |
| 3-7-10 after | catumaxo |
| start of |  |
| treatment. | i.p. |
| Catumaxoma | therapy |
| $b$ treatment is |  |
| followed by |  |
| intravenous |  |
| chemotherap |  |
| y within day |  |

30 to 90 . A
regimen of
oxaliplatin,
leucovorin,
and 5-
fluorouracil
(FOLFOX4,
FOLFOX6, or
FOLFIRI) for
colorectal and
fluorouracil,
leucovorin
oxaliplatin
(FLO) or
fluorouracil,
leucovorin,
oxaliplatin,
and docetaxel
(FLOT) for
gastric cancer
is
recommende
d, but any
other
chemotherap
y according to
previous
chemotherap
y and
decision of
the medical
oncologist is
allowed. This
is followed by
a second cycle
of
catumaxoma
b i.p.
immunothera
py between
day 91 and
120; followed
by another
i.v.-
chemotherap
y between
day 121 and
day 180.
Multimodal
chemotherap
y including

|  |  | biological modifiers (i.e. |  |  |  |  |  |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  |  | Cetuximab, |  |  |  |  |  |  |  |
|  |  | Bevacizumab, |  |  |  |  |  |  |  |
|  |  | Trastuzumab |  |  |  |  |  |  |  |
|  |  | or others) is |  |  |  |  |  |  |  |
|  |  | not |  |  |  |  |  |  |  |
|  |  | permitted. |  |  |  |  |  |  |  |
| Not | stage I-III | Control | Not | Interve | Parallel | 50 | Immunosu | Incidence | 01/01/2010 |
| Recruiting | stomach | group<br>PS | selecte | ntional | Randomize |  | ppressive | of Surgical |  |
|  |  | K before | d |  | d |  | parameter ( | Site |  |
|  |  | surgery |  |  |  |  | IL-6, IL-10, | Infections< |  |
|  |  | group<br>3 |  |  |  |  | TGF- | br>Surgica |  |
|  |  | times per day |  |  |  |  | beta)<br>E | 1 stress |  |
|  |  | $(3 \mathrm{~g})<\mathrm{br}>2$ |  |  |  |  | ach | marker |  |
|  |  | weeks p.o. |  |  |  |  | parameter | (MCP-1; |  |
|  |  | daily |  |  |  |  | is | Monocyte |  |


| measured | Chemoattr |
| :--- | :--- |
| to $\quad$ the | actant |
| following | Protein- |
| timing.<br | $1)<$ br>Seru |
| $>$ Before | m |
| PSK | albumin<b |
| administra | r>Perioper |
| tion before | ative |
| surgery<br | changes of |
| $>$ After PSK | CRP<br> |
| administra | Withdraw |
| tion before | al rate of |
| surgery<br | clinical |
| $>$ Within 3 | path<br>P |
| days after | eriod of |
| surgery<br | hospitaliza |
| $>3$ weeks | tion |


|  |  |  |  |  |  |  | after <br> surgery |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| Not | colon | Vaccination | Phase | Interve | Single arm | 10 | Safety | Immunolo | 01/04/2005 |
| Recruiting | cancer, | with peptide- | I,II | ntional | Non- |  |  | gical and |  |
|  | stomach | pulsed |  |  | randomized |  |  | clinical |  |
|  | cancer | dendritic cells |  |  |  |  |  | efficacy |  |
| Not | Breast | Biological: | Phase | Interve | Endpoint | 14 | Safety | Immune | 01/01/2002 |
| recruiting | Cancer;Colo | TRICOM- | 1 | ntional | Classificatio |  |  | response |  |
|  | rectal | CEA(6D) |  |  | n: Safety |  |  |  |  |
|  | Cancer;Gall |  |  |  | Study, |  |  |  |  |
|  | bladder |  |  |  | Intervention |  |  |  |  |
|  | Cancer;Gast |  |  |  | Model: |  |  |  |  |
|  | ric |  |  |  | Single |  |  |  |  |
|  | Cancer; Hea |  |  |  | Group |  |  |  |  |
|  | d and Neck |  |  |  | Assignment, |  |  |  |  |
|  | Cancer;Live |  |  |  | Masking: |  |  |  |  |
|  | r |  |  |  | Open Label, |  |  |  |  |


|  | Cancer;Ova |  |  |  | Primary |  |  |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  | rian |  |  |  | Purpose: |  |  |  |  |
|  | Cancer;Panc reatic |  |  |  | Treatment |  |  |  |  |
|  | Cancer;Testi cular Germ |  |  |  |  |  |  |  |  |
|  | Cell Tumor |  |  |  |  |  |  |  |  |
| Not | Breast | Biological: | Phase | Interve | Allocation: | 0 | Determine | Characteri | 01/03/2000 |
| recruiting | Cancer;Gast | MVF-HER- | 1 | ntional | Non- |  | the | ze the |  |
|  | ric | 2(628-647)- |  |  | Randomize |  | optimum | nature and |  |
|  | Cancer;Lun | CRL 1005 |  |  | d, Endpoint |  | biologic | severity of |  |
|  | g | vaccine |  |  | Classificatio |  | dose of | toxicity of |  |
|  | Cancer;Ova |  |  |  | n : |  | MVF-HER- | this drug |  |
|  | rian |  |  |  | Safety/Effic |  | 2 (628- | in these |  |
|  | Cancer;Uns |  |  |  | acy Study, |  | 647)-CRL | patients.;D |  |
|  | pecified |  |  |  | Intervention |  | 1005 | ocument |  |
|  | Adult Solid |  |  |  | Model: |  | vaccine | any clinical |  |


|  | Tumor, |  |  |  | Single |  | that will | responses |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  | Protocol |  |  |  | Group |  | induce | to thi |  |
|  | Specific |  |  |  | Assignment, |  | snit-HER-2 | drug |  |
|  |  |  |  |  | Masking: |  | antibody | these |  |
|  |  |  |  |  | Open Label, |  | in patients | patients. |  |
|  |  |  |  |  | Primary |  | with |  |  |
|  |  |  |  |  | Purpose: |  | metastatic |  |  |
|  |  |  |  |  | Treatment |  | or |  |  |
|  |  |  |  |  |  |  | recurrent |  |  |
|  |  |  |  |  |  |  | cancer |  |  |
| Not | Breast | Biological: | N/A | Interve | Endpoint | 3 | Safety |  | 01/02/2000 |
| recruiting | Cancer;Gast | HER-2/neu |  | ntional | Classificatio |  |  |  |  |
|  | ric | intracellular |  |  | n: Safety |  |  |  |  |
|  | Cancer;Ova | domain |  |  | Study, |  |  |  |  |
|  | rian Cancer | protein;Biolo |  |  | Intervention |  |  |  |  |
|  |  | gical: |  |  | Model: |  |  |  |  |
|  |  | therapeutic |  |  | Single |  |  |  |  |


|  |  | autologous |  |  | Group |  |  |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  |  | dendritic cells |  |  | Assignment, |  |  |  |  |
|  |  |  |  |  | Masking: |  |  |  |  |
|  |  |  |  |  | Open Label, |  |  |  |  |
|  |  |  |  |  | Primary |  |  |  |  |
|  |  |  |  |  | Purpose: |  |  |  |  |
|  |  |  |  |  | Treatment |  |  |  |  |
| Not | Breast | Biological: | Phase | Interve | Endpoint | 24 | Safety | Immune | 01/02/1997 |
| recruiting | Cancer;Colo | CEA RNA- | 1 | ntional | Classificatio |  |  | response |  |
|  | rectal | pulsed DC |  |  | n : Safety |  |  |  |  |
|  | Cancer;Extr | cancer |  |  | Study, |  |  |  |  |
|  | ahepatic Bile | vaccine |  |  | Intervention |  |  |  |  |
|  | Duct |  |  |  | Model: |  |  |  |  |
|  | Cancer;Gall |  |  |  | Single |  |  |  |  |
|  | bladder |  |  |  | Group |  |  |  |  |
|  | Cancer;Gast |  |  |  | Assignment, |  |  |  |  |
|  | ric |  |  |  | Masking: |  |  |  |  |


| Cancer;Hea | Open Label, |
| :--- | :--- |
| d and Neck | Primary |
| Cancer;Live | Purpose: |
| r | Treatment |
| Cancer;Lun |  |
| g |  |
| Cancer;Met |  |
| astatic |  |
| Cancer;Ova |  |
| rian |  |
| Cancer;Panc |  |
| reatic |  |
| Cancer;Testi |  |
| cular Germ |  |


| COMPLETE | Advanced | BIOLOGICA | EARL | INTER | Allocation: | 9 | Objective |
| :--- | :--- | :--- | :--- | :--- | :--- | :--- | :--- | Duration $2 / 9$


| Esophageal | (PR). | sample |
| :--- | :--- | :--- |
| Adenocarci | Responses | size |
| noma AJCC | are based | permits., |
| v8\|Clinical | on | From first |
| Stage IV | assessment | documente |
| Gastric | s by the | d evidence |
| Cancer | blinded | of CR or |
| AJCC | MD | PR up to 4 |
| v8\|Clinical | Anderson | years \|Dise |
| Stage IVA | radiology | ase control |
| Esophageal | per | rate, |
| Adenocarci | Response | Defined as |
| noma AJCC | Evaluation | the |
| v8 \|Clinical | Criteria in | percentage |
| Stage IVA | Solid | of subjects |
| Gastric | Tumors | who have |
| Cancer | (RECIST) | achieved |

AJCC
v8|Clinical
Stage IVB
Esophageal
Adenocarci
noma AJCC
v8 |Clinical
Stage IVB
Gastric
Cancer
AJCC
v8|Gastroes
ophageal
Junction
Adenocarci
noma|Meta
static
1.1. Exact CR, PR, or
method stable
based on disease
binomial (SD) for at
distributio least 24
n weeks
(Clopper- based on
Pearson assessment
method)., s by MD
Up to 4 Anderson
years radiology
per
RECIST
1.1. Exact
method
based on
binomial

| Gastroesoph | distributio |
| :--- | :--- |
| ageal | n |
| Junction | (Clopper- |
| Adenocarci | Pearson |
| noma \|Path | method)., |
| ologic Stage | Up to 4 |
| III | years \|Tim |
| Esophageal | e |
| Adenocarci | progressio |
| noma AJCC | n, |
| v8\|Patholo | Assessed |
| gic Stage III | per |
| Gastric | RECIST 1.1 |
| Cancer | basedon <br> AJCC |
| v8\|Patholo | assessment |
| gic Stage | s by MD |


| IIIA | radiology. |
| :--- | :--- |
| Esophageal | Summary |
| Adenocarci | statistics |
| noma AJCC | using |
| v8\|Patholo | Kaplan- |
| gic Stage | Meier |
| IIIA Gastric | method., |
| Cancer | From the |
| AJCC | first day of |
| v8\|Patholo | study |
| gic Stage | treatment |
| IIIB | up to 4 |
| Esophageal | years $\mid$ Pro |
| Adenocarci | gression- |
| noma AJCC | free |
| v8\|Patholo | survival |
| gic Stage | per |


| IIIB Gastric | RECIST 1.1 |
| :--- | :--- |
| Cancer | based on |
| AJCC | assessment |
| v8\|Patholo | s by MD |
| gic Stage | Anderson |
| IIIC Gastric | radiology, |
| Cancer | Summary |
| AJCC | statistics |
| v8\|Patholo | using |
| gic Stage IV | Kaplan- |
| Esophageal | Meier |
| Adenocarci | method., |
| noma AJCC | From the |
| v8\|Patholo | first day of |
| gic Stage IV | study |
| Gastric | treatment |
| Cancer | to the first |


| AJCC | documente |
| :--- | :--- |
| v8\|Patholo | d disease |
| gic Stage | progressio |
| IVA | n up to 4 |
| Esophageal | years $\mid$ Ove |
| Adenocarci | rall |
| noma AJCC | survival, |
| v8\|Patholo | Summary |
| gic Stage | statistics |
| IVB | using |
| Esophageal | Kaplan- |
| Adenocarci | Meier |
| noma AJCC | method., |
| v8\|Postneo | From first |
| adjuvant | doseof <br> Therapy <br> Stage III$\quad$ study |


| Gastric | up to 4 |
| :--- | :--- |
| Cancer | years \| Inci |
| AJCC | dence of <br> v8\|Postneo <br> adjuvant <br> Therapy <br> Stage adverse <br> Gastric |
| Cancer | events, |
| AJCC | Defined by |
| v8\|Unresect | National |
| able | Cancer |
| Gastroesoph | Institute |
| ageal | Common |
| Junction | Terminolo |
| Adenocarci | gy Criteria |
| noma | for |

events will
be
assessed.
Specific
events will
be
collected
and
designated
as events
of clinical
interest
(ECIs)., Up
to 30 days
post
treatment

| ACTIVE_NO | Non-Small | DRUG: N-803 | PHAS | INTER | Allocation: | 147 | Objective | Disease- | 2018/12/11 |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| T_RECRUITI | Cell Lung | + | E2 | VENTI | NON_RAN |  | Response | specific |  |
| NG | Cancer 15 Sm | Pembrolizum |  | ONAL | DOMIZED |  | Rate, | Survival, |  |
|  | all Cell Lung | ab\|DRUG: |  |  | Intervention |  | Assess | Assess |  |
|  | Cancer \\| Uro | N-803 + |  |  | Model: |  | ORR, | time from |  |
|  | thelial | Nivolumab \| |  |  | PARALLEL |  | defined as | first |  |
|  | Carcinoma | DRUG: N-803 |  |  | \| Masking: |  | Investigato | treatment |  |
|  | Head and | + |  |  | NONE \| Pri |  | r-assessed | to death |  |
|  | Neck | Atezolizuma |  |  | mary |  | $C R+\mathrm{PR}$, | resulting |  |
|  | Squamous | b\|DRUG: N- |  |  | Purpose: |  | per | from |  |
|  | Cell | $803+$ |  |  | TREATME |  | RECIST | cancer., 24 |  |
|  | Carcinoma | Avelumab\|D |  |  | NT |  | 1.1., 24 | months ${ }^{\text {O }}$ |  |
|  | Merkel Cell | RUG: N-803 + |  |  |  |  | months | verall |  |
|  | Carcinoma | Durvalumab |  |  |  |  |  | Survival, |  |
|  | Melanoma | \| DRUG: N- |  |  |  |  |  | Assess |  |
|  | Renal Cell | $803+$ |  |  |  |  |  | time from |  |
|  | Carcinoma | Pembrolizum |  |  |  |  |  | first |  |


| Gastric | ab + PD-L1 t- | treatment |
| :--- | :--- | :--- |
| Cancer\|Cer | haNK\|DRU | to death |
| vical | G: N-803 + | resulting |
| Cancer\|He | Nivolumab + | from any |
| patocellular | PD-L1 t- | cause., 24 |
| Carcinoma \| haNK|DRU | months \|Ti |  |
| Microsatellit G: N-803 + | me to |  |
| e | Atezolizuma | Response, |
| Instability\| | b + PD-L1 t- | Assess |
| Mismatch | haNK\|DRU | time to |
| Repair | G: N-803 + | response, |
| Deficiency \| Avelumab + | 24 |  |
| Colorectal | PD-L1 t- | months \|D |
| Cancer | haNK\|DRU | uration of |
|  | G: N-803 + | Response, |
|  | Durvalumab | Assess |

+ PD-L1 t- response,haNK24
months | In
cidence of
AdverseEvents,
Assess
incidenceof adverseevents., 24months $\mid Q$
uality ofLife (QOL),
Comparechanges in
QOLscores

Free
Survival,
Assess
time from
first
treatment
to disease
progressio
n or death
from any
cause,
whichever

|  |  |  |  |  |  |  |  | occurs |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  |  |  |  |  |  |  |  | first., 24 months |  |
| UNKNOWN | Gastric | DRUG: | PHAS | INTER | Allocation: | 70 | Major | Objective | May-20 |
|  | Cancer | Camrelizuma | E2 | VENTI | RANDOMI |  | pathologic | response |  |
|  |  | b\|DRUG: |  | ONAL | ZED\|Interv |  | response | rate(ORR), |  |
|  |  | Oxaliplatin \| |  |  | ention |  | (MPR), It is | It is |  |
|  |  | DRUG: S1 |  |  | Model: |  | defined as | defined as |  |
|  |  |  |  |  | PARALLEL |  | residual | the |  |
|  |  |  |  |  | \| Masking: |  | tumors less | proportion |  |
|  |  |  |  |  | NONE \| $\operatorname{Pri}$ |  | than 10\% | of patients |  |
|  |  |  |  |  | mary |  | after | whose |  |
|  |  |  |  |  | Purpose: |  | neoadjuva | tumors |  |
|  |  |  |  |  | TREATME |  | nt | shrink to a |  |
|  |  |  |  |  | NT |  | chemother | predetermi |  |
|  |  |  |  |  |  |  | apy., At | ned size |  |
|  |  |  |  |  |  |  |  | and |  |



Pathologic
al
complete
response,
From the
initiation
date of first
cycle (each
cycle is 21
days) to
the date of
operation,
an average
of 12
weeks|Dis
ease-free
survival
(DFS), The
time from
the
beginning
of
randomiza
tion to the
recurrence
of the
disease or
the death
of the
patient due
to disease
progressio
n,
3years $\mid \mathrm{Ov}$
erall
survival(O
S), The

Kaplan-
Meier
survival
from the
initiation
date of first
cycle until
death from
any cause
or the last
follow-up
date., From
the
initiation
date of first
cycle to the
date of first
documente
d
progressio
$n$ or date of

|  |  |  |  |  |  |  |  | death from any cause, whichever came first,assess ed up to 3 years \|OSR , overall survival rate, 3years |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| RECRUITIN | Lung | DIAGNOSTI | PHAS | INTER | Allocation: | 200 | Differentia | Associatio | 2020/12/15 |
| G | Cancer, | C_TEST: | E1\|PH | VENTI | RANDOMI |  | 1ly | n of pre- |  |
|  | Nonsmall | Blood | ASE2 | ONAL | ZED\|Interv |  | expressed | treatment |  |
|  | Cell\|Renal | screening\|DI |  |  | ention |  | genes in | BMI, |  |
|  | Cell | AGNOSTIC_ |  |  | Model: |  | circulating | neutrophil |  |
|  | Carcinoma | TEST: Tissue |  |  | PARALLEL |  | immune | -to- |  |
|  | Melanoma \| | screening |  |  | \| Masking: |  | cells | lymphocyt |  |


| Gastric | NONE \| Pri | between | e ratio and |
| :---: | :---: | :---: | :---: |
| Cancer ${ }^{\text {He }}$ | mary | patients | other |
| patocellular | Purpose: | with and | clinical |
| Carcinoma | DIAGNOST | without | parameters |
| Endometrial | IC | irAEs., | with |
| Cancer \\| Mes |  | This | irAEs., |
| othelioma |  | objective | Week 0-48 |
|  |  | will be |  |
|  |  | achieved |  |
|  |  | through |  |
|  |  | single-cell |  |
|  |  | sequencing |  |
|  |  | ., Week 0- |  |
|  |  | 48\|Expres |  |
|  |  | sion of |  |
|  |  | TIM-3, |  |
|  |  | LAG3, |  |

VISTA and
other
inhibitory
checkpoint
molecules
on
tumour-
infiltrating
T cells., In
order to
ascertain
this result,
our
objective is
to utilize
spatial
transcripto

|  |  |  |  |  |  |  |  |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  |  |  |  |  |  |  | mass |  |  |
|  |  |  |  |  |  |  | spectromet |  |  |
|  |  |  |  |  |  |  | ry., Week |  |  |
|  |  |  |  |  |  |  | 0-48 |  |  |
| UNKNOWN | Advanced | DRUG: PD-1 | PHAS | INTER | Allocation: | 20 | Objective | Disease | 2021/1/15 |
|  | Gastric | inhibitor(Tisl | E2 | VENTI | NA \| Interve |  | response | control |  |
|  | Cancer $/$ Ad | elizumab) ,S |  | ONAL | ntion |  | rate (ORR), | rate (DCR), |  |
|  | vanced | OX(S-1+ |  |  | Model: |  | Defined as | Defined as |  |
|  | Gastroesoph | Oxaliplatin) |  |  | SINGLE_G |  | the | the |  |
|  | ageal |  |  |  | ROUP \\| Mas |  | proportion | proportion |  |
|  | Junction |  |  |  | king: |  | of patients | of patients |  |
|  | Adenocarci |  |  |  | NONE \| Pri |  | whose | whose |  |
|  | noma |  |  |  | mary |  | tumors | tumors |  |
|  |  |  |  |  | Purpose: |  | shrink for a | shrink or |  |
|  |  |  |  |  | TREATME |  | certain | remain |  |
|  |  |  |  |  | NT |  | period of | stable for a |  |


| time, From certain |  |
| :--- | :--- |
| the | period of |
| initiation | time, From |
| date of first | the |
| cycle (each | initiation |
| cycle is 21 | date of first |
| days) to cycle (each |  |
| the date of cycle is 21 |  |
| first | days) to |
| documente | the date of |
| d | first |
| progressio | documente |
| n or date of | d |
| death from | progressio |
| any cause, | n or date of |
| whichever | death from |
| came first, | any cause, |


| assessed | whichever |
| :---: | :---: |
| up to | 1 came first, |
| years | assessed |
|  | up to 1 |
|  | years $\mid \mathrm{pCR}$ |
|  | rate, |
|  | Pathologic |
|  | al |
|  | complete |
|  | response, |
|  | From the |
|  | initiation |
|  | date of first |
|  | cycle (each |
|  | cycle is 21 |
|  | days) to |
|  | the date of |

an average
of 12
weeks. | R0
resection
rate, Rate
of
microscopi
cally
margin-
negative
resection,
From the
initiation
date of first
cycle (each
cycle is 21
days) to
the date of operation, an average
of $\quad 12$
weeks.|po
stoperative
complicati
ons,
Complicati
ons refer to
the
occurrence
of another
or several
diseases
related to
during the
treatment
of a certain
disease,
Investigato
r
assessment
,from the
initiation
date of the operation
day,

|  |  |  |  |  |  |  |  |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  |  |  |  |  |  |  |  | $\text { up to } 1$ |  |
|  |  |  |  |  |  |  |  | years. |  |
| UNKNOWN | Stomach | BIOLOGICA | NA | INTER | Allocation: | 19 | Disease | Duration | Nov-15 |
|  | Neoplasms | L: EPCAM- |  | VENTI | NA \| Interve |  | control | of |  |
|  |  | targeted |  | ONAL | ntion |  | rates, 0 to | remission, |  |
|  |  | CAR-T cells |  |  | Model: |  | 180 days | 0 to 180 |  |
|  |  |  |  |  | SINGLE_G |  |  | days |  |
|  |  |  |  |  | ROUP / Mas |  |  |  |  |
|  |  |  |  |  | king: |  |  |  |  |
|  |  |  |  |  | NONE \| Pri |  |  |  |  |
|  |  |  |  |  | mary |  |  |  |  |
|  |  |  |  |  | Purpose: |  |  |  |  |
|  |  |  |  |  | TREATME |  |  |  |  |
|  |  |  |  |  | NT |  |  |  |  |


| RECRUITIN | Metastatic | DRUG: | PHAS | INTER | Allocation: 52 | Safety run- The safety 2020/2/11 |
| :--- | :--- | :--- | :--- | :--- | :--- | :--- | :--- |
| G | Esophageal | Atezolizuma | E1\|PH | VENTI | NA\|Interve | in phase: of DKN-01 |




| RECIST 1.1 | 1 year PFS |
| :--- | :--- |
| criteria, | will also be |
| ORR will | reported. |
| be defined | PFS will be |
| in the | defined as |
| mITT | time from |
| population | first drug |
| as the | administra |
| proportion | tion |
| of patients | (C1D1) to |
| who have | clinical/ra |
| achieved | diological |
| CR or PR | progressio |
| (as | n or death |
| assessed | from any |
| according | cause., Up |
| to RECIST | to |


| 1.1 criteria) | months $\mid O$ |
| :--- | :--- |
| as their | verall |
| best | survival, |
| overall | OS will be |
| response | estimated |
| during | in the |
| treatment. | mITT |
| The rate | population |
| will be | using the |
| presented | Kaplan |
| as a | Meier |
| proportion | method |
| with an | and |
| exact $95 \%$ | presenting |
| confidence | median |
| interval., | survival |
| 24 months | with $95 \%$ |

confidence
intervals. 6
month and
1 year OS
will also be
reported.
PFS will be
defined as
time from
first drug
administra
tion
(C1D1) to
clinical/ra
diological
progressio
n or death


| Adenocarci | Olaparib\|DR | Model: | will be | experienci |
| :---: | :---: | :---: | :---: | :---: |
| noma | UG: | SINGLE_G | measured | ng study |
|  | Pembrolizum | ROUP $/$ Mas | from the | drug- |
|  | ab | king: | time of | related |
|  |  | NONE \| $\operatorname{Pri}$ | drug | toxicities., |
|  |  | mary | administra | Number of |
|  |  | Purpose: | tion at | patients |
|  |  | TREATME | Cycle 1, | experienci |
|  |  | NT | Day 1 until | ng study |
|  |  |  | death due | drug- |
|  |  |  | to any | related |
|  |  |  | cause. All | adverse |
|  |  |  | subjects | adverse |
|  |  |  | who | events |
|  |  |  | receive at | Grade 3 or |
|  |  |  | least one | higher as |
|  |  |  | dose of the | defined by |

3-drug CTCAE
combinatio v5.0., 4
n will be years
included.
Subjects
who
discontinu
e treatment
prior to
Cycle 2
will not be
included in
the
analysis.
Any
patient not
known to
have died
at the time
of analysis
will be
censored
based on
the last
recorded
date on
which that
patient
was
known to
be alive.
Estimation
based on
the

|  |  |  |  |  |  |  | Kaplan- |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  |  |  |  |  |  |  | Meier <br> curve., 4 <br> years |  |  |
| RECRUITIN | Gastric | DRUG: | PHAS | INTER | Allocation: | 60 | 1 year | R0 surgical | 2021/8/7 |
| G | Cancer | Sintilimab\|D | E2\|PH | VENTI | NA \| Interve |  | Progressio | resection |  |
|  |  | RUG: | ASE3 | ONAL | ntion |  | $\mathrm{n} \quad$ Free | percentage |  |
|  |  | Albumin- |  |  | Model: |  | Survival | , |  |
|  |  | Paclitaxel\|D |  |  | SINGLE_G |  | (PFS), | Approxim |  |
|  |  | RUG: |  |  | ROUP \\| Mas |  | Approxim | ately 2 |  |
|  |  | Capecitabine |  |  | king: |  | ately 3 | years after |  |
|  |  | \| DRUG: |  |  | NONE \|Pri |  | years after | the first |  |
|  |  | Oxaliplatin\| |  |  | mary |  | the first | participant |  |
|  |  | RADIATION: |  |  | Purpose: |  | participant | is |  |
|  |  | Radiation $\mid$ P |  |  | TREATME |  | is included | included \| |  |
|  |  | ROCEDURE: |  |  | NT |  |  | Operative |  |
|  |  | Radical |  |  |  |  |  | conversion |  |


| gastric cancer | percentage |
| :---: | :---: |
| surgery | , |
|  | Approxim |
|  | ately 2 |
|  | years after |
|  | the first |
|  | participant |
|  | is |
|  | included |
|  | Overall |
|  | survival |
|  | (OS), |
|  | Approxim |
|  | ately 4 |
|  | years after |
|  | the first |
|  | participant |

Number of
participant
s
experienci
ng clinical
and
laboratory
adverse
events
(AEs),
Approxim
ately 4
years after
the first
participant


| Adenocarci | Model: | assessed | assessed |
| :---: | :---: | :---: | :---: |
| noma | SINGLE_G | by | by |
|  | ROUP \\| Mas | radiograph | radiograph |
|  | king: | ic imaging, | ic imaging, |
|  | NONE \| Pri | Examinati | Examinati |
|  | mary | on of | on of |
|  | Purpose: | patients | subjects |
|  | TREATME | with a | with stable |
|  | NT | partial | disease, a |
|  |  | response | partial |
|  |  | or | response, |
|  |  | complete | or |
|  |  | response., | complete |
|  |  | 2 year | response., |
|  |  |  | 1 |
|  |  |  | year \| Dura |
|  |  |  | tion of |

response,
as assessed
by
radiograph
ic imaging,
Defined as
the
duration
that
subjects
who have
responded
to
combinatio
n therapy
remain
without
n. $\quad 1$
year|Over
all
survival, as
assessed
by
survival,
Defined as
the time
from
registratio
n to death
from any
cause., 1
year $\mid$ Prog
n to cancer
progressio
n or death

|  |  |  |  |  |  |  |  | cause, 1 <br> year |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| RECRUITIN | Gastric | DRUG: | PHAS | INTER | Allocation: | 60 | Progressio | Overall | Apr-23 |
| G | Cancer | Fruquintinib | E2 | VENTI | NA \| Interve |  | n free | survival |  |
|  |  | +PD-1 |  | ONAL | ntion |  | survival | (OS), |  |
|  |  |  |  |  | Model: |  | (PFS), | Tumor |  |
|  |  |  |  |  | SINGLE_G |  | Tumor | assessment |  |
|  |  |  |  |  | ROUP \| Mas |  | assessment | will be |  |
|  |  |  |  |  | king: |  | will be | performed |  |
|  |  |  |  |  | NONE \| Pri |  | performed | using |  |
|  |  |  |  |  | mary |  | using | radiograph |  |
|  |  |  |  |  | Purpose: |  | radiograph | $y$ method |  |
|  |  |  |  |  | TREATME |  | $y$ method | $\text { every } 8$ |  |
|  |  |  |  |  | NT |  | every 8 | weeks |  |
|  |  |  |  |  |  |  | weeks, | until the |  |
|  |  |  |  |  |  |  | until the | occurrence |  |
|  |  |  |  |  |  |  |  |  |  |


| of | progressiv |
| :--- | :--- |
| progressiv | e disease |
| e disease (PD), using |  |
| (PD), using | RECIST v |
| RECIST v | 1.1 , from |
| 1.1, from randomiza |  |
| randomiza tion until |  |
| tion up to death due |  |
| progressiv | to any |
| e disease or cause, |  |
| EOT due to | assessed |
| any cause, | up to 3 |
| assessed | year\|Obje |
| up to 2 | ctive |
| year | response |
| rate (ORR), |  |

Tumor
performed
using
radiograph
y method
every 8
weeks
until the
occurrence
of
progressiv
e disease
(PD), using
RECIST v
1.1. from
randomiza
tion up to progressiv
e disease or EOT due to any cause,
assessed
up to 2
year|Disea
se control
rate ( DCR ),
Tumor
assessment
will be
performed
using
radiograph
y method
every
weeks
until the
occurrence
of
progressiv
e disease
(PD), using
RECIST v
1.1. from
randomiza
tion up to
progressiv
e disease or
EOT due to
any cause,
assessed
tolerance
evaluated
by
incidence,
severity
and
outcomes
of AEs,
Safety and
tolerance
will be
evaluated
by
incidence,
severity
and
outcomes
of AEs and
categorize
d by
severity in
accordance
with the
NCI CTC
AE
Version
5.0, from
first dose
to 30 days
post the
last dose

| TERMINATE | Advanced | DRUG: | PHAS | INTER | Allocation: | 409 | Number of | Cmax | 2015/11/9 |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| D | Cancer | Avelumab\|D | E1\|PH | VENTI | RANDOMI |  | participant | avelumab |  |
|  |  | RUG: | ASE2 | ONAL | ZED\|Interv |  | s with | (MSB00107 |  |
|  |  | Utomilumab |  |  | ention |  | Dose- | 18C), |  |
|  |  | \|DRUG: PF- |  |  | Model: |  | Limiting | Cmax |  |
|  |  | 04518600 \| DR |  |  | \| Masking: |  | Toxicities | defined as |  |
|  |  | UG: PD |  |  | NONE \| $\operatorname{Pri}$ |  | (DLT), For | the |  |
|  |  | 0360324 \\| DR |  |  | mary |  | Phase 1b: | maximum |  |
|  |  | UG: CMP-001 |  |  | Purpose: |  | DLTs for | plasma |  |
|  |  |  |  |  | TREATME |  | Combinati | concentrati |  |
|  |  |  |  |  | NT |  | on A | on of |  |
|  |  |  |  |  |  |  | (avelumab | avelumab |  |
|  |  |  |  |  |  |  | and PF- | (MSB00107 |  |
|  |  |  |  |  |  |  | 05082566) | 18C), Pre |  |
|  |  |  |  |  |  |  | or | dose and 1 |  |
|  |  |  |  |  |  |  | Combinati | hour post |  |
|  |  |  |  |  |  |  | on B | dose on |  |


| (avelumab | Days 1, 8, |
| :---: | :---: |
| and PF- | and 15 of |
| 04518600) | Cycle 1, |
| or | then on |
| Combinati | Day 1 of |
| on C | Cycles 2, 4, |
| (avelumab | 6, and |
| and PD | 10\|Cmax |
| 0360324) or | of PF- |
| Combinati | 05082566, |
| on D | Cmax |
| (Avelumab | defined as |
| and | the |
| utomiluma | maximum |
| b and PF- | plasma |
| 04518600)o | concentrati |
| ccurring | on of PF- |


| during the first 8 | 05082566, <br> Pre-dose |
| :---: | :---: |
| weeks of | and 1 hour |
| treatment | post-dose |
| $\text { (first } \quad 2$ | on Days 1, |
| cycles). For | 8 , and 15 of |
| Phase 1b: | Cycle 1, |
| DLT for | and then |
| Combinati | on Day 1 of |
| on | Cycles 3, 5, |
| (avelumab | 8, and |
| plus CMP- | 12\|Ctroug |
| 001 and |  |
| utomiluma | avelumab |
| b or PF- | (MSB00107 |
| 04518600) | 18C), |
| occurring | Ctrough is |


| during the <br> first 4 | defined as the trough |
| :---: | :---: |
| weeks of | plasma |
| treatment | concentrati |
| (first | on at the |
| cycle)., | end of an |
| First | avelumab |
| weeks of | dosage |
| treatment | interval., |
| (Combinat | Pre-dose |
| ion A-D) | and 1 hour |
| First | post-dose |
| weeks of | on Days 1, |
| treatment | 8, and 15 of |
| (Combinat | Cycle |
| ionF)\|Obje | then |
| ctive | Day 1 of |


| Respons | Cycles 2, 4, |
| :---: | :---: |
| Number of | 6, and |
| Participant | 10\|Ctroug |
| With | h of PF- |
| Objective | 05082566, |
| Response, | Ctrough is |
| For Phase | defined as |
| 2: Number | the trough |
| of | plasma |
| participant | concentrati |
| with | on at the |
| objective | end of |
| response | PF- |
| (ie, | 05082566 |
| confirmed | dosage |
| complete | interval., |
| or partial | Pre-dose |


| response | and 1 hour |
| :---: | :---: |
| according | post-dose |
| to RECIST | on Days 1, |
| Version | 8 , and 15 of |
| 1.1)., | Cycle 1, |
| Baseline | and then |
| up to | on Day 1 of |
| approxima | Cycles 3, 5, |
| tely 24 | 8, and |
| months | 12\| Anti- |
|  | Drug |
|  | Antibody |
|  | (ADA) |
|  | levels of |
|  | avelumab |
|  | (MSB00107 |
|  | 18C), |

Immunoge
nicity
assessment
of
avelumab
(MSB00107
18C)., Pre-
dose on
Day 1 of
Cycles 1, 2,
4, 6, and
10|Anti-
Drug
Antibody
(ADA)
levels of
PF-

05082566,
Immunoge
nicity
assessment
of PF-
05082566.

Pre-dose
on Day 1 of
Cycles 1, 3,
5,8 , and
12 |Time to
Tumor
Response
(TTR),
Time to
Tumor
Response
defined for
patients
with
confirmed
objective
response
(CR or PR)
as the time
from the
date of
randomiza
tion
(NSCLC)
or date of
first dose
of study
treatment
(melanoma
and
SCCHN) to
the first
documenta
tion of
objective
tumor
response.,
Baseline
up to
approxima
tely 24
months | D
uration of
Response

Duration

Response
(DR) is
defined for
patients
with
confirmed
objective
response
(CR or PR)
as the time
from the
first
documenta
tion of
objective
tumor
response to
the first
documenta
tion of
objective
tumor
progressio
n or to
death due
to
any
cause,
whichever
occurs
first.,
Baseline
approxima
tely 24
months $\mid \operatorname{Pr}$
ogression-
Free
Survival
(PFS),
Progressio
n-Free
Survival
(PFS) is
defined as
the time
from the
date of
randomiza
the date of disease
progressio
n by
RECIST
v1.1 or
death due
to any
whichever
occurs
first.,
Baseline
up to
approxima
tely $\quad 24$
months |O
verall
Survival
(OS),
Overall
Survival
(OS) is
defined as
the time
randomiza
tion
(NSCLC)
or date of
first dose
of study
treatment
(melanoma
and
SCCHN) to
the date of
death.,
Baseline
up
to
approxima
umor
tissue
biomarker
s, Tumor
tissue
biomarker
s,
including,
but not
limited to,
PD-L1
expression
and tumor
infiltrating
CD8+ T
lymphocyt
es,
Baseline |C
max of PF-
04518600,
Cmax
defined as
the
maximum
plasma
concentrati
on of PF-
04518600,
Pre-dose
and 1 hour
post-dose
on Days 1,

8, and 15 of
Cycle 1,
then on
Day 1 of
Cycles 2, 4,
6, and
10 | Anti-
Drug
Antibody
(ADA)
levels of
PF-
04518600,
Immunoge
nicity
assessment
of PF-

Pre-dose
on Day 1 of
Cycles 1, 2,
4, 6, and
10|Ctroug
$h$ of PF-
04518600,
Ctrough is
defined as
the trough
plasma
concentrati
on at the
end of a
PF-
04518600


| plasm | Leucovorin \| | PARALLEL | of NUC-3373 in each of |
| :---: | :---: | :---: | :---: |
| Malignant | DRUG: | \| Masking: | the combinations in each |
| Metastatic | Pembrolizum | NONE \| Pri | patient, Assessed from |
| Cancer (Mel | ab\|DRUG: | mary | baseline to 30 days after |
| anoma\|Clas | Docetaxel | Purpose: | last dose of study |
| sical |  | TREATME | drug ${ }^{\text {Number }}$ of |
| Hodgkin |  | NT | patients reporting |
| Lymphoma |  |  | treatment-emergent |
| \|Non Small |  |  | adverse events (TEAEs) |
| Cell Lung |  |  | in each of the |
| Cancer / Ren |  |  | combinations, TEAEs in |
| al Cell |  |  | each patient, including |
| Carcinoma |  |  | clinically significant |
| Urothelial |  |  | laboratory changes, and |
| Carcinoma |  |  | changes in physical |
| Head and |  |  | exam, vital signs and |
| Neck |  |  | serial |

Squamous
Cell
Carcinoma
Subungual
Squamous
Cell
Carcinoma
Oesophagea
1
Carcinoma
MSI-H
Colorectal
Cancer \| Gas
tric
Cancer
ple Negative
Breast

## electrocardiograms

(ECGs), Assessed from
baseline to 30 days after
last dose of study
drug | Number of
patients achieving a
reduction in tumour
volume (Objective
response rate; ORR),
ORR, defined as the
percentage of patients
achieving a confirmed
complete or partial
response to treatment,
based on Response
Evaluation Criteria in
Solid Tumours (RECIST)

|  | Cancer $\mid$ End ometrial |  |  |  |  |  | v1.1 criteria or immunerelated RECIST criteria |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  | Carcinoma |  |  |  |  |  | (iRECIST)., Assessed |
|  | Pleural |  |  |  |  |  | from baseline to 30 days |
|  | Mesothelio <br> ma |  |  |  |  |  | after last dose of study drug |
| UNKNOWN | Breast | DRUG: | PHAS | INTER | Allocation: | 29 | Number of Participants Jan-14 |
|  | Cancer \\| Gas | Trastuzumab | E1\|PH | VENTI | NA \| Interve |  | with Serious and Non- |
|  | tric Cancer | + NK cells | ASE2 | ONAL | ntion |  | Serious Adverse Events, |
|  |  |  |  |  | Model: |  | During cycle 1 (21 days) |
|  |  |  |  |  | SINGLE_G |  | and for at least 21 days |
|  |  |  |  |  | ROUP \| Mas |  | following a second NK |
|  |  |  |  |  | king: |  | cell infusion if |
|  |  |  |  |  | NONE \| Pri |  | administered: |
|  |  |  |  |  | mary |  |  |
|  |  |  |  |  | Purpose: |  | - Patients will be |
|  |  |  |  |  |  |  | reviewed twice a week |

## TREATME <br> with <br> NT

* Limited physical examination to include
blood pressure, heart rate, weight
* Full blood count, renal
function and liver
function tests
* Toxicity rating using the NCI CTC scale
* 

Concomitant
medication notation and
number of units
required for transfusions

Any
significant
later.

During other cycles
when only trastuzumab is administered (without NK cells infusion or IL-
2) Patients will be reviewed once every cycle of every 3-weekly cycle, Up to 12-18

Tumor Response
Measure, Among tumor responders, the duration of tumor response is measured from the date of enrolment until the first date of documented disease progression or death due to any cause, whichever occurs first. Duration of tumor response will be censored at the date of the last follow-up visit for tumor responders who are still alive and
who have not
progressed., Up to 36
months |Time-to-Event
Outcome Measure, Time
to documented disease
progression is defined as
the time from the date of enrolment to the first date of documented disease progression. Time to documented disease progression will be censored at the date of death for patients who have not had documented disease progression. For patients


| NONE \| Pri | Common | who |
| :---: | :---: | :---: |
| mary | Toxicity | undergo |
| Purpose: | Criteria for | retreatmen |
| TREATME | Adverse | with |
| NT | Events | durvaluma |
|  | (CTCAE | b, The |
|  | v5.0), | analysis of |
|  | Type, | ORR will |
|  | frequency | be based |
|  | and | on |
|  | severity of | investigato |
|  | adverse | r |
|  | events | assessment |
|  | (including | s using |
|  | those | RECIST |
|  | treatment | 1.1, 3 |
|  | and post- | years \|Effic |


| treatment periods) | acy of durvaluma |
| :---: | :---: |
| will be | $b$ in terms |
| listed | of |
| according | Duration |
| to CTCAE | of |
| v5.0, | Response |
| Estimated | (DOR) in |
| to be up to | patients |
| 3 years | who |
|  | undergo |
|  | retreatmen |
|  | with |
|  | durvaluma |
|  | b, The |
|  | analysis of |
|  | DOR will |

be based
on
investigato
r
assessment
s using
RECIST
1.1, $\quad 3$
years |Ove
rall
Survival
(OS),
Assessmen
ts $\quad$ of
Overall
Survival
will be

|  |  |  |  |  |  |  |  | made at periodic time points until death, 3 years |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| RECRUITIN | Gastric | DRUG: | PHAS | INTER | Allocation: | 25 | Effect of | Overall | 2021/11/5 |
| G | Adenocarci | Capecitabine | E2 | VENTI | NA \| Interve |  | chemo- | survival, |  |
|  | noma\|Esop | \| DRUG: |  | ONAL | ntion |  | and | Determine |  |
|  | hageal | Oxaliplatin\| |  |  | Model: |  | immunoth | overall |  |
|  | Adenocarci | DRUG: |  |  | SINGLE_G |  | erapy on | survival of |  |
|  | noma | Retifanlimab |  |  | ROUP \\| Mas |  | the | patients |  |
|  |  |  |  |  | king: |  | interferon | within the |  |
|  |  |  |  |  | NONE \|Pri |  | gamma | $\text { study, } 60$ |  |
|  |  |  |  |  | mary |  | expression | months $\mathrm{O}^{\text {O }}$ |  |
|  |  |  |  |  | Purpose: |  | signature | verall |  |
|  |  |  |  |  |  |  | in the | survival, |  |


| TREATME | tumor | Compare |
| :--- | :--- | :--- |
| NT | microenvi | overall |
| ornment, | survival |  |
|  | RNA | with a |
|  | expression | propensity |
| analysis | score |  |
|  | (Nanostrin | matched |
|  | g) to | cohort, 60 |
|  | determine | months \|Pr |
| changes in | ogression |  |
|  | Interferon | free |
| gamma | survival |  |
|  | expression | (PFS), |
| signature | Assess the |  |
| before and | PFS of |  |
| during | patients |  |
| treatment, | within the |  |


| 40 | study, 60 |
| :--- | :--- |
| months $\mid$ Ef | months $\mid \mathrm{Pr}$ |
| fect $\quad$ of | ogression |
| chemo- | free |
| and | survival |
| immunoth | (PFS), |
| erapy on | Compare |
| the | PFS with a |
| immune | propensity |
| infiltrate in | score |
| the tumor | matched |
| microenvir | cohort, 60 |
| onment, | months $\mid R$ |
| Flow | esponse |
| cytometry | rate, |
| to | Determine |
| determine | response |



| on the | b, 60 |
| :--- | :--- |
| tumor | months $\mid M$ |
| microenvir | easure |
| onment, | PROMs via |
| Multicolor | established |
| immunohi | PROFILES, |
| stochemstr | Patient |
| y to | reported |
| determine | outcome |
| changes in | measures |
| immune | (PROMs) |
| infiltrate in | are |
| the tumor | measured |
| before and | with the |
| during | established |
| treatment, | PROFILES |
| 40 months | infrastruct |

## Evaluation

ip).
PROMs
will be
assessed
and
and
throughou
t
treatment,
months | P
ercentage
subsequen
t treatment
lines, The
percentage
of patients
proceeding
to
subsequen


| metastasis, para-aortic | TREATME <br> NT | survival rate, | certain <br> degree and |
| :---: | :---: | :---: | :---: |
| lymph node |  | Defined as | maintaine |
| metastasis ) |  | the ratio of |  |
|  |  | patients | certain |
|  |  | surviving | period of |
|  |  | two years |  |
|  |  | after | including |
|  |  | randomiza | CR+PR., 2 |
|  |  | tion., 2- | years \|Path |
|  |  | years | ologic |
|  |  |  | complete |
|  |  |  | response, |
|  |  |  | Defined as |
|  |  |  | the |
|  |  |  | number of |
|  |  |  | people |

who have
achieved
complete
pathologic
al
remission
accounted
for the
proportion
of people
who met
the plan., 6
months
verall
survival,
Defined as
the time

|  |  |  |  |  |  |  |  | from the start of randomiza tion to the death of the patient., 2 years |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| ACTIVE_NO | HER2- | DRUG: ZW49 | PHAS | INTER | Allocation: | 174 | Incidence | Serum | 2019/4/15 |
| T_RECRUITI | expressing |  | E1 | VENTI | NA \| Interve |  | of dose- | concentrati |  |
| NG | Cancers |  |  | ONAL | ntion |  | limiting | ons of |  |
|  |  |  |  |  | Model: |  | toxicities | ZW49, End |  |
|  |  |  |  |  | PARALLEL |  | (DLTs), |  |  |
|  |  |  |  |  | \| Masking: |  | Number of | concentrati |  |
|  |  |  |  |  | NONE \| Pri |  | participant | on, |  |
|  |  |  |  |  | mary |  |  | maximum |  |
|  |  |  |  |  | Purpose: |  | experience | serum |  |


| TREATME | d a DLT. concentrati |  |
| :--- | :--- | :--- |
| NT | DLTs are on, and |  |
| events that trough |  |  |
| occur concentrati |  |  |
| following | on of |  |
|  | administra ZW49, Up |  |
| tion of any to | 7 |  |
|  | amount of months In |  |
|  | ZW49 and cidence of |  |
|  | are | anti-drug |
| considered | antibodies |  |
| related to | (ADAs), |  |
| ZW49 per | Number of |  |
| the | participant |  |
| investigato | s who |  |


| include | to |
| :---: | :---: |
| only | months ${ }^{\text {O }}$ |
| events | bjective |
| considered | response |
| related to | rate (ORR), |
| ZW49., Up | Number of |
| to | participant |
| weeks \| Inc | o |
| idence of | achieved a |
| adverse | best |
| events, | response of |
| Number of | either |
| participant | complete |
| who | or partial |
| experience | response |
| d an | during |
| adverse | treatment |


| $\begin{array}{lr} \text { event, } & \text { Up } \\ \text { to } & 7 \end{array}$ | according <br> to the |
| :---: | :---: |
| months \| In | Response |
| cidence of | Evaluation |
| lab | Criteria in |
| abnormalit | Solid |
| ies, | Tumors |
| Number of | (RECIST) |
| participant | version 1.1, |
| who | Up to 6 |
| experience | months \|D |
| d a | isease |
| maximum | control |
| severity of | rate, |
| Grade 3 or | Number of |
| higher | participant |
| post- | who |


| baseline | achieved a |
| :--- | :--- |
| laboratory | best |
| abnormalit | response of |
| y, | complete |
| including | response, |
| either | partial |
| hematolog | response, |
| y and | or stable |
| chemistry. | disease |
| Grades are | during |
| defined | treatment |
| using | according |
| National | to the |
| Cancer | Response |
| Institute's | Evaluation |
| Common | Criteria in |
| Terminolo | Solid |


| gy Criteria | Tumors |
| :--- | :--- |
| for | (RECIST) |
| Adverse | version 1.1, |
| Events | Up to 6 |
| (CTCAE), | months\|D |
| version | uration of |
| $5.0 .$, Up to | response, |
| 7 | Median |
| months\| In | duration of |
| cidence of | response |
| electrocard | (in |
| iogram | months) |
| (ECG) and | and range |
| left | (minimum, |
| ventricular | maximum) |
| ejection | , Up to 2 |
| fraction | years \|Pro |


| (LVEF) | gression- |
| :---: | :---: |
| abnormalit | free |
| ies, | survival, |
| Number of | Median |
| participant | progressio |
| who | n -free |
| experience | survival |
| d an | (in |
| abnormal | months) |
| ECG or | and range |
| LVEF, Up | (minimum, |
| to 7 | maximum) |
| months \| In | , Up to 2 |
| cidence of | years \|Ove |
| dose | rall |
| reductions | survival, |
| of ZW49, | Median |


|  |  |  |  |  |  |  | Number of overall doses survival reduced (in and months) number of and range participant (minimum s who maximum) require $\mathrm{a}, \mathrm{Up}$ to dose years reduction, Up to 7 months |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| RECRUITIN | Gastric | DRUG: PRL3- | PHAS | INTER | Allocation: | 30 | Objective response rate, |
| G | Cancer ${ }^{\text {(He }}$ | zumab | E2 | VENTI | NA \| Interve |  | From start of treatment |
|  | patocellular |  |  | ONAL | ntion |  | to first occurence |
|  | Carcinoma |  |  |  | Model: |  | disease progression or |
|  |  |  |  |  | SINGLE_G |  | death, up to 2 |


|  | Advanced |  |  |  | ROUP \\| Mas |  | years\|Number of |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  | Solid Tumor |  |  |  | king: |  | patients that do not have |  |
|  |  |  |  |  | NONE \| Pri |  | disease progression at 16 |  |
|  |  |  |  |  | mary |  | weeks from start of |  |
|  |  |  |  |  | Purpose: |  | treatment, Clinical |  |
|  |  |  |  |  | TREATME |  | benefit rate at 16 weeks, |  |
|  |  |  |  |  | NT |  | 16 weeks after start of |  |
|  |  |  |  |  |  |  | treatment\| Treatment |  |
|  |  |  |  |  |  |  | related adverse events |  |
|  |  |  |  |  |  |  | rate, From start of treatment to 30 days |  |
|  |  |  |  |  |  |  | after last dose of study drug |  |
| COMPLETE | Gastric | DRUG: PD-1 | PHAS | INTER | Allocation: | 30 | The Overall | 2019/5/30 |
| D | Cancer | antibody, | E2 | VENTI | NA \| Interve |  | Overall survival, |  |
|  |  | paclitaxel or |  | ONAL | ntion |  | Response Time from |  |
|  |  | irinotecan, |  |  | Model: |  | Rate, The the start of |  |


| Apatinib | SINGLE_G | proportion | treatment |
| :---: | :---: | :---: | :---: |
| mesylate | ROUP\|Mas | of CR and | to the |
|  | king: | PR, From | occurrence |
|  | NONE \| Pri | date of | of death, |
|  | mary | randomiza | From date |
|  | Purpose: | tion until | of |
|  | TREATME | the date of | randomiza |
|  | NT | first | tion until |
|  |  | documente | the date of |
|  |  | d | death from |
|  |  | progressio | any cause |
|  |  | n or date of | or the last |
|  |  | death from | visit date, |
|  |  | any cause, | whichever |
|  |  | whichever | came first, |
|  |  | came first, | assessed |
|  |  | assessed | up to 60 |


| up to 24 <br> months $\mid \mathrm{Pr}$ | months \|D <br> isease |
| :---: | :---: |
| ogression | Control |
| Free | rate, The |
| Survival, | proportion |
| Time from | of CR,PR |
| the start of | and SD, |
| treatment | From date |
| to the | of |
| progressio | randomiza |
| $n$ of the | tion until |
| disease, | the date of |
| From date | first |
| of | documente |
| randomiza | d |
| tion until | progressio |
| he date of | n or date of |


| first | death from |
| :--- | :--- |
| documente | any cause, |
| d | whichever |
| progressio | came first, |
| n or date of | assessed |
| death from | up to 24 |
| any cause, | months \|a |
| whichever | dverse |
| came first, | events, The |
| assessed | incidence |
| up to 36 | of various |
| months | adverse <br> events, |
|  | Until <br> months <br> after the |


| TERMINATE | Carcinoma, | BIOLOGICA | PHAS | INTER | Allocation: | 21 | Frequency | end of the treatment |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  |  |  |  |  |  |  |  | Antitumor | 2019/1/14 |
| D | Squamous | L: | E1 | VENTI | RANDOMI |  | of adverse | Objective |  |
|  | Cell of Head | ilixadencel\|D |  | ONAL | ZED\|Interv |  | events | Response |  |
|  | and | RUG: |  |  | ention |  | (AEs) | Rate (ORR) |  |
|  | Neck \| Gastr | Pembrolizum |  |  | Model: |  | (Phase 1b), | RECIST 1.1 |  |
|  | ic | ab |  |  | SEQUENTI |  | Number of | (Phase 1b |  |
|  | Adenocarci |  |  |  | AL\|Maskin |  | adverse | and Phase |  |
|  | noma \| Gastr |  |  |  | g: |  | events, Up | 2), |  |
|  | oesophageal |  |  |  | NONE \| Pri |  | to Week | Antitumor |  |
|  | Junction |  |  |  | mary |  | 27\|Severit | activity of |  |
|  | Adenocarci |  |  |  | Purpose: |  | $y \quad o f$ | ilixadencel |  |
|  | noma \| Non- |  |  |  | TREATME |  | adverse | plus CPI |  |
|  | small Cell |  |  |  | NT |  | events | (checkpoin |  |
|  | Lung |  |  |  |  |  | (AEs) | t inhibitor) |  |
|  | Cancer |  |  |  |  |  | (Phase 1b), | in each |  |


| Grading | tumor |
| :--- | :--- |
| per | type, |
| Common | investigato |
| Terminolo | r $\quad$ and |
| gy Criteria | centrally |
| for | assessed |
| Adverse | using |
| Events | RECIST |
| (CTCAE) | (Response |
| v5.0, Up to | Evaluation |
| Week | Criteria in |
| 27\|Numbe | Solid |
| r of Dose | Tumors) |
| Limiting | v1.1, Up to |
| Toxicities | Week |
| (DLTs) | $27 \mid A n t i t u ~$ |
| (Phase 1b), | mor |


| Dose | Objective |
| :--- | :--- |
| Limiting | Response |
| Toxicities | Rate (ORR) |
| measured | iRECIST |
| using | (Phase 1b |
| CTCAE | and Phase |
| v5.0 and | 2), |
| protocol | Antitumor |
| DLT | activity of |
| definition., | ilixadencel |
| Up $\quad$ to | plus CPI |
| Week | (checkpoin |
| 27\|Numbe | t inhibitor) |
| r | of |
| in each |  |
| subjects | tumor |
| with | type, |
| clinically | investigato |


| significant | r assessed |
| :--- | :--- |
| laboratory | using |
| test | iRECIST |
| abnormalit | (Immune |
| ies (Phase | Response |
| 1b), | Evaluation |
| Grading | Criteria in |
| per | Solid |
| Common | Tumors), |
| Terminolo | Up $\quad$ to |
| gy Criteria | Week |
| for | $27 \mid C l i n i c a l$ |
| Adverse | Benefit |
| Events | Rate |
| (CTCAE) | (Phase 1b |
| v5.0, Up to | and Phase |
| Week | 2), Rate of |


| $27 \mid$ Numbe | complete |
| :--- | :--- |
| r of | and partial |
| subjects | response |
| with vital | and stable |
| sign | disease by |
| abnormalit | investigato |
| ies (Phase | r and |
| 1b), Vital | centrally |
| signs | assessed |
| grading | RECIST |
| per | (Response |
| Common | Evaluation |
| Terminolo | Criteria in |
| gy Criteria | Solid |
| for | Tumors) |
| Adverse | v1.1, Up to |
| Events | Week |


| (CTCAE) | $27 \mid$ Durati |
| :--- | :--- |
| v5.0, Up to | on of |
| Week | response |
| $27 \mid$ Antitu | (Phase 1b |
| mor | and Phase |
| Objective | 2 ), |
| Response | Measured |
| Rate (ORR) | in weeks. |
| (Phase 2), | Assessed |
| Antitumor | using |
| activity of | RECIST |
| ilixadencel | v1.1 and |
| plus CPI | iRECIST, |
| (checkpoin | Up to 24 |
| t inhibitor) | months |
| in each | after Cycle |
| tumor | 1 |


| type, | 1\|Time to |
| :---: | :---: |
| centrally | Progressio |
| assessed | n (TTP) |
| using | (Phase 1b |
| RECIST | and Phase |
| (Response | 2), |
| Evaluation | Measured |
| Criteria in | in weeks. |
| Solid | Assessed |
| Tumors) | using |
| v1.1, Up to | RECIST |
| Week 27 | v1.1 and |
|  | iRECIST, |
|  | Up to 24 |
|  | months |
|  | after Cycle |
|  | 1 Day |

2),

Measured
in weeks.
Centrally
assessed
using
RECIST
v1.1, Up to
24 months
after Cycle
1 Day

1 |Overall
Survival
(OS)
(Phase 1b
and Phase
2),

Measured
in months,
Up to 5
years $\mid$ Freq
uency of
adverse
events
(AEs)
(Phase 2),
Number of adverse
events, Up
to Week
27|Severit
$y$ of
adverse
events
(AEs)
(Phase 2),
Grading
per
Common
Terminolo
gy Criteria
for
Adverse
Events
(CTCAE)
v5.0, Up to
Week
27 \| Numbe
r of Dose
Limiting
Toxicities
(DLTs)
(Phase 2),
Dose
Limiting
Toxicities
measured
using
CTCAE
v5.0 and
protocol
DLT

Up to week
27 | Numbe
r of
subjects
with
clinically
significant
laboratory
test
abnormalit
ies (Phase
2), Grading
per
Common
Terminolo
gy Criteria

Adverse
Events
(CTCAE)
v5.0, Up to
Week
27|Numbe
r of
subjects
with vital
sign
abnormalit
ies (Phase
2), Vital
signs
grading
per

|  |  |  |  |  |  |  |  | Common |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  |  |  |  |  |  |  |  | Terminolo |  |
|  |  |  |  |  |  |  |  | gy Criteria |  |
|  |  |  |  |  |  |  |  | for |  |
|  |  |  |  |  |  |  |  | Adverse |  |
|  |  |  |  |  |  |  |  | Events |  |
|  |  |  |  |  |  |  |  | (CTCAE) |  |
|  |  |  |  |  |  |  |  | v5.0, Up to |  |
|  |  |  |  |  |  |  |  | Week 27 |  |
| RECRUITIN | Advanced | DRUG: | PHAS | INTER | Allocation: | 382 | Overall | Progressio | 2023/1/23 |
| G | Esophageal | Fluorouracil\| | E3 | VENTI | RANDOMI |  | survival | n -free |  |
|  | Adenocarci | DRUG: |  | ONAL | ZED\|Interv |  | (OS), Will | survival |  |
|  | noma\| Adva | Leucovorin |  |  |  |  | compare | (PFS), PFS |  |
|  | nced Gastric | Calcium \\| DR |  |  | Model: |  | the | will be |  |
|  | Adenocarci | UG: |  |  | PARALLEL |  | distributio | evaluated |  |
|  | noma \| Adva | Oxaliplatin\| |  |  | \| Masking: |  | ns of OS | as a time to |  |
|  | nced | DRUG: |  |  | NONE \| $\operatorname{Pri}$ |  | between | event |  |


| Gastroesoph | Irinotecan\|BI | mary | the two outcome |  |
| :--- | :--- | :--- | :--- | :--- |
| ageal | OLOGICAL: | Purpose: | treatment and |  |
| Junction | Nivolumab | TREATME | arms to compared |  |
| Adenocarci | PROCEDUR | NT | determine | in | a

ageal | Administrati |
| :--- |
| Junction on |
| Adenocarci |
| noma AJCC |
| v8\|Clinical |
| Stage IV |
| Esophageal |
| Adenocarci |
| noma AJCC |
| v8\|Clinical |
| Stage IV |
| Gastric |
| Cancer |
| AJCC |
| v8\|Clinical |
| Stage IV |
| Gastroesoph | $l$

ageal
Junction
Adenocarci
noma AJCC
v8 |Metastat
ic
Esophageal
Adenocarci
noma|Meta
static
Gastric
Adenocarci
noma|Meta
static
Gastroesoph
ageal
Junction
nivolumab response
). Kaplan- rate, The
Meier
methodolo response
gy will be achieved
used to after
estimate initiation
the
distributio on
ns for the protocol
treatment will also be
arms. To assessed
compare based on
the OS
distributio
ns between
Evaluation
the two

Meier best
methodolo response
gy will be achieved
used to after
estimate initiation
the of therapy
distributio on
ns for the protocol
treatment will also be
arms. To assessed
compare based on
the OS the
distributio Response
ns between Evaluation
the two Criteria in

| Adenocarci | treatment Solid |
| :---: | :---: |
| noma\|Unre | arms, we Tumors |
| sectable | will use a (RECIST) |
| Esophageal | one-sided 1.1 criteria |
| Adenocarci | logrank and will be |
| noma\|Unre | test to summarize |
| sectable | evaluate if d by |
| Gastric | mFOLFIRI treatment |
| Adenocarci | NOX (with arm. The |
| noma \| Unre | or without overall |
| sectable | nivolumab response |
| Gastroesoph | is rate will be |
| ageal | superior to calculated |
| Junction | mFOLFOX as the |
| Adenocarci | (with or number of |
| noma | without patients |
|  | nivolumab who |


| ) based on | achieve a |
| :--- | :--- |
| an | response |
| intention | (partial |
| to treat | response, |
| analysis. | complete |
| The hazard | response) |
| ratio, | divided by |
| median | the total |
| OS, and | number of |
| estimated | patients |
| OS rates at | randomize |
| 1 and 2 | d to the |
| years will | correspon |
| be | ding |
| estimated | treatment |
| along with | arm., Up to |
| correspon | 3 |


| ding 95\% confidence | years\|Dur <br> ation of |
| :---: | :---: |
| intervals. | Response, |
| Multivaria | The time |
| ble Cox | between |
| proportion | each |
| al hazards | patient's |
| models | best tumor |
| will also be | response |
| used to | and |
| assess the | progressio |
| impact of | n (or date |
| treatment | of last |
| arm on OS | disease |
| when | assessment |
| stratifying | for patients |
| n the | o die |


| stratificatio <br> n factors., | without <br> progressio |
| :---: | :---: |
| Up to 2 years from | n or are lost to |
| the time of randomiza | follow-up), assessed |
| tion. | up to 3 |
|  | years \| Inci |
|  | dence of |
|  | adverse |
|  | events, The |
|  | toxicity |
|  | and |
|  | tolerability |
|  | of each of |
|  | these |
|  | regimens |

will be
evaluated
and
captured
using the
National
Cancer
Institute
(NCI)
Common
Terminolo
gy Criteria
for
Adverse
Events
(CTCAE)
version (v.)
5, where
the type
and
severity
grade of
each
adverse
event will
be
collected
and
tabulated
within
each of the
treatment
arms.
Perceived
to study
treatment
will also be
captured.
Tolerabilit
y will
further be
assessed
by
summarizi
ng the
numbers of
patients
who
require
dose
delays, and
reasons for
patients to
go off
treatment.,
Up to 3
years|Pati
ent
reported
outcomes,
Patient-
reported
side effect
assessment
s (Patient

Reported
Outcomes
$\backslash[\mathrm{PRO} \backslash]-$
CTCAE)
will also be
collected
before and
during
therapy
and will be
summarize
d within
and
compared
between
treatment
arms. To
evaluate
between-
arm
differences
in patient-
reported
symptoma
tic adverse
events as
assessed
by the
PRO-
CTCAE,
the
frequency
and
proportion
of patients
with a
maximum
post-
baseline
score
greater
than 0 will
be
compared
across
arms using
a chi $\wedge^{\wedge} 2$
test or
Fisher's
exact test
with a

```
nominal
significanc
e level of
alpha =
0.10.
Similarly,
the
frequency
and
proportion
of patients
with a
maximum
post-
baseline
score
greater
```

than or
equal to 3
will be
compared
across
arms using
a chi $\wedge^{\wedge} 2$
test or
Fisher's
exact test
with a
nominal
significanc
e level of
alpha =
0.10., At
baseline,

|  |  |  |  |  |  |  |  | day 1 of cycles 1-8 and day 1 of each oddnumbered cycle thereafter |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| NOT_YET_R | Clinical | BIOLOGICA | PHAS | INTER | Allocation: | 15 | Change of | Histologic | Nov-23 |
| ECRUITING | Stage IV | L: | E1 | VENTI | NA \| Interve |  | reduction | al response |  |
|  | Gastric | Aldesleukin \| |  | ONAL | ntion |  | in the | of the |  |
|  | Cancer | PROCEDUR |  |  | Model: |  | peritoneal | peritoneal |  |
|  | AJCC | E: |  |  | SINGLE_G |  | carcinomat | metastasis, |  |
|  | v8\|Gastric | Biopsy\|PRO |  |  | ROUP \\| Mas |  | osis index, | Will be |  |
|  | Adenocarci | CEDURE: |  |  | king: |  | About 90 | assessed |  |
|  | noma \| Gastr | Biospecimen |  |  | NONE \|Pri |  | days after | using the |  |
|  | oesophageal | Collection \| P |  |  | mary |  | last dose of | peritoneal |  |


| Junction | ROCEDURE: | Purpose: | aldesleuki | regression |
| :---: | :---: | :---: | :---: | :---: |
| Adenocarci | Computed | TREATME | n (IL- | grading |
| noma\|Meta | Tomography | NT | 2) \| Inciden | score. Will |
| static | \|PROCEDU |  | ce of | be |
| Gastric | RE: |  | adverse | reported |
| Carcinoma \| | Diagnostic |  | events, | descriptive |
| Metastatic | Laparoscopy |  | About 90 | ly, |
| Malignant | \| DRUG: |  | days after | including |
| Neoplasm | Fluorouracil\| |  | last dose of | reporting |
| in the | DRUG: |  | aldesleuki | of |
| Peritoneum | Leucovorin |  | n (IL-2) | frequencie |
|  | Calcium ${ }^{\text {PR }}$ |  |  | s, |
|  | OCEDURE: |  |  | percentage |
|  | Magnetic |  |  | s and $95 \%$ |
|  | Resonance |  |  | confidence |
|  | Imaging \| BIO |  |  | intervals., |
|  | LOGICAL: |  |  | About 90 |


| Nivolumab\| | days after |
| :--- | :--- |
| DRUG: | last dose of |
| Oxaliplatin\|P | aldesleuki |
| ROCEDURE: | $\mathrm{n} \quad$ (IL- |
| Positron | 2)\|Progres |
| Emission | sion free |
| Tomography | survival, |
|  | Summary |
|  | statistics, <br> including |
|  | the median |
|  | and other |
|  | various |
| timepoints |  |
|  | will be |
|  | reported as |
| well as |  |

confidence
intervals.,
From
study
entry to the
first of
either
disease
progressio
n or death,
assessed
up to 3
years|Ove
rall
survival,
Summary
statistics,
including
the median
and other
various
timepoints
will be
reported as
well
as
95\%
confidence
intervals.,
From date
of study
entry to
date of
death or

|  |  |  |  | last follow |
| :--- | :--- | :--- | :--- | :--- | :--- | :--- | :--- |
| up, |  |  |  |  |


| Solid | cohort | partial |
| :---: | :---: | :---: |
| Tumor \| Adv | within the | response |
| anced Solid | first 28 | (PR) or |
| Tumors \| HE | days after | complete |
| R2-positive | FATE- | response |
| Breast | NK100 | (CR) per |
| Cancer ${ }^{\text {He }}$ | administra | Response |
| patocellular | tion (ie, | Evaluation |
| Carcinoma | Day | Criteria in |
| Non Small | through | Solid |
| Cell Lung | Day 29)., | Tumors |
| Cancer \\| Ren | 28 days | (RECIST) |
| al Cell |  | 1.1 at any |
| Carcinoma |  | time on |
| Pancreatic |  | study., 28 |
| Cancer 1 Mel |  | days, 57 |
| anoma |  | days, 113 |

days, 169
days, 225
days, 281
days, 337
days, and
366
days.|Pha
rmacokinet
ics (PK) of
FATE-
NK100,
The PK of
FATE-
NK100, as
assessed
by the
proportion
lymphocyt
es in
peripheral
blood that
are of
donor/pro
duct origin
at the
specified
time
points., 0
days, 1
day, 3
days, 5
days, 8
days, 12

|  |  |  |  |  |  |  |  | days, |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  |  |  |  |  |  |  |  | days, | 22 |
|  |  |  |  |  |  |  |  | days, | 29 |
|  |  |  |  |  |  |  |  | days, | 43 |
|  |  |  |  |  |  |  |  | days, | 57 |
|  |  |  |  |  |  |  |  | days, | 85 |
|  |  |  |  |  |  |  |  | days, | 113 |
|  |  |  |  |  |  |  |  | days |  |
| UNKNOWN | Hepatocellu | BIOLOGICA | PHAS | INTER | Allocation: | 10 | Phase I: | Phase |  |
|  | lar | L: anti-MUC1 | E1\|PH | VENTI | NA \| Interve |  | Adverse | Objectiv |  |
|  | Carcinoma | CAR-pNK | ASE2 | ONAL | ntion |  | events | Respo |  |
|  | Non-small | cells |  |  | Model: |  | attributed | Rate, |  |
|  | Cell Lung |  |  |  | SINGLE_G |  | to the | objectiv |  |
|  | Cancer \| Pan |  |  |  | ROUP \\| Mas |  | administra | respon |  |
|  | creatic |  |  |  | king: |  | tion of the | rate (O |  |
|  | Carcinoma |  |  |  | NONE \| Pri |  | anti-MUC1 | is defi |  |
|  | Triple- |  |  |  | mary |  | CAR-pNK | as | the |


| Negative | Purpose: | cells, | proportion |
| :---: | :---: | :---: | :---: |
| Invasive | TREATME | Determine | of patients |
| Breast | NT | the toxicity | who |
| Carcinoma |  | profile of | achieve |
| Malignant |  | the MUC1 | radiograph |
| Glioma of |  | targeted | ic partial or |
| Brain \| Color |  | CAR-pNK | complete |
| ectal |  | cells with | response |
| Carcinoma |  | Common | (PR or CR) |
| Gastric |  | Toxicity | according |
| Carcinoma |  | Criteria for | to the |
|  |  | Adverse | Response |
|  |  | Effects | Evaluation |
|  |  | (CTCAE) | Criteria in |
|  |  | version | Solid |
|  |  | 4.0., 2 years | Tumors |
|  |  |  | (RECIST) |


|  |  |  |  |  |  |  |  | v1.1 <br> guideline., <br> 2 years |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| NOT_YET_R | Gastric | DRUG: | NA | INTER | Allocation: | 46 | R0 | Overall | 2021/7/31 |
| ECRUITING | Cancer, | HIPEC, anti- |  | VENTI | NA \| Interve |  | resection, | survival |  |
|  | HIPEC, | PD-1 |  | ONAL | ntion |  | the rate of | time, the |  |
|  | Anti-PD-1 | antibody |  |  | Model: |  | R0 | overall |  |
|  | Antibody | Camrelizuma |  |  | SINGLE_G |  | resection, 3 | survival |  |
|  | Camrelizum | b (SHR-1210), |  |  | ROUP\|Mas |  | months | time, 3 |  |
|  | ab (SHR- | Chemotherap |  |  | king: |  |  | years \| Dise |  |
|  | 1210), | y and Surgery |  |  | NONE \| Pri |  |  | ase-Free |  |
|  | Chemothera |  |  |  | mary |  |  | Survival, |  |
|  | py and |  |  |  | Purpose: |  |  | Disease- |  |
|  | Surgery |  |  |  | TREATME |  |  | Free |  |
|  |  |  |  |  | NT |  |  | Survival of |  |
|  |  |  |  |  |  |  |  | participant |  |
|  |  |  |  |  |  |  |  | $s$ with with |  |

advanced
gastric
cancer
with
peritoneal
metastasis
followed
by surgery,
3
years |OR
R,
Objective
Response
Rate, 3
years |Adv
erse
Events,

|  |  |  |  |  |  |  |  | Number and degree of Adverse Events, 3 years |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| ACTIVE_NO | HER2 | DRUG: | PHAS | INTER | Allocation: | 58 | The | Objective | 2020/7/27 |
| T_RECRUITI | Positive | SBT6050\|DR | E1 | VENTI | NON_RAN |  | proportion | response |  |
| NG | Solid | UG: |  | ONAL | DOMIZED \| |  | of subjects | rate, |  |
|  | Tumors | pembrolizum |  |  | Intervention |  | experienci | defined as |  |
|  |  | ab\|DRUG: |  |  | Model: |  | ng dose | confirmed |  |
|  |  | Cemiplimab |  |  | PARALLEL |  | limiting | Complete |  |
|  |  |  |  |  | \| Masking: |  | toxicities, | Response |  |
|  |  |  |  |  | NONE \| Pri |  | Part 1 and | (CR) or |  |
|  |  |  |  |  | mary |  | 3 only, 28 | Partial |  |
|  |  |  |  |  | Purpose: |  | days ${ }^{\text {\| The }}$ | Response |  |
|  |  |  |  |  | TREATME |  | incidence | (PR), |  |
|  |  |  |  |  | NT |  | and | Parts1 and |  |



| Response | stable |
| :---: | :---: |
| (CR) or | disease for |
| Partial | at least 6 |
| Response | months, |
| (PR), Parts | Parts 1, 2, |
| 2, 4, and 5, | 3, 4, and 5, |
| 2 | 2 |
| years \| Dur | years \|Esti |
| ation of | mates of |
| response, | selected |
| defined as | pharmacok |
| the time | inetics |
| from date | (PK |
| of first | parameters |
| response | for |
| (CR or PR), | SBT6050, |
| Parts 2, 4, | ax: |

and 5, 2 Parts 1, 2,
years 3,4 , and 5 ,
2
years $\mid$ Esti
mates of
selected
pharmacok
inetics
(PK )
parameters
for
SBT6050,
AUC: Parts
$1,2,3,4$,
and 5, 2
years | Inci
dence of

|  |  |  |  |  |  |  |  | antidrug <br> antibodies |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  |  |  |  |  |  |  |  | (ADA) to |  |
|  |  |  |  |  |  |  |  | SBT6050, |  |
|  |  |  |  |  |  |  |  | Parts 1 and |  |
|  |  |  |  |  |  |  |  | $2, \quad 2$ |  |
|  |  |  |  |  |  |  |  | years\|Pro |  |
|  |  |  |  |  |  |  |  | gression |  |
|  |  |  |  |  |  |  |  | free |  |
|  |  |  |  |  |  |  |  | survival, |  |
|  |  |  |  |  |  |  |  | Parts 2, 4, and 5, 2 years |  |
| COMPLETE | Gastric or | BIOLOGICA | PHAS | INTER | Allocation: | 114 | Number of | Percentage | 2015/3/31 |
| D | Gastroesoph | L: MEDI4736 | E1\|PH | VENTI | RANDOMI |  | Participant | of |  |
|  | ageal | + | ASE2 | ONAL | ZED\|Interv |  | s With | Participant |  |
|  | Junction | tremelimuma |  |  | ention |  | Treatment- | s With |  |


| Adenocarci | $\mathrm{b} \mid$ BIOLOGIC | Model: | emergent | Objective |
| :---: | :---: | :---: | :---: | :---: |
| noma | AL: | PARALLEL | Adverse | Response |
|  | MEDI4736 + | \| Masking: | Events | in Phase |
|  | tremelimuma | NONE \| $\operatorname{Pri}$ | (TEAEs) | 1b, OR: |
|  | b \|BIOLOGIC | mary | and | best |
|  | AL: | Purpose: | Treatment | overall |
|  | MEDI4736\|B | TREATME | Emergent | response |
|  | IOLOGICAL: | NT | Serious | (BOR) of |
|  | Tremelimum |  | Adverse | confirmed |
|  | ab\|BIOLOGI |  | Events | complete |
|  | CAL: |  | (TESAEs) | response |
|  | MEDI4736+tr |  | in Phase | (CR) or |
|  | emelimumab |  | 1b, An | partial |
|  | \| BIOLOGIC |  | adverse | response |
|  | AL: |  | event (AE) | (PR) per |
|  | MEDI4736 + |  | is any | RECIST |
|  |  |  | untoward | v1.1. BOR: |

## tremelimuma

b

| medical | best |
| :--- | :--- |
| occurrence | response |
| in | a |
| participant $\quad$ PR, | stable |
| who | disease |
| received | $\backslash[\mathrm{SD} \backslash]$, |
| study drug | progressiv |
| without | e disease |
| regard to | $\backslash[\mathrm{PD} \backslash]$, |
| possibility | and not |
| of causal | evaluable) |
| relationshi | among all |
| p. $\quad$ A | overall |
| serious | responses |
| adverse | recorded |
| event | from date |
| (SAE) is an | of |


| AE | randomiza |
| :--- | :--- |
| resulting | tion of |
| in any of | participant |
| the | s or date of |
| following | first dose |
| outcomes | of study |
| or deemed | drug until |
| significant | progressio |
| for any | n, or last |
| other | evaluable |
| reason: | disease |
| death; | assessment |
| initial or | or |
| prolonged | discontinu |
| inpatient | ation from |
| hospitaliza | the study, |
| tion; life | whichever |


| threatenin | occurred |
| :--- | :--- |
| g | first. CR: |
| experience | disappeara |
| (immediat | nce of all |
| e risk of | target/non |
| dying); | -target |
| persistent | lesions; PR: |
| or | at least |
| significant | $30 \%$ |
| disability/ | decrease in |
| incapacity; | sum of |
| congenital | diameters |
| anomaly. | (SOD) of |
| TEAEs are | target |
| defined as | lesions |
| events | from |
| present at | baseline; |


| baseline | SD: neither |
| :--- | :--- |
| that | sufficient |
| worsened | shrinkage |
| in intensity | to qualify |
| after | for PR nor |
| administra | sufficient |
| tion of | increase to |
| study drug | qualify for |
| or events | PD from |
| absent at | smallest |
| baseline | SOD on |
| that | study; PD: |
| emerged | at least |
| after | $20 \%$ |
| administra | increase in |
| tion of | SOD of |
| study | target |



| Phase 1b, | nor |
| :---: | :---: |
| A DLT was | burden |
| defined as | leading to |
| any Grade | discontinu |
| 3 or higher | ation of |
| toxicity | therapy., |
| that occurs | From Day |
| during the | 1 up to End |
| DLT | of |
| evaluation | Treatment |
| period | (EOT), 90 |
| (From first | days post- |
| dose of | EOT, every |
| Study drug | 3 months |
| $\backslash[$ Day $1 \backslash]$ | (Q3M) |
| through 28 | after Day |
| days after | 90 post- |


| the | EOT up to |
| :---: | :---: |
| administra | 12 months |
| tion of | post-EOT, |
| MEDI4736 | and every |
| and | 6 months |
| tremelimu | after |
| $\mathrm{mab})$. The | month 12 |
| DLTs are: | post-EOT |
| any Grade | (approxim |
| 4 immune- | ately up to |
| related | 4 years and |
| adverse | one |
| event | month)\|D |
| (irAE), any | uration of |
| Grade | Stable |
| $\>=3$ non- | Disease |
| irAE, \>= | (DSD) in |


| Grade 3 | Phase 1b, |
| :--- | :--- |
| colitis, | The DSD |
| Grade 3 or | was |
| 4 | defined as |
| noninfectio | the time |
| us | from the |
| pneumonit | date of first |
| is | dose of |
| irrespectiv | study |
| e of | treatment |
| duration, | for Phase |
| Grade 2 | $1 b$ until the |
| pneumonit | first date of |
| is, liver | documente |
| transamina | d PD (per |
| se | RECIST |
| elevation | v1.1), or |


| $\text { \|> } 8 \text { 脳 }$ upper limit | death due to any |
| :---: | :---: |
| of normal |  |
| (ULN) or | whichever |
| total | occurre |
| bilirubin | first. PD is |
| \> 5 脳 | at least $20 \%$ |
| ULN. | increase |
| Immune- | sum of |
| related | diameters |
| AEs are | of target |
| defined as | lesions |
| AEs of an | from |
| immune | smallest |
| nature (ie, | sum on |
| inflammat | study (at |
| ory) in the |  |


| absence of a clear | least $5 \mathrm{~mm})$, |
| :---: | :---: |
| alternative | appearanc |
| etiology., | e of one or |
| From first | more new |
| dose of | lesions, |
| Study drug | substantial |
| (Day 1) | worsening |
| through 28 | in non- |
| days after | target |
| the | disease, |
| administra | increase in |
| tion of | tumor |
| MEDI4736 | burden |
| and | leading to |
| tremelimu | discontinu |
| mab\|Num | ation |


| ber of | therapy. |
| :--- | :--- |
| Participant | Kaplan |
| s $\quad$ With | Meier |
| Clinical | method |
| Laboratory | was used |
| Abnormali | to evaluate |
| ties | DSD., |
| Reported | From Day |
| as TEAEs | 1 up to End |
| in Phase | of the |
| 1b, | Treatment |
| Number of | (EOT), 90 |
| participant | days post- |
| s with | EOT, every |
| clinical | 3 |
| months |  |


| ies | $90 \quad$ post- |
| :--- | :--- |
| reported as | EOT up to |
| TEAEs are | 12 months |
| reported. | post-EOT, |
| Clinical | and every |
| laboratory | 6 months |
| abnormalit | after |
| ies are | month 12 |
| defined as | post-EOT |
| any | (approxim |
| abnormal | ately up to |
| findings in | 4 years and |
| analysis of | one |
| serum | month) $\mid \mathrm{M}$ |
| chemistry, | edian Best |
| hematolog | Percentage |
| y, and | Change |


| urine., Day | From |
| :---: | :---: |
| 1 up to 90 | Baseline of |
| days after | the Sum of |
| the last | Longest |
| dose | Diameters |
| (approxim | (SLD) of |
| ately | Target |
| years and | Lesions in |
| one | Phase 1b, |
| month) \|N | Best |
| umber of | percentage |
| Participant | change |
| With | from |
| Abnormal | baseline of |
| Vital Signs | the SLD of |
| and | target |
| Physical | lesions per |


| Examinati | RECIST |
| :--- | :--- |
| ons | v1.1 was |
| Reported | derived as |
| as TEAEs | the biggest |
| in Phase | decease or |
| 1b, | the |
| Number of | smallest |
| participant | increase |
| s with | from |
| abnormal | baseline on |
| vital signs | the SLD |
| reported as | among all |
| TEAEs are | post- |
| reported. | baseline |
| Abnormal | disease |
| vital signs | assessment |
| are defined | including |


| as any abnormal | unschedul ed |
| :---: | :---: |
| findings in | assessment |
| the vital | s. Best |
| signs | percent |
| parameters | change is |
| (temperatu | the |
| re, blood | maximum |
| pressure | reduction |
| $\backslash[\mathrm{BP} \backslash]$, | from |
| pulse rate | baseline or |
| $\backslash$ [or pulse | the |
| oximetry | minimum |
| at | increase |
| screening $\backslash$ | from |
| ], and | baseline in |
| respiratory | the |


| rate). | absence of |
| :--- | :--- |
| Abnormal | a |
| physical | reduction., |
| examinatio | From Day |
| ns are | 1 up to End |
| defined as | of the |
| any | Treatment |
| abnormal | (EOT), 90 |
| impact on | days post- |
| measurem | EOT, every |
| ents of | 3 |
| height and | (Q3M) |
| weight., | after Day |
| Day 1 up to | $90 \quad$ post- |
| $90 \quad$ days | EOT up to |
| after the | 12 months |
| last dose | post-EOT, |



| s with $1 \mathrm{l}, \quad$ The |  |
| :--- | :--- |
| abnormal | disease |
| electrocard | control |
| iograms | rate at 16 |
| (ECGs) | weeks was |
| reported as | defined as |
| TEAEs are | the |
| reported. | percentage |
| Abnormal | of |
| ECGs are | participant |
| defined as | s who |
| any | achieved a |
| abnormal | BOR of |
| findings in | confirmed |
| heart rate, | CR, |
| PR, RR, | confirmed |
| QRS and | PR, or had |


| QT | SD with |
| :---: | :---: |
| intervals | duration of |
| from the | SD for a |
| primary | minimum |
| lead of the | duration of |
| digital 12- | 110 days, |
| lead ECG., | following |
| Day 1 up to | the date of |
| 90 days | first dose |
| after the | of study |
| last dose | drug. The |
| (approxim | DC |
| ately | defined |
| years and | a BOR of |
| one | confirmed |
| month)\|Ea | CR, |
| stern | confirmed |


| Cooperativ | PR or SD |
| :--- | :--- |
| e Oncology | per |
| Group | RECIST |
| (ECOG) | v1.1. CR: |
| Performan | disappeara |
| ce Status at | nce of all |
| Baseline in | target/non |
| Phase 1b, | -target |
| The ECOG | lesions; PR: |
| scale of | at least |
| performan | $30 \%$ |
| ce status | decrease in |
| describes | sum |
| the level of | diameters |
| functionin | (SOD) of |
| g of | target |
| participant | lesions |


| s in terms of their | from <br> baseline; |
| :---: | :---: |
| ability to | SD: neither |
| care for | sufficient |
| themselves | shrinkage |
| daily | to qualify |
| activity, | for PR nor |
| and | sufficient |
| physical | increase to |
| ability. | qualify for |
| ECOG | PD from |
| Performan | smallest |
| ce Status | SOD on |
| Scorings | study., |
| are: $0=$ | From Day |
| fully | 1 up to 16 |
| active, able | weeks $\mid$ Per |


| to carry on | centage of |  |
| :--- | :--- | :--- |
| all | pre- | Participant |
| disease | s | With |
| performan | Disease |  |
| ce without | Control at |  |
| restriction; | 24 | Weeks |
| 1= | in | Phase |
| restricted | $1 b$, | The |
| in | disease |  |
| physically | control |  |
| strenuous | rate at 24 |  |
| activity but | weeks was |  |
| ambulator | defined as |  |
| y and able | the |  |
| to carry | percentage |  |
| out work | of |  |
| of a light or | participant |  |


| sedentary | s who |
| :--- | :--- | ---: |
| nature (for | achieved a |
| example, | BOR of |
| light house | confirmed |
| work, | CR, |
| office | confirmed |
| work); $2=$ | PR, or had |
| ambulator | SD with |
| y and | duration of |
| capable of | SD for a |
| all self-care | minimum |
| but unable | duration of |
| to carry | 166 days, |
| out any | following |
| work | the date of |
| activities, | first dose |
| up and | of study |

```
about drug. The
more than DC was
50% of defined as
waking a BOR of
hours; 3= confirmed
capable of CR,
only confirmed
limited PR or SD
selfcare, per
confined to RECIST
bed or v1.1. CR:
chair more disappeara
than 50% nce of all
of waking target/non
hours; 4= -target
completely lesions;PR:
disabled, at least
```

| cannot | $30 \%$ |
| :--- | :--- |
| carry on | decrease in |
| any self- | sum of |
| care, |  |
| totally | (SOD) of |
| confined to | target |
| bed or | lesions |
| chair; $5=$ | from |
| dead. The | baseline; |
| baseline | SD: neither |
| performan | sufficient |
| ce status of | shrinkage |
| participant | to qualify |
| s | is |
| for $P R$ nor |  |
| presented., | sufficient |
| Baseline | increase to |
| (Day | qualify for |


| 1)\|Percent | PD from |
| :---: | :---: |
| age of | smallest |
| Participant | SOD on |
| With | study., |
| Objective | From Day |
| Response | 1 up to 24 |
| (OR) in | weeks\|Pro |
| Phase 2, | gression |
| OR: best | Free |
| overall | Survival at |
| response | 6 Month in |
| (BOR) of | Phase 1b, |
| confirmed | The PFS-6 |
| complete | is the 6- |
| response | month |
| (CR) or | progressio |
| partial | n-free |


| response | survival |
| :---: | :---: |
| (PR) per | rate, which |
| RECIST | was the |
| v1.1. BOR: | percentage |
| best | of |
| response | participant |
| (CR, PR, | s who were |
| stable | progressio |
| disease | n free and |
| $\backslash[\mathrm{SD} \backslash]$ | alive at 6 |
| progressiv | months. |
| e disease | PFS |
| $\backslash[\mathrm{PD} \backslash]$, | defined as |
| and not | the time |
| evaluable) | from the |
| among all | ate of first |
| overall | se |


| responses | study drug |
| :---: | :---: |
| recorded | for Phase |
| from date | 1b |
| of | participant |
| randomiza | $s$ to the |
| tion for | earlier of |
| Arm A, B, | the dates of |
| C | the first |
| participant | objective |
| s or date of | documenta |
| first dose | tion |
| of study | radiograph |
| drug for | ic disease |
| Arms D, E | progressio |
| participant | n (per |
| until | RECIST |
| progressio | v1.1) or |

$n$, or last death due
evaluable to any
disease cause. PFS
assessment was
or censored at
discontinu the date of
ation from their last
the study, evaluable
whichever tumor
occurred assessment
first. CR: . Kaplan
disappeara Meier
nce of all method
target/non was used
-target to evaluate
lesions; PR: PFS., From
at least Day 1 upto

| $30 \%$ | 6 |
| :--- | :--- |
| decrease in | months $\mid \mathrm{N}$ |
| sum of | umber of |
| diameters | Participant |
| (SOD) of | s With |
| target | Treatment- |
| lesions | emergent |
| from | Adverse |
| baseline; | Events |
| SD: neither | (TEAEs) |
| sufficient | and |
| shrinkage | Treatment |
| to qualify | Emergent |
| for PR nor | Serious |
| sufficient | Adverse |
| increase to | Events |
| qualify for | (TESAEs) |


| PD from smallest | in Phase 2, <br> An adverse |
| :---: | :---: |
| SOD on | event (AE) |
| study; PD: | is any |
| at least | untoward |
| 20\% | medical |
| increase in | occurrence |
| SOD of | in |
| target | participant |
| lesions | who |
| from | received |
| smallest | study drug |
| sum on | without |
| study (at | regard to |
| least | possibility |
| 5 mm ), | of causal |
| appearanc | relationshi |


| e of one or | p. A |
| :--- | :--- |
| more new | serious |
| lesions, | adverse |
| substantial | event |
| worsening | (SAE) is an |
| in non- | AE |
| target | resulting in |
| disease, | any of the |
| increase in | following |
| tumor | outcomes |
| burden | or deemed |
| leading to | significant |
| discontinu | for any |
| ation of | other |
| therapy., | reason: |
| From Day | death; |
| 1 up to End | initial or |


| the | prolonged |
| :---: | :---: |
| Treatment | inpatient |
| (EOT), 90 | hospitaliza |
| days post- | tion; |
| EOT, every | threatenin |
| 3 months | g |
| (Q3M) | experience |
| after Day | (immediat |
| 90 post- | e risk of |
| EOT up to | dying); |
| 12 months | persistent |
| post-EOT, | or |
| and every | significant |
| 6 months | disability/ |
| after | incapacity; |
| month 12 | congenital |
| post-EOT | anomaly. |


| (approxim ately up to | TEAEs are defined as |
| :---: | :---: |
| 4 years and | events |
| one | present at |
| month) $\mid$ Pr | baseline |
| ogression | that |
| Free | worsened |
| Survival at | in intensity |
| 6 (PFS-6) | after |
| Month in | administra |
| Phase 2, | tion |
| The PFS-6 | study drug |
| is the 6- | or events |
| month | absent at |
| progressio | baseline |
| n -free | that |
| survival | emerged |


| rate, which was the | after |
| :---: | :---: |
| percentage | tion of |
| of | study |
| participant | drug., Day |
| s who were | 1 up to 90 |
| prog | days after |
| $n$ free and | the last |
| alive at 6 | dose |
| months. | (approxim |
| PFS was | ately |
| defined as | ears and |
| the time | one |
| from the | month) \| N |
| date of first | umber of |
| dose of | Participant |
| study drug | s With |


| for Arm A, <br> $B$, and $C$ | Clinical <br> Laboratory |
| :---: | :---: |
| participant | Abnormali |
| $s$ or the | ties |
| date of first | Reported |
| dose of | as TEAEs |
| study drug | 2, |
| for Arm D | Number of |
| and Arm E | participant |
| participant | with |
| $s$ to the | clinical |
| earlier of | laboratory |
| the dates of | abnormalit |
| the first | ies |
| objective | reported as |
| documenta | TEAEs are |
| tion of | reported. |


| radiograph ic disease | Clinical <br> laboratory |
| :---: | :---: |
| progressio | abnormalit |
| n (per | ies are |
| RECIST | defined as |
| v1.1) or | , |
| death due | abnormal |
| to any | findings in |
| cause. PFS | analysis of |
| was | serum |
| censored at | chemistry, |
| the date of | hematolog |
| their last | $y$, and |
| evaluable | urine., Day |
| tumor | 1 up to 90 |
| assessment | days after |
| Kaplan | the last |


| Meier | dose |  |
| :--- | :--- | ---: |
| method | (approxim |  |
| was used | ately | 4 |
| to evaluate | years and |  |
| PFS-6., | one |  |
| From Day | month) \|N |  |
| 1 upto 6 | umber of |  |
| months | Participant |  |
|  | s With |  |
|  | Abnormal |  |
|  | Vital Signs |  |
|  | and |  |
|  | Physical |  |
|  | Examinati |  |
|  | ons |  |
|  | Reported |  |
|  | as TEAEs |  |

in Phase 2,
Number of
participant
s with
abnormal
vital signs
reported as
TEAEs are
reported.
Abnormal
vital signs
are defined
as any
abnormal
findings in
the vital
signs
rate).

Abnormal
physical
examinatio
ns are
defined as
abnormal
impact on
measurem
ents of
height and
weight.,
Day 1 up to
90 days
after the
last dose
(approxim
ately 4
years and
one
month)|N
umber of
Participant
s With
Abnormal
Electrocar
diograms
Reported
as TEAEs
in Phase 2,
Number of
participant
s with
abnormal
electrocard
iograms
(ECGs)
reported as
TEAEs are
reported.
Abnormal
ECGs are
defined as
any
abnormal
findings in
heart rate,
PR, RR,
QRS and
QT
intervals
from the
primary
lead of the
digital 12-
lead ECG.,
Day 1 up to
90 days
after the
last dose
(approxim
ately 4
years and
one
month)|Ea
stern
Cooperativ
e Oncology
Group
(ECOG)
Performan
ce Status at
Baseline in

## Phase <br> 2,

The ECOG
scale of
performan
ce status
describes
the level of
functionin
g of
participant
$s$ in terms
of their
ability to
care for
themselves
daily
activity,

## Performan

ce Status
Scorings
are: $0=$
fully
active, able
to carry on
all pre-
disease
performan
ce without
restriction;
$1=$
restricted
in
physically
strenuous
activity but
ambulator
y and able
to carry
out work
of a light or
sedentary
nature (for
example,
light house
work,
office
work); 2=
ambulator
y and
capable of
all self-care
but unable
to carry
out any
work
activities,
up and
about
more than
$50 \%$ of
waking
hours; 3=
capable of
only
limited
selfcare,
confined to
bed or
chair more
than 50\%
of waking
hours; 4=
completely
disabled,
cannot
carry on
any self-
care,
totally
confined to
bed or
chair; 5=
dead. The
baseline
performan
ce status of
participant
s is
presented.,
Baseline
(Day
1)| Percent
age of
Participant
s With
Disease
Control at
16 Weeks
in Phase 2,
The
disease
control
rate at 16
weeks was
defined as
the
percentage
of
participant
s who
achieved a
BOR of
confirmed
CR,
confirmed

PR, or had
SD with
duration of
SD for a
minimum
duration of
110 days,
following
the date of
randomiza
tion for
Arm A, B,
and C
participant
$s$ and the
date of first
dose
of
study drug
for Arm D
and E
participant
s. The DC
was
defined as
a BOR of
confirmed
CR,
confirmed
PR or SD
per
RECIST
v1.1. CR:
disappeara
nce of all
target/non
-target
lesions; PR:
at least
30\%
decrease in
sum of
diameters
(SOD) of
target
lesions
from
baseline;
SD: neither
sufficient
shrinkage
to qualify
for PR nor
sufficient
increase to
qualify for
PD from
smallest
SOD on
study.,
From Day
1 up to 16
weeks $\mid$ Per
centage of
Participant
s With
Disease
Control at
24 Weeks
in Phase 2,
The
disease
control
rate at 24
weeks was
defined as
the
proportion
of
participant
s who
achieved a
BOR of
confirmed
CR,
confirmed

PR, or had
SD with
duration of
SD for a
minimum
duration of
166 days,
following
the date of
randomiza
tion for
Arm A, B,
and C
participant
$s$ and the
date of first
dose
of
study drug
for Arm D
and E
participant
s. The DC
was
defined as
a BOR of
confirmed
CR,
confirmed
PR or SD
per
RECIST
v1.1. CR:
disappeara
nce of all
target/non
-target
lesions; PR:
at least
30\%
decrease in
sum of
diameters
(SOD) of
target
lesions
from
baseline;
SD: neither
sufficient
shrinkage
to qualify
for PR nor
sufficient
increase to
qualify for
PD from
smallest
SOD on
study.,
From Day
1 up to 24
weeks $\mid \mathrm{Du}$
ration of
Response
(DoR) in
Phase 2,
The DoR
was
defined as
the time
from the
date of first
documente
d response
( CR or PR )
until the
first date of
documente
d
progressio
n
according
to RECIST
v1.1 that
occurred
subsequen
tly after
response
or death
due to any
cause,
whichever
occurred
first. CR:
disappeara
nce of all
target/non
-target
lesions; PR:
at least
30\%
decrease in
diameters
(SOD) of
target
lesions
from
baseline.
Kaplan
Meier
method
was used
to evaluate
DoR.,
From Day
1 up to End
of the
Treatment
(EOT), 90
days post-
EOT, every
3 months
(Q3M)
after Day
90 post-
EOT up to
12 month
post-EOT,
and every
6 months
after
month 12
post-EOT
(approxim
ately up to
month) $\mid \mathrm{Ti}$
me to
Response
(TTR) in
Phase 2,
TTR: time
from date
of
randomiza
tion of
participant
s for Arm
A, B, and C
or date of
first dose

Arm D and
Arm E
until first
documente
d OR per
RECIST
v1.1. OR:
BOR of
confirmed
CR or PR
per
RECIST
v1.1. BOR:
best
response
and not
evaluable)
among all
overall
responses
recorded
from date
of
randomiza
tion/date
of first
dose of
study drug
until
progressio
n, or last
evaluable
disease
assessment
or
discontinu
ation from
the study,
whichever
occurred
first. CR:
disappeara
nce of all
target/non
-target
lesions; PR:
at least
lesions
from
baseline;
SD: neither
sufficient
shrinkage
to qualify
for PR nor
sufficient
increase to
qualify for
PD from
smallest
increase in
SOD of
target
lesions
from
smallest
sum (at
least
5 mm ),
appearanc
e of one or
more new
lesions,
substantial
worsening
in non-targetdisease,increase in
tumorburdenleading todiscontinu
ation of
therapy.
KaplanMeier
method
used ..... to
evaluate
TTR., From
Day 1 up to
End of the
Treatment
(EOT), 90
days post-
EOT, every
$3 \quad$ months
(Q3M)
after Day
$90 \quad$ post-
EOT up to
$12 \quad$ month
post-EOT,
and every
$6 \quad$ months
after
month 12
ately up to
4 years and
one
month)|D
uration of
Stable
Disease in
Phase 2,
The DSD
was
defined as
the time
from the
date of
randomiza
tion for
Arm A, B,
and $C$
participant
s or the
date of first
dose of
study drug
for Arm D
and Arm E
participant
$s$ until the
first date of
documente
d PD (per
RECIST
v1.1), or
death due
to any
cause,
whichever
occurred
first. PD is
at least a
20\%
increase in
sum of
diameters
of target
lesions
from
smallest
sum on
study (at
least 5
mm ),
appearanc
e of one or
more new
lesions,
substantial
worsening
in non-
target
disease,
increase in
tumor
burden
leading to
discontinu
ation of
therapy.
Kaplan
Meier
method
was used
to evaluate
DSD.,
From Day
1 up to End
of the
Treatment
(EOT), 90
days post-
EOT, every
3 months
(Q3M)
after Day
post-EOT,
and every
6 months
after
month 12
post-EOT
(approxim
ately up to
4 years and
one
month) |M
edian Best
Percentage
Change
From
Baseline of
the Sum of
Longest
Diameters
(SLD) of
Target
Lesions in
Phase 2,
Best
percentage
change
from
baseline of
the SLD of
target
lesions per

## RECIST

v1.1 was
derived as
the biggest
decease or
the
smallest
increase
from
baseline on
the SLD
among all
post-
baseline
disease
assessment
including
unschedul
ed
assessment
s. Best
percent
change is
the
maximum
reduction
from
baseline or
the
minimum
increase
from
baseline in
the
reduction.
From Day
1 up to End
of the
Treatment
(EOT), 90
days post-
EOT, every
3 months
(Q3M)
after Day
90 post-
EOT up to
12 month
post-EOT,
and every
6 months
after
month 12
post-EOT
(approxim
ately up to
4 years and
one
month) $\mid \operatorname{Pr}$
ogression
Free
Survival in
Phase 2,
The PFS
was
defined as
from the
date of
randomiza
tion for
Arm A, B,
and C
participant
s or the
date of first
dose of
study
treatment
for Arm D
and E
participant
s to the
earlier
the dates of
the first
objective
documenta
tion of
radiograph
ic disease
progressio
n (per
RECIST
v1.1) or
death due
to any
cause. PFS
was
censored at
the date of
their last
evaluable
tumor
assessment

- Kaplan

Meier
method
was used
to evaluate
PFS., From
Day 1 up to
End of the
Treatment
(EOT), 90
days post-
EOT, every
post-EOT, and every

6 months
after
month 12
post-EOT
(approxim
ately up to
4 years and
one
month)|Pr

Free
Survival at
9 Month
(PFS-9) in
Phase 2,
The PFS-9
is the 9-
month
progressio
n-free
survival
rate, which
was the
percentage
of
participant
s who were
progressio
n free and
alive at 9
months.
PFS
was
defined as
the time
from the
date of first
dose of
study drug
for Arm A,
B, C
participant
$s$ or the
date of first
study drug
for Arm D
and E
participant
$s$ to the
earlier of
the dates of
the first
objective
documenta
tion of
radiograph
ic disease
progressio
n (per
RECIST
death due
to any
cause. PFS
was
censored at
the date of
their last
evaluable
tumor
assessment
. Kaplan
Meier
method
was used
to evaluate
PFS., From
months $\mid \mathrm{O}$
verall
Survival
(OS) in
Phase 2,
The OS
was
defined as
the time
from date
of
randomiza
tion for
Arm A, B,
and $C$
for Arm D
and Arm E
participant
s until
death due
to any
cause. OS
was
censored at
last known
alive date.
Kaplan

## Meier

method
was used
to evaluate
OS. Kaplan
Meier
method
was used
to evaluate
OS., From
Day 1 up to
End of the
Treatment
(EOT), 90
days post-
EOT, every
3 months

```
(Q3M)
after Day
90 post-
EOT up to
1 2 ~ m o n t h
post-EOT,
and every
6 ~ m o n t h s
after
month 12
post-EOT
(approxim
ately up to
4 years and
one
month)|O
verall
```

in Phase 2,
The OS
was
defined as
the time
from date
of
randomiza
tion for
Arm A, B,
and C
participant
$s$ or the
date of first
dose of
study drug
for Arm D
and Arm E
participant
s until 12
months.
OS was
censored at
last known
alive date.
Kaplan
Meier
method
was used
to evaluate
OS. Kaplan
Meier
method
was used
to evaluate
OS and
95\%
confidence
interval.,
From Day
1 up to 12
months |P
ercentage
of
Participant
s With
Objective
Response
With

Positive
Interferon
Gamma
(IFN- 纬)
Gene
Expression
in Phase 2,
Percentage
of
participant
s with OR
with
positive
IFN- 纬
gene
expression
is reported.

OR: BOR
of
confirmed
CR or PR
per
RECIST
v1.1. BOR:
best
response
(CR, PR,
SD, PD,
and not
evaluable)
among all
overall
responses
recorded
from date
of
randomiza
tion for
Arm A, B,
C
participant
$s$ or date of
first dose
of study
drug for
Arms D, E
participant
suntil
progressio
n , or last
evaluable
first. CR:
disappeara
nce of all
target/non
-target
lesions; PR:
at least
30\%
decrease in
diameters
(SOD) of
target
lesions
from
baseline;
SD: neither
sufficient
shrinkage
to qualify
for PR nor
sufficient
increase to
qualify for
PD from
smallest
SOD ..... onstudy; PD:
at least20\%
increase in
SOD ..... oftargetlesionsfromsmallestsum onstudy (atleast5 mm ),appearanc
e of one ormore new
lesions,
substantial
worsening
in non-
target
disease,
increase in
tumor
burden
leading to
discontinu
ation of
therapy.,
Day 1
through
Day 30
post EOT
years and
one
month) $\mid \mathrm{Pe}$
rcentage of
Participant
s With
Progressio
n Free
Survival
(PFS) at 6
Month
With
Positive
IFN- 纬
Gene

Expression
in Phase 2,
Percentage
of
participant
s with PFS
at 6 month
with
positive
IFN- 纬
gene
expression
is reported.
The PFS-6
is the 6-
month
progressio

## n-free

survival
rate, which
was the
percentage
of
participant
s who were
progressio
n free and
alive at 6
months.
PFS was
defined as
the time
from the
date of first
study drug
for Arm A,
$B$, and $C$
participant
s or the
date of first
dose of
study drug
for Arm D
and Arm E
participant
$s$ to the
earlier of
the dates of
the first
objective
radiograph ic disease
progressio
n (per
RECIST
v1.1) or
death due
to any
cause. PFS
was
censored at
the date of
their last
evaluable
tumor

- Kaplan

Meier
method
was used
to evaluate
PFS-6.,
Day 1
through
Day 30
post EOT
(approxim
ately 4
years and
one
month) $\mid \mathrm{Pe}$
rcentage of

Objective
Response
in Phase 2
by
Programm
ed Death-
ligand
(PD-L1)
Status,
Percentage
of
participant
s with
objective
response in

```
Phase 2 by
programm
ed death-
ligand
(PD-L1)
status is
reported
PD-L1 is a
protein
that may
be found
on some
normal
cells and in
higher-
than-
normal
```

types of
cancer
cells. It
plays a role
in
regulating
the
immune
response
against
some types
of cancers
and
therefore,
is the
some
anticancer
drugs. PD-
L1 status
was based
on the
percentage
of tumor
cells from
baseline
tumor
tissue
samples
with PD-
L1
membrane
staining:
PD-L1
high if $\backslash>=$
1\% tumor
cells (better
response),
PD-L1
low/neg if
\< 1\%
tumor cells
(low
response).,
Day 1
through
Day 30
post EOT
(approxim

|  |  |  |  |  |  |  |  | ately 4 <br> years and one month) |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| COMPLETE | Ovarian ${ }^{\text {M }}$ | BIOLOGICA | PHAS | INTER | Allocation: | 12 | To | to | Feb-07 |
| D | elanoma $\mathrm{Re}^{\text {e }}$ | L: | E1 | VENTI | RANDOMI |  | determine | determine |  |
|  | nal\|Prostate | PSMA/PRA |  | ONAL | ZED\|Interv |  | the | the blood |  |
|  | \| Colorectal | ME\|BIOLOG |  |  | ention |  | immunolo | plasmid |  |
|  | \| Endometri | ICAL: |  |  | Model: |  | gic | levels by |  |
|  | al | PSMA/PRA |  |  | SINGLE_G |  | response to | PCR |  |
|  | Carcinoma | ME |  |  | ROUP \\| Mas |  | the | analysis, |  |
|  | Cervical |  |  |  | king: |  | treatment | Every 6 |  |
|  | Carcinoma |  |  |  | NONE \| Pri |  | with | Weeks \\| me |  |
|  | Testicular |  |  |  | mary |  | MKC1106- | asure |  |
|  | Cancer \\| Thy |  |  |  | Purpose: |  | PP | cytokine |  |
|  | roid |  |  |  | TREATME |  | regimen | levels, |  |
|  | Cancer ${ }^{\text {Sm }}$ |  |  |  | NT |  | and 2) to | Every 6 |  |

all Cell Lung
Carcinoma|
Mesothelio
ma |Breast
Carcinoma |
Esophageal
Carcinoma
Gastric
Cancer | Pan
creatic
Carcinoma
Neuroendoc
rine
Cancer|Liv
er
Cancer |Gall
bladder
determine Weeks|to
the safety describe
and any
adverse objective
event tumor
profile of responses
MKC1106- to the
PP, Every 6 treatment
Weeks with
MKC1106-
PP, Every 6
Weeks

|  | Cancer \| Bili |  |  |  |  |  |  |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  | ary Tract |  |  |  |  |  |  |  |  |
|  | Cancer \\| Ana |  |  |  |  |  |  |  |  |
|  | 1 |  |  |  |  |  |  |  |  |
|  | Carcinoma |  |  |  |  |  |  |  |  |
|  | Bone |  |  |  |  |  |  |  |  |
|  | Sarcomas \|S |  |  |  |  |  |  |  |  |
|  | oft Tissue |  |  |  |  |  |  |  |  |
|  | Sarcomas \| C |  |  |  |  |  |  |  |  |
|  | arcinoma of |  |  |  |  |  |  |  |  |
|  | Unknown |  |  |  |  |  |  |  |  |
|  | Origin, |  |  |  |  |  |  |  |  |
|  | Primary |  |  |  |  |  |  |  |  |
| RECRUITIN | Lung | DRUG: | EARL | INTER | Allocation: | 24 | Subject | Disease | 2023/3/30 |
| G | Cancer \\| Bro | Recombinant | Y_PH | VENTI | NA \| Interve |  | incidence | Assessmen |  |
|  | nchial | oncolytic | ASE1 | ONAL | ntion |  | of adverse | $t$ for |  |
|  | Cancer ${ }^{\text {No }}$ | herpes |  |  | Model: |  | events, To | Disease |  |

```
n Small Cell simplex virus
Lung type 1 (R130)
Cancer|Sm
all Cell Lung
Cancer|Sarc
oma|Colore
ctal
Cancer |Gas
tric
Cancer|Liv
er
Cancer | Bre
ast
Cancer|Pan
creatic
Cancer|Hea
d and Neck
```

| SINGLE_G | characteriz | Control |
| :---: | :---: | :---: |
| ROUP \\| Mas | e the safety | Rate, |
| king: | profile of | Evaluate |
| NONE \| Pri | R130 | the efficacy |
| mary | injection in | endpoints |
| Purpose: | patients | of DCR by |
| TREATME | with | the |
| NT | advanced | investigato |
|  | solid | with |
|  | tumors as | RECIST |
|  | measured | v1.1 and |
|  | by the | iRECIST, |
|  | incidence | Every 10 |
|  | of Grade | weeks for |
|  | 鈮 ? 3 | 12 |
|  | Common | months \| D |
|  | Terminolo | isease |


| Cancer \\| Ova | gy Criteria | Assessmen |
| :---: | :---: | :---: |
| rian Cancer | for | for |
|  | Adverse | Duration |
|  | Events, | of |
|  | version 5.0 | Response, |
|  | (CTCAE | Evaluate |
|  | v5.0), Up | the efficacy |
|  | to 6 | endpoints |
|  | months \|S | of DOR by |
|  | ubject | the |
|  | incidence | investigato |
|  | of | r with |
|  | laboratory | RECIST |
|  | abnormalit | v1.1 and |
|  | ies, | iRECIST, |
|  | Detection | Every 10 |
|  | of liver and | weeks for |


| renal | 12 |
| :--- | :--- |
| function, | months $\mid Q$ |
| electrocard | uality of |
| iogram, | Life |
| routine | Assessmen |
| blood | $t$, Evaluate |
| examinatio | with |
| n etc., Up | EORTC |
| to $\quad 1$ | QLQ-C30, |
| month $\mid$ Sy | Every 6 |
| stemic | weeks for |
| Immune | 12 months |
| Response, |  |
| Detection |  |
| of |  |
| increased |  |
| systemic |  |

immune
Response
markers in
sera
（IL2，IL4，IL
6，IL8，IL10，
TNFa 镇子子
FN 纬，etc．）
and
peripheral
blood
mononucle
ar cells by
multi－
Color
fluorescen
ce－


| ageal | complete | remains at |
| :---: | :---: | :---: |
| Junction | response, | all |
| Adenocarci | Up to 6 |  |
| noma | months | 1b: Less |
|  |  | than 10\% |
|  |  | of the |
|  |  | tumor |
|  |  | remains 2: |
|  |  | 10\%-50\% |
|  |  | tumor |
|  |  | residual 3: |
|  |  | More than |
|  |  | $50 \%$ of the |
|  |  | tumor |
|  |  | remains or |
|  |  | there is no |
|  |  | change in |

the tumor,
Up to 3
years |Obj
ective
response
rate (ORR),
Proportion
of subjects
with initial
RECIST 1.1
measurabl
e disease
who have
complete
response
(CR) or
partial
according
to
iRECIST,
Up to 3
years|Dise
ase-free
survival
(DFS),
Time from
Cycle
Day 1
treatment
administra
tion to the
first
disease
progressio
n, disease
recurrence
following
surgery
(preferably
biopsy
proven), or
death
whichever
occurs
first., Up to 3
years |Ove
rall
survival
(OS), Time
from Cycle
1 Day 1
treatment
administra
tion to
death due
to any
cause., Up
to 3
years | Inci
cende of
Adverse
Events
(AEs),

Number of
patients
with AE,
treatment-
related AE
(TRAE),
immune-
related
AEs (irAE),
AE of
special
interest
(AESI),
serious
adverse
event
(SAE)
assessed
by CTCAE
v5.0., Up
to3
years | Bio
marker
assessment
, To
analyze the
differences
of gene
and
immune
microenvir
onment
biomarker
s among
explore the
relationshi
p with the
efficacy of
clinical
treatment.

To analyze
the
correlation
between

|  |  |  |  |  |  | peripheral |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  |  |  |  |  |  | blood |  |
|  |  |  |  |  |  | indexes |  |
|  |  |  |  |  |  | and the |  |
|  |  |  |  |  |  | efficacy of |  |
|  |  |  |  |  |  | clinical |  |
|  |  |  |  |  |  | treatment., |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  | years |  |
| ENROLLING | Hepatocellular | OBSER | Observation | 1000 | Evaluate | Evaluate | 2017/2/16 |
| _BY_INVITA | Carcinoma \| Cholangiocarcinoma | Gal | VATI | al Model: |  | the overall |  |  |
| TION | lbladder Cancer\|Biliary Tract | ONAL | \| Time |  | survival | recurrence |  |
|  | Cancer \\| Gastric Cancer \| Colorectal |  | Perspective: |  | rate of all | free |  |
|  | Cancer |  | p |  | patients | survival |  |
|  |  |  |  |  | with | rate of |  |
|  |  |  |  |  | hepatobilia | patients |  |
|  |  |  |  |  | ry tumor, | with |  |


| In order to identify | hepatobilia <br> ry tumor, |
| :---: | :---: |
| the | In order to |
| potential | identify |
| influence | the |
| factors of | potential |
| hepatobilia | influence |
| ry tumor | factors of |
| patients | tumor |
| survival, 5 | recurrence |
| years | samples |
|  | from |
|  | patients |
|  | with |
|  | hepatobilia |
|  | ry cancers, |
|  | 5 |

cancer-
specific
survival
rate of
patients
with
hepatobilia
ry tumor,
In order to
identify
the
potential
influence
factors of
tumor-
induced
death in
patients
with
hepatobilia
ry tumors,
5
years |Eval
uate the
Progressio
n Free
Survival
rate
patients
with
hepatobilia
ry tumor,

|  |  |  |  |  |  |  |  | In order to identify |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  |  |  |  |  |  |  |  | the |  |
|  |  |  |  |  |  |  |  | potential |  |
|  |  |  |  |  |  |  |  | influence |  |
|  |  |  |  |  |  |  |  | factors of |  |
|  |  |  |  |  |  |  |  | tumor |  |
|  |  |  |  |  |  |  |  | progressio |  |
|  |  |  |  |  |  |  |  | n from |  |
|  |  |  |  |  |  |  |  | patients |  |
|  |  |  |  |  |  |  |  | with |  |
|  |  |  |  |  |  |  |  | hepatobilia |  |
|  |  |  |  |  |  |  |  | ry cancers, |  |
|  |  |  |  |  |  |  |  |  |  |
| UNKNOWN | Gastric | DRUG: | NA | INTER | Allocation: | 120 | The | The change | 2019/12/20 |
|  | Cancer ${ }^{\text {Col }}$ | adjuvant |  | VENTI | NA \| Interve |  | change of | of the |  |
|  | on Cancer |  |  | ONAL | ntion |  | diversity | number of |  |


| chemotherap | Model: | of | Gastrin in |
| :---: | :---: | :---: | :---: |
| y | SINGLE_G | intestinal | blood |
|  | ROUP / Mas | flora in | during |
|  | king: | faeces | chemother |
|  | NONE \| Pri | during | apy, the 1st |
|  | mary | chemother | day before |
|  | Purpose: | apy, The | the start of |
|  | OTHER | 1st day | each cycle |
|  |  | before the | of |
|  |  | start of | chemother |
|  |  | each cycle | apy(each |
|  |  | of | cycle is 21 |
|  |  | chemother | days,excep |
|  |  | apy, and | for the |
|  |  | the 1st day | FOLFOX |
|  |  | after the | regimen of |
|  |  | completion | colon |



the 1st day ugh
after the chemother
completion apy
of each completion
cycle of ,
chemother months.|T
apy(each he change
cycle is 21 of the
days,excep
number of
for the
Interleukin
FOLFOX
(IL)-
regimen of
colon

| apy | chemother |
| :---: | :---: |
| completion | apy, the 1st |
| six | day before |
| months. \|T | the start of |
| he change | each cycle |
| of | of |
| abundance | chemother |
| of | apy (each |
| intestinal | cycle is 21 |
| flora in | days,excep |
| faeces | $t$ for the |
| during | FOLFOX |
| chemother | regimen of |
| apy, The | colon |
| 1st day | cancer is 14 |
| before the | days),thro |
| start of | ugh |


| each cycle of | chemother apy |
| :---: | :---: |
| chemother | completion |
| apy, and | 6 |
| the 1st day | months. \|T |
| after the | he change |
| completion | of the |
| of each | number of |
| cycle of | tumor |
| chemother | necrosis |
| apy (each | factor(TNF |
| cycle is 21 | )- 伪 in |
| days,excep | blood |
| $t$ for the | during |
| FOLFOX | chemother |
| regimen of | apy, the 1st |
| colon | day before |


| cancer is 14 days),thro | the start of each cycle |
| :---: | :---: |
| ugh | of |
| chemother | chemother |
| apy | apy (each |
| completion | cycle is 21 |
| six | days,excep |
| months. \|T | $t$ for the |
| he change | FOLFOX |
| of | regimen of |
| abundance | colon |
| of urethral | cancer is 14 |
| flora in | days),thro |
| urine | ugh |
| during | chemother |
| chemother | apy |
| apy, The |  |

1st day completion
before the , 6 months.
start of
each cycle
of
chemother
apy, and
the 1st day
after the
completion
of each
cycle of
chemother
apy(each
cycle is 21
days,excep
$t$ for the

## FOLFOX

regimen of
colon
cancer is 14
days),thro
ugh
chemother
apy
completion
, six
months.|T
he change
of
concentrati
on of
purine
metabolite
$s$ in urine
during
chemother
apy, The
1st day
before the
start of
each cycle
of
chemother
apy, and
the 1st day
after the
completion
of each
cycle of
chemother
apy(each
cycle is 21
days,excep
$t$ for the
FOLFOX
regimen of
colon
cancer is 14
days),thro
ugh
chemother
apy
completion
, $\operatorname{six}$
months.|T
he change
of
concentrati
on of P -
hydroxyph
enylalanin
e
metabolite
s in urine
during
chemother
apy, The
1st day
before the
start of
each cycle
of
chemother
apy, and
the 1st day
after the
completion
of each
cycle of
chemother
apy(each
cycle is 21
days,excep
$t$ for the
FOLFOX
regimen of
colon
cancer is 14
days),thro
ugh
chemother

|  |  |  |  |  |  |  | apy completion |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  |  |  |  |  |  |  | six |  |  |
|  |  |  |  |  |  |  | months. |  |  |
| COMPLETE | Liver | BIOLOGICA | PHAS | INTER | Allocation: | 8 | Safety of | Treatment | Apr-15 |
| D | Metastases | L: anti-CEA | E1 | VENTI | NA \| Interve |  | CAR-T cell | response |  |
|  |  | CAR-T |  | ONAL | ntion |  | hepatic | (Liver |  |
|  |  | cells \|DEVIC |  |  | Model: |  | artery | tumor |  |
|  |  | E: Sir-Spheres |  |  | SINGLE_G |  | infusions | response |  |
|  |  |  |  |  | ROUP \\| Mas |  | in | by MRI, |  |
|  |  |  |  |  | king: |  | combinatio | PET, CEA |  |
|  |  |  |  |  | NONE \| Pri |  | n with Sir- | level, and |  |
|  |  |  |  |  | mary |  | Spheres as | biopsy), |  |
|  |  |  |  |  | Purpose: |  | Measured | Liver |  |
|  |  |  |  |  | TREATME |  | by | tumor |  |
|  |  |  |  |  | NT |  | Number of | response |  |
|  |  |  |  |  |  |  | Participant | by MRI, |  |


| s with PET, CEA |  |
| :--- | :--- |
| Adverse level, and |  |
| Events, To biopsy |  |
| determine |  |
| the safety | 1. RECIST |
| and | and |
| regimen | immune |
| limiting | related |
| toxicity | response |
| (RLT) of a criteria |  |
| standard |  |
| of care | PET) |
| treatment | 2. |
| with By | evidence of |
| Yttrium-90 | tumor |
| Sir- | necrosis |
| Spheres | and |


| Microsphe | fibrosis |
| :--- | :--- |
| res when | (biopsy), |
| following | 14 |
| anti-CEA | weeks\|Ser |
| CAR-T | um |
| hepatic | cytokine |
| artery | levels, |
| infusions | Measurem |
| (HAI) for | ent of |
| CEA- | cytokines |
| expressing | as |
| liver | indicators |
| metastases | of immune |
| ., 14 weeks | response, |
|  | 14 |
|  | weeks\|CA |

tumors,
normal
liver, and
extrahepati
c sites,
Quantificat
ion of
CAR-T
cells in
biopsy and
blood
samples,
14 weeks

| COMPLETE | Gastric | BIOLOGICA | PHAS | INTER | Allocation: | 100 | Objective | ORR | 2018/3/26 |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| D | Cancer | L: | E2 | VENTI | NON_RAN |  | response | according |  |
|  |  | Pembrolizum |  | ONAL | DOMIZED \| |  | rate (ORR) | to |  |
|  |  | ab\|DRUG: |  |  | Intervention |  | according | immune- |  |
|  |  | Oxaliplatin \| |  |  | Model: |  | to | related |  |
|  |  | DRUG: TS- |  |  | PARALLEL |  | Response | Response |  |
|  |  | 1\|DRUG: |  |  | \| Masking: |  | Evaluation | Evaluation |  |
|  |  | Cisplatin |  |  | NONE \| Pri |  | Criteria In | Criteria In |  |
|  |  |  |  |  | mary |  | Solid | Solid |  |
|  |  |  |  |  | Purpose: |  | Tumors | Tumors |  |
|  |  |  |  |  | TREATME |  | version 1.1 | (iRECIST) |  |
|  |  |  |  |  | NT |  | (RECIST | assessed |  |
|  |  |  |  |  |  |  | 1.1) | by BICR, |  |
|  |  |  |  |  |  |  | assessed | For the |  |
|  |  |  |  |  |  |  | by Blinded | secondary |  |
|  |  |  |  |  |  |  | Independe | efficacy |  |
|  |  |  |  |  |  |  | nt Central | analysis, |  |


| Review | ORR is |
| :--- | :--- |
| (BICR), For | defined as |
| the | the |
| primary | percentage |
| efficacy | of |
| analysis, | participant |
| ORR is | s whose |
| defined as | best |
| the | response |
| percentage | based on |
| of | imaging is |
| participant | CR |
| s who have | (disappear |
| a best | ance of all |
| response of | lesions) or |
| Complete | PR (鈮?0\% |
| Response | decrease in |


| (CR: | the SOD of |
| :--- | :--- |
| Disappear | target |
| ance of all | lesions, |
| target | taking as |
| lesions) or | reference |
| Partial | the |
| Response | baseline |
| (PR: At | sum |
| least a 30\% | diameters) |
| decrease in | according |
| the sum of | to iRECIST |
| diameters | as assessed |
| \[SOD $\backslash]$ | by BICR. |
| of target | iRECIST is |
| lesions, | a |
| taking as | modificati |
| reference | on $\quad$ to |


| the | RECIST |
| :--- | :--- |
| baseline | that takes |
| sum | into |
| diameters) | account |
| per | unique |
| RECIST 1.1 | patterns of |
| as assessed | atypical |
| by BICR., | response in |
| Up to $\sim 2$ | immunoth |
| years | erapy and |
|  | enables |
|  | treatment |
|  | beyond |
|  | initial |
|  | radiograph |
|  | ic |

n. At initial

Progressiv
e Disease
(PD) by
RECIST
1.1, if
participant
is clinically
stable the
investigato
r may
continue to
treat and
scan again
4-8 weeks
later to see
if PD
confirmed
by
iRECIST
criteria.,
Up to $\sim 2$
years |Dur
ation of
Response
(DOR)
according
to RECIST
1.1
assessed
by BICR,
For
participant
s who
te CR or PR
according
to RECIST
1.1 as
assessed
by BICR,
DOR is
defined as
the time
from the
earliest
date of
qualifying
response
(CR or PR)
until
earliest
date of
disease
progressio
$n$ or death
from any
cause,
whichever
comes first.
DOR will
be
censored at
the last
tumor
assessment
date if a
responder
have PD or
death., Up
to $\sim 2$
years|DO
R
according
to iRECIST
assessed
by BICR,
For
participant
s who
demonstra
te CR or PR
according
to iRECIST
by BICR,
DOR is
defined as
the time
from the
earliest
date of
qualifying
response
(CR or PR)
until
earliest
date of
disease
progressio
n or death
whichever
comes first.
DOR will
be
censored at
the last
tumor
assessment
date if a
responder
does not
have PD or
death.
iRECIST is
into
account
unique
patterns of
atypical
response in
immunoth
erapy and
enables
treatment
beyond
initial
radiograph
progressio
n., Up to $\sim 2$
years |Dise
ase Control
Rate (DCR)
according
to RECIST
1.1
assessed
by BICR,
DCR is
defined as
the
percentage
of
participant
population
who have
CR
(disappear
ance of all
lesions),
PR (鈮? $0 \%$
decrease in
the SOD of
target
lesions,
taking as
reference
the
baseline
diameters),
or stable
disease
(SD:
neither
sufficient
shrinkage
to qualify
for PR nor
sufficient
increase to
qualify for
PD).
Responses
are
according
assessed
by BICR.,
Up to $\sim 2$
years |DC
R
according
to iRECIST
1.1
assessed
by BICR,
DCR is
defined as
the
percentage
of
participant
$s$ in the
analysis
population
who have
CR
(disappear
ance of all
lesions),
PR (鈮? $0 \%$
decrease in
the SOD of
target
lesions,
taking as
reference
the
baseline
sum
diameters),
or stable
disease
(SD:
neither
sufficient
shrinkage
to qualify
for PR nor
sufficient
increase to
qualify for
PD).
Responses
are
to iRECIST
1.1 as
assessed
by BICR.
iRECIST is
a
modificati
on
to
RECIST
that takes
into
account
unique
patterns of
atypical
response in
immunoth
erapy and
enables
treatment
beyond
initial
radiograph
ic
progressio
n., Up to $\sim 2$
years|Tim
e
to
Response
(TTR)
according
to RECIST
1.1
assessed
by BICR,
TTR is
defined as
the time
from the
date of
enrollment
day to the
first date of
confirmed
CR
(disappear
ance of all
lesions) or
PR (鈮? $0 \%$
decrease in
the SOD of
target
lesions,
taking as
reference
the
baseline
sum
diameters).
Responses
are
according
to RECIST
1.1 as
assessed
by BICR.,
Up to $\sim 2$
years|TTR
according
to iRECIST
1.1
assessed
by BICR,
TTR is
defined as
the time
from the
date of
enrollment
day to the
first date of
confirmed
CR
(disappear
ance of all
lesions) or
PR (鈮?0\%
decrease in
the SOD of
target
lesions,
taking as
reference
the
baseline
sum
diameters).
Responses
are
according
to iRECIST
assessed
by BICR.
iRECIST is
a
modificati
on to
RECIST
that takes
into
account
unique
patterns of
atypical
response in
immunoth
erapy and
enables
treatment
beyond
initial
radiograph
ic
progressio
n., Up to $\sim 2$
years|Pro
gression-
free
Survival
(PFS)
according
to RECIST
1.1
assessed
by BICR,
PFS is
defined as
the time
from the
date of
enrollment
day to the
first
documente
d disease
progressio
n or death
due to any
cause,
whichever
occurs
first.
Responses
are
according
to RECIST
1.1 as
assessed
by BICR.,
Up to $\sim 2$
years|PFS
according
to iRECIST
1.1
assessed
by BICR,
PFS is
defined as
from the
date of
enrollment
day to the
first
documente
d disease
progressio
n or death
due to any
cause,
whichever
occurs
first.
Responses
are
to iRECIST
1.1 as
assessed
by BICR.
iRECIST is
a
modificati
on
to
RECIST
that takes
into
account
unique
patterns of
atypical
response in
immunoth
erapy and
enables
treatment
beyond
initial
radiograph
ic
progressio
n., Up to $\sim 2$
years|Ove
rall
survival
(OS), OS is
defined as
the time
from the
enrollment
day to
death due
to
any
cause.
Participant
s without
documente
d death at
the time of
the final
analysis
will be
censored at
the date of
the last
follow-up.,
Up to $\sim 2$
years |Adv
erse events
(AEs), The
number of
participant
s that
experience
an AE will
be
reported
for each
arm. An
AE is any
untoward
medicalparticipant
that ..... istemporallyassociatedwith theuse ofstudytreatment,whether or
not
considered
related to
the study
treatment.
An AE can
therefore
be any
unfavorabl
e and
unintende
d sign
(including
an
abnormal
laboratory
finding),
symptom,
or disease
(new or
exacerbate
d)
temporally
associated
with the
use of a
study
treatment,
From time
of
allocation
up to 30
days
following
cessation
of study
treatment
(up to $\sim 2$
years)|Tre
atment
discontinu
ations due
to AEs, The
number of
participant
s that
discontinu
e study
drug due
to an AE
will be
reported
for each
arm. An
AE is any
untoward
medicalparticipant
that ..... istemporallyassociatedwith theuse ofstudytreatment,whether or
not
considered
related to
the study
treatment.
An AE can
therefore
be any
unfavorabl
e and
unintende
d sign
(including
an
abnormal
laboratory
finding),
symptom,
or disease
(new or
exacerbate
d)
temporally
associated
with the
use of a
study
treatment.,
From time
of
allocation
up to 30
days
following
cessation
of study
treatment
(up to $\sim 2$
years)

immunoth
erapy
baseline at
any time
point after
immunoth
erapy will
be
considered
as
continuous
outcomes.,
Baseline to
up to 12
months |C
hanges in
phenotypi
ng induced
by
immunoth
erapy in
peripheral
blood
mononucle
ar cells
(PBMC),
PBMC
from the
patients
will be
obtained
before and
after
immunoth
erapy to
determine
if there are
any
phenotype
changes
induced by
immunoth
erapy.
Paired t-
test will be
used
to
compare
the
difference
between

```
baseline
and after
any time
point of
armed T
cells
treatment
in T cell
subpopula
tion
(FACS),
tumor
marker
(CBA/ELI
SA) and
tumor
killing
```

ability of
PBMC.,
Baseline to
up to 12
months $\mid \mathrm{Cl}$
inical
response
rate
(including
clinical
symptoms
and signs,
complete
response,
partial
response,
progressiv
e disease,
and stable
disease,
imaging
examinatio
n
of
pretherapy
and post-
treatment)
will be
measured
by follow-
up
investigati
on., Point
and exact
confidence
interval
estimates
will be
calculated
for
response
rate., Up to
12
months |O
verall
survival,
Will be
estimated
with the
standard
Kaplan-
Meier
method,
from
which
summary
statistics of
interest
(median, 6
month, 1-
year rate,
etc.) will be
derived.
Both point
and 95\%
confidence
interval
estimates
will be
calculated.,
Up to 12
months $\mid \operatorname{Pr}$
ogression
free
survival,
Will be
estimated
with the
standard
Kaplan-
Meier
method,
from
which
summary
statistics of
interest
(median, 6
month, 1-
year rate,
etc.) will be
derived.
Both point
and 95\%
confidence
interval
estimates
will be
calculated.,
From the
beginning
of
immunoth

|  |  |  |  |  |  |  |  | erapy to <br> progressio <br> n or death, <br> assessed <br> up to 12 <br> months |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| COMPLETE | Gastric | DRUG: | PHAS | INTER | Allocation: | 97 | Overall | Incidence | 2018/3/1 |
| D | Cancer ${ }^{\text {E }}$ Eso | Nivolumab\| | E2 | VENTI | RANDOMI |  | Survival, | of |  |
|  | phageal | DRUG: |  | ONAL | ZED\|Interv |  | Overall | Treatment- |  |
|  | Cancer 1 Ade | Nivolumab \| |  |  | ention |  | survival | Emergent |  |
|  | nocarcinom | DRUG: |  |  | Model: |  | including | Adverse |  |
|  | a | Ipilimumab |  |  | PARALLEL |  | milestone | Events |  |
|  | Gastric\|HE |  |  |  | \| Masking: |  | rate at 12 | [Safety and |  |
|  | R2 Positive |  |  |  | NONE \| Pri |  | months, | Tolerabilit |  |
|  | Gastric |  |  |  | mary |  | Milestone | y], |  |
|  | Cancer ${ }^{\text {Met }}$ |  |  |  | Purpose: |  | at 12 | according |  |
|  | astatic |  |  |  |  |  |  |  |  |


| Gastric | TREATME | max | Common |
| :---: | :---: | :---: | :---: |
| Cancer \\| Gas | NT | observatio | Terminolo |
| troEsophage |  | n period 48 | gy Criteria |
| al Cancer |  | months | for |
|  |  |  | Adverse |
|  |  |  | Events and |
|  |  |  | to the |
|  |  |  | obtained |
|  |  |  | data on |
|  |  |  | vital signs, |
|  |  |  | clinical |
|  |  |  | parameters |
|  |  |  | and |
|  |  |  | feasibility |
|  |  |  | of the |
|  |  |  | regimen, |

months $\mid \mathrm{Pr}$
ogression
Free
Survival,
Response
Evaluation
Criteria in
Solid
Tumors
(RECIST
1.1.), 48
months $\mid R$
esponse
Rate,
Response
Rate (RR)
according
to RECIST
v1.1, 15
months | H
ealth
related
Quality of
Life,
EORTC
QLQ-C30
(European
Organisati
on for
Research
and
Treatment
of Cancer -
Quality of

## Life Core

Questionn
aire
(30
items)
Version
3.0. The

QLQ-C30
is
composed
of multi-
item scales
and single-
item
measures,
including
five
functional
scales,
three
symptom
scales, a
global
health
status /
QoL scale,
and six
single
items.

All of the
scales and
single-item
measures
have a
score range
from 0 to
100. A high
score
shows a
high
response
level. A
high score
for a
functional
scale
represents
a high /
healthy
level of
functionin
the global
health
status /
QoL
represents
a high
QoL, but a
high score
for a
symptom
scale /
item
represents
a high level
of
tology /
problems,
months | H
ealth
related
Quality of
Life,
EORTC
STO-22
(European
Organisati
on for
Research
and
Treatment
of Cancer -
Quality of
Life
Questionn
aire Gastric
Module
(STO =
stomach)
(22 items),
comprisin
g five
multi-item
and four
single-item
subscales.
The multi-
item
subscales
include
questions
about
dysphagia
(4 items),
dietary
restriction
(5 items),
pain (3
items),
upper
gastro-
esophageal
symptoms
such as
reflux (3
items), and
emotional
problems
such as
anxiety (3
items). The
single-item
subscales
include
questions
related to
four gastric
cancer-
specific
symptoms:
dry mouth,
body
image, hair
loss, and
problems
with taste.
Items are
assessed
on a 4-level
numerical
scale with
$1=$ "not at
all", 2= "a
little", 3=
"quite a
bit", and 4=
"very
much".
Scores are
linearly
converted
and
summated
into a
scaled
score from
0 to 100,
with a
higher
score
representi
ng a worse
QOL., 48
months |Tr
anslational
research
tumor
block,
Tumor-
infiltrating
lymphocyt
es (TiL)
repertoire
determinat
ion from
tumor, 48
months $\mid \mathrm{Tr}$
anslational
research
blood
immunopr
ofiling,
Liquid
biopsy
next-
generation
sequencing
(NGS)
immunopr
ofiling
(TCR 尾
<br>\& Ig H )
before
treatment
initiation
and before
second
cycle to
determine
response
predictive
immune
signature,
Up to 7
weeks|Tra
nslational
research
blood
circulating
Tumor
cells
(СТС),
CTC will
be
evaluated
for
changes in

HER2 and
PD-L1
status, 48
months | Tr
anslational
research
blood
circulating
Tumor
DNA
(ctDNA),
ctDNA
will be
evaluated
for HER
signaling
alterations,
months $\mid \mathrm{C}$
entral
Imaging
Review $\qquad$
ORR,
Retrospecti
ve central
radiologica
1 review of
ORR
according
to
modified
RECIST, 48
months |C
entral

|  |  |  |  |  |  |  |  | Imaging |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  |  |  |  |  |  |  |  | Review |  |
|  |  |  |  |  |  |  |  | PFS, |  |
|  |  |  |  |  |  |  |  | Retrospecti |  |
|  |  |  |  |  |  |  |  | ve central |  |
|  |  |  |  |  |  |  |  | radiologica |  |
|  |  |  |  |  |  |  |  | 1 review of |  |
|  |  |  |  |  |  |  |  | PFS |  |
|  |  |  |  |  |  |  |  | according |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  | modified |  |
|  |  |  |  |  |  |  |  | RECIST, 48 |  |
|  |  |  |  |  |  |  |  | months |  |
| RECRUITIN | Gastric | DRUG: | PHAS | INTER | Allocation: | 714 | Progressio | Confirmed | 2021/12/2 |
| G | Neoplasms | Zanidatamab | E3 | VENTI | RANDOMI |  | n -free | objective |  |
|  | Gastroesoph | \| DRUG: |  | ONAL | ZED\|Interv |  | survival | response |  |
|  | ageal | Tislelizumab |  |  | ention |  | (PFS) by | rate (ORR) |  |


| Adenocarci | \| DRUG: | Model: | blinded | by BICR, |
| :---: | :---: | :---: | :---: | :---: |
| noma\|Esop | Trastuzumab | PARALLEL | independe | Number of |
| hageal | \| DRUG: | \| Masking: | nt central | patients |
| Adenocarci | Capecitabine | NONE \| Pri | review | who |
| noma | \| DRUG: | mary | (BICR), | achieved a |
|  | Oxaliplatin \| | Purpose: | The time | best |
|  | DRUG: | TREATME | from | overall |
|  | Cisplatin 1 DR | NT | randomiza | response of |
|  | UG: 5- |  | tion to the | complete |
|  | Fluorouracil \| |  | date of | response |
|  | DIAGNOSTI |  | documente | (CR) or |
|  | C_TEST: In |  | d disease | (PR) as |
|  | situ |  | progressio | determine |
|  | hybridization |  | n (per | d per |
|  | (ISH)-based |  | Response | RECIST 1.1 |
|  | companion |  | Evaluation | as assessed |
|  | diagnostic |  | Criteria in | by BICR, |


| assay \|DIAG | Solid | Up to 2.5 |
| :---: | :---: | :---: |
| NOSTIC_TES | Tumors | years \|Dur |
| T: | $\backslash$ [RECIST | ation of |
| Immunohisto | \] version | response |
| chemistry | 1.1) as | (DOR) by |
| (IHC)-based | assessed | BICR, The |
| companion | by BICR or | time from |
| diagnostic | death from | the first |
| assay | any cause, | objective |
|  | Up to 2.5 years\|Ove | response <br> (CR or PR) |
|  | rall | per BICR |
|  | survival, | to |
|  | The time | documente |
|  | from | d |
|  | randomiza | progressiv |
|  | tion to | e disease |

```
death due per
to any RECIST 1.1
cause, Up as assessed
to 3.5 years by BICR or
death from
```

any cause,
Up to 2.5
years|PFS
per
Investigato
r
assessment
, The time
from
randomiza
tion to the
date of
d disease
progressio
n (per
RECIST
1.1) as
assessed
by
Investigato
r or death
from any
cause, Up
to $\quad 2.5$
years |Con
firmed
ORR per
Investigato
assessment
, Number
of patients
who
achieved a
best
overall
response of
CR or PR
as
determine
d per
RECIST 1.1
as assessed
by
Investigato
r, Up to 2.5
years|DO
R per
Investigato
r
assessment
, The time
from the
first
objective
response
(CR or PR)
per
Investigato
r to
documente
d
e disease
per
RECIST 1.1
as assessed
by
Investigato
r or death
from any
cause, Up
to $\quad 2.5$
years | Inci
dence of
adverse
events,
Number of
subjects
experience
d adverse
events or
serious
adverse
events, Up
to
2
years | Inci
dence of
clinical
laboratory
abnormalit
ies,
Number of patients
who

```
d a
maximum
severity of
Grade 3 or
higher
post-
baseline
laboratory
abnormalit
y,
including
either
hematolog
y or
chemistry.
Grades are
```

defined
using
National
Cancer
Institute's
Common
Terminolo
gy Criteria
for
Adverse
Events
(CTCAE),
version 5.0,
Up to 2
years $\mid$ Нea
lth-related
quality of
as assessed
by the
European
Organisati
on for
Research
and
Treatment
of Cancer (EORTC)

Quality of
Life
Questionn
aire (core
cancer
ire) C30
(QLQ-
C30),
Changes
from
baseline in
the EORTC
QLQ-C30
scores, Up
to $\quad 2.5$
years |HR
QoL as
assessed
by the
EORTC
Quality of
Life
Questionn
aire
(oesophag
o-gastric
module)
OG25
(QLQ-
OG25),
Changes
from
baseline in
the EORTC
QLQ-
OG25
scores, Up
to 2.5
years |HR
QoL as
assessed
by the
EuroQol 5-
dimension
s 5-levels
(EQ-5D-
5L)
questionna
ire,
Changes
from
baseline in
the EORTC
EQ-5D-5L
questionna
ire scores,
Up to 2.5
years $\mid$ Seru
m
concentrati
on of
zanidatam
ab and
tislelizuma
b, Up to 2
years | Inci
dence of
anti-drug
antibodies
(ADAs),
Number of patients


| Stage | I | Oxaliplatin\|P |
| :--- | :--- | :--- |
| Gastric | ROCEDURE: |  |
| Cancer | Therapeutic |  |
| AJCC | Conventional |  |
| v8\|Clinical | Surgery |  |
| Stage $\quad$ I |  |  |
| Gastroesoph |  |  |
| ageal |  |  |
| Junction |  |  |
| Adenocarci |  |  |
| noma AJCC |  |  |
| v8\|Clinical |  |  |
| Stage $\quad$ IIB |  |  |
| Gastric |  |  |
| Cancer |  |  |
| AJCC |  |  |
| v8\|Clinical |  |  |


| Safety | Up to 5 |
| :--- | :--- |
| data will | years $\mid$ Inci |
| be | dence of |
| summarize | adverse |
| d using | events in |
| frequency | patients |
| tables by | with |
| organ | resected |
| system, | gastroesop |
| grade and | hageal |
| attribution | junction |
| for the | (GEJ) or |
| neoadjuva | gastric |
| nt period | cancer, The |
| and | Bayesian |
| adjuvant | method of |
| period | Thall, |


| Stage IIB | separately. | Simon and |
| :---: | :---: | :---: |
| Gastroesoph | , Up to 30 | Estey will |
| ageal | days | be |
| Junction |  | implement |
| Adenocarci |  | ed for |
| noma AJCC |  | toxicity |
| v8\|Clinical |  | monitoring |
| Stage III |  | Safety |
| Gastroesoph |  | data will |
| ageal |  | be |
| Junction |  | summarize |
| Adenocarci |  | d using |
| noma AJCC |  | frequency |
| v8\|Clinical |  | tables by |
| Stage IVA |  | organ |
| Gastric |  | system, |
| Cancer |  | grade and |

AJCC
v8|Clinical
Stage IVA
Gastroesoph
ageal
Junction
Adenocarci
noma AJCC
v8|Gastric
Adenocarci
noma | Local
ized Gastric
Carcinoma
Localized
Gastroesoph
ageal
Junction
attribution
for the
neoadjuva
nt period
and
adjuvant
period
separately.
, Up to 5
years|Dise
ase-free
survival,
Will be
estimated
using the
method of
Kaplan

| Adenocarci | and Meier., |
| :---: | :---: |
| noma \| Path | From the |
| ologic Stage | date of |
| 0 Gastric | surgery |
| Cancer | until |
| AJCC | disease |
| v8\|Patholo | relapse or |
| gic Stage 0 | death, |
| Gastroesoph | whichever |
| ageal | occurred |
| Junction | first, |
| Adenocarci | assessed |
| noma AJCC | up to 5 |
| v8\|Patholo | years |
| gic Stage I |  |
| Gastric |  |
| Cancer |  |

AJCC
v8|Patholo
gic Stage IA
Gastric
Cancer
AJCC
v8|Patholo
gic Stage IA
Gastroesoph
ageal
Junction
Adenocarci
noma AJCC
v8|Patholo
gic Stage IB
Gastric
Cancer

## AJCC

v8|Patholo
gic Stage IB
Gastroesoph
ageal
Junction
Adenocarci
noma AJCC
v8 | Patholo
gic Stage IC
Gastroesoph
ageal
Junction
Adenocarci
noma AJCC
v8 | Patholo
gic Stage II

## Gastroesoph

ageal
Junction
Adenocarci
noma AJCC
v8 | Patholo
gic Stage IIA

## Gastric

Cancer
AJCC
v8|Patholo
gic Stage IIA
Gastroesoph
ageal
Junction
Adenocarci
noma AJCC
v8 | Patholo
gic Stage IIB
Gastric
Cancer
AJCC
v8|Patholo
gic Stage IIB
Gastroesoph
ageal
Junction
Adenocarci
noma AJCC
v8|Patholo
gic Stage
IIIA Gastric

## Cancer

AJCC
v8|Patholo
gic Stage
IIIB
Gastroesoph
ageal
Junction
Adenocarci
noma AJCC
v8 | Patholo
gic Stage
IVA
Gastroesoph
ageal
Junction
Adenocarci
noma AJCC

| TERMINATE | Solid | DRUG: | PHAS | INTER | Allocation: 16 | Recommen Safety and 2018/9/11 |
| :--- | :--- | :--- | :--- | :--- | :--- | :--- |
| D | Tumor\|Hep | Vorolanib\|D | E1 | VENTI | NON_RAN | ded phase toxicity of |


| the dose | s and |
| :--- | :--- |
| level at grading |  |
| which | 2 |
| pcales |  |
| patients of | found in |
| a cohort (of | the revised |
| 2 to 6 | NCI |
| patients) | Common |
| experience | Terminolo |
| dose- | gy Criteria |
| limiting | for |
| toxicity | Adverse |
| during the | Events |
| first cycle. | (CTCAE) |
| Dose | version 5.0 |
| escalations | will be |
| will | utilized for |
| proceed | all toxicity |



| cohorts | number |
| :--- | :--- |
| (estimated | and type of |
| to be 13 | adverse |
| months) $\mid R$ | events |
| ecommend | experience |
| ed phase II | d by |
| dose | participant |
| (RP2D) of | -The |
| vorolanib | description |
| plus | s and |
| nivolumab | grading |
| -The | scales |
| maximum | found in |
| tolerated | the revised |
| dose | NCI |
| (MTD) is | Common |
| defined as | Terminolo |


| the dose | gy Criteria |
| :--- | :--- |
| level | for |
| immediate | Adverse |
| ly below | Events |
| the dose | (CTCAE) |
| level at version 5.0 |  |
| which 2 | will be |
| patients of | utilized for |
| a cohort (of | all toxicity |
| 2 to 6 | reporting., |
| patients) | $30 \quad$ days |
| experience | after |
| dose- | completion |
| limiting | of |
| toxicity | treatment |
| during the | (estimated |
| first cycle. |  |

Dose to be 7
escalations months)
will
proceed
for both
nivolumab
and
pembroliz
umab until
the MTD
or highest
dose level
(level 2),
which is
defined as
RP2D.,
Completio


| HR－1701 镇沜 | Purpose： |
| :--- | :--- |
| apecitabine 镇 | TREATME |
| 沷 xaliplatin | NT |


| events | hase Ib 镇？ |
| :---: | :---: |
| （AEs），and | An |
| serious | average of |
| adverse | approxima |
| events | tely 18 |
| （SAEs）， | months｜P |
| Safety will be assessed | FS 锛 圥 |
| for | hase Ib 镇？ |
| approxima | An |
| tely 24 | average of |
| months | approxima |
| from | tely 18 |
| informed | months ${ }^{\text {O }}$ |
| consent｜P | S 镇光 hase |
| hase II： | Ib 锛？An |
| Objective |  |


| Response | approxima |
| :---: | :---: |
| Rate | tely 30 |
| （ORR）［，An | months｜D |
| average of | oR 锛 圥 |
| approxima | hase II 镇？ |
| $\text { tely } \quad 12$ | hase II 㔍？ |
| months | An |
|  | average of |
|  | approxima |
|  | tely 18 |
|  | months｜P |
|  | FS 镇 光 |
|  | hase II 锛？ |
|  | An |
|  | average of |
|  | approxima |
|  | tely 18 |

months $\mid \mathrm{O}$
$S$ 锛光 hase

II 镇？An
average of
approxima
tely 30
months｜O
ccurrence
of adverse
events
（AEs），and
serious
adverse
events
（SAEs）镇

光 hase II

|  |  |  |  |  |  |  |  | 镇? Safety |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  |  |  |  |  |  |  |  | will be |  |
|  |  |  |  |  |  |  |  | assessed |  |
|  |  |  |  |  |  |  |  | for |  |
|  |  |  |  |  |  |  |  | approxima |  |
|  |  |  |  |  |  |  |  | tely 24 |  |
|  |  |  |  |  |  |  |  | months |  |
|  |  |  |  |  |  |  |  | from |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
| COMPLETE | Neoplasms | DRUG: PF- | PHAS | INTER | Allocation: | 174 | Number of | Objective | 2015/4/23 |
| D |  | 04518600 \\| DR | E1 | VENTI | NON_RAN |  | Participant | Response |  |
|  |  | UG: PF- |  | ONAL | DOMIZED \| |  | s With | Rate (ORR) |  |
|  |  | 04518600 \\| DR |  |  | Intervention |  | Dose | Assessed |  |
|  |  | UG: PF- |  |  | Model: |  | Limiting | by |  |
|  |  | 04518600 plus |  |  | SINGLE_G |  | Toxicities | Response |  |
|  |  | PF- |  |  | ROUP\|Mas |  | (DLTs) in | Evaluation |  |


| 05082566 \| DR | king: | Part A1, | Criteria in |
| :---: | :---: | :---: | :---: |
| UG: PF- | NONE \| Pri | DLT was | Solid |
| 04518600 plus | mary | defined as | Tumor |
| PF-05082566 | Purpose: | any of the | (RECIST) |
|  | TREATME | following | Version 1.1 |
|  | NT | adverse | and |
|  |  | events | Immune |
|  |  | occurring | Related |
|  |  | in the first | Response |
|  |  | two cycle | Evaluation |
|  |  | of | Criteria in |
|  |  | treatment | Solid |
|  |  | (28 days), | Tumors |
|  |  | unless | (irRECIST) |
|  |  | there was a | in Part A, |
|  |  | clear | ORR was |
|  |  | alternative | defined as |


| explanatio | the |
| :--- | :--- |
| n: | percentage |
| hematologi | of patients |
| c: grade 4 | with best |
| neutropeni | overall |
| a lasting | response |
| \>7 days, | (BOR) of |
| febrile | CR or PR |
| neutropeni | relative to |
| a; grade | the |
| 鈮 | appropriat |
| neutropeni | e analysis |
| c infection; | set. |
| grade 鈮? |  |
| CR: |  |
| thrombocy | Complete |
| topenia | response is |
| with |  |


| clinically | defined |
| :--- | :--- |
| significant | (per |
| bleeding or | RECIST |
| requiring | 1.1 as |
| medical | disappeara |
| interventio | nce of all |
| n; grade 4 | target and |
| thrombocy | non target |
| topenia; | lesions. |
| grade $\quad 4$ | Any |
| anemia; | pathologic |
| grade 鈮? | al lymph |
| anemia | nodes |
| related to | (whether |
| hemolysis | target or |
| or | non target) |
| autoimmu | must have |


| ne disease. non | reduction in short |
| :---: | :---: |
| hematologi | axis to |
| c: grade | \<10 mm. |
| 鈮 ? |  |
| toxicities | PR: Partial |
| that were | response is |
| considered | difined |
| clinically | (per |
| significant | RECIST |
| including | 1.1) as at |
| cytokine | least a 30\% |
| release | decrease in |
| syndrome, | the sum of |
| infusion | diameters |
| reactions | of target |
|  | lesions, |


| allergic | taking as |
| :--- | :--- |
| reactions, | reference |
| except | the |
| those that | baseline |
| had not | sum |
| been | diameters. |
| maximally |  |
| treated or | Overall |
| could be | immune |
| easily | related |
| treated. | complete |
| The | response |
| severity of | (irCR): |
| adverse | Complete |
| events was | disappeara |
| graded | as |


| common | (whether |  |
| :--- | :--- | ---: |
| terminolog | measurabl |  |
| y criteria | e or | not) |
| for adverse | and | no |
| events(CT | new |  |
| CAE) | lesions. All |  |
| version | measurabl |  |
| 4.03, and | e lymph |  |
| there were | nodes also |  |
| no DLTs | must have |  |
| reported., | a reduction |  |
| The first 2 | in short |  |
| cycles of | axis | to |
| treatment | l<10 mm. |  |
| (Day 1 up |  |  |
| to | Day | Overall |
| 28) \|Numb | immune |  |


| er of | related |
| :--- | :--- |
| Participant | partial |
| s With All- | response |
| Causality | (irPR): |
| Treatment | Sum of the |
| Emergent | diameters |
| Adverse | (longest for |
| Events(TE | non nodal |
| AEs) and | lesions, |
| Serious | shortest for |
| Adverse | nodal |
| Event(SAE | lesions) of |
| s), | target and |
| Treatment- | new |
| Related | measurabl |
| TEAEs and | e lesions |
| SAEs in | decreases |


| Part A, 鈮 ?0\%., |  |
| :--- | :--- |
| Adverse | Baseline |
| event (AE) | up to 24 |
| was | months |
| graded by | post first |
| the | dose.\|Kap |
| investigato | lan-Meier |
| r according | Estimate of |
| to CTCAE | Median |
| version | Progressio |
| $4.03 \quad$ and | n-Free |
| coded | Survival |
| using the | (PFS) in |
| Medical | Part A, PFS |
| Dictionary | was |
| for | defined as |
| Regulatory | the time |


| Activities | from |
| :--- | :--- |
| (MedDRA) | randomiza |
| : Grade 3 | tion date to |
| (Severe) | date of first |
| events=un | documenta |
| acceptable | tion of |
| or | progressiv |
| intolerable | e |
| events. | disease(PD |
| Grade $\quad 4$ | ) based on |
| (Life- | RECIST, |
| threatenin | irRECIST |
| g) events | or death |
| caused | due to any |
| participant | cause. |
| to be in |  |
| imminent | PD was |



| were | Median |
| :--- | :--- |
| absent | Time to |
| before | Progressio |
| treatment | n (TTP) in |
| or that | Part A, |
| worsened | TTP was |
| relative to | defined as |
| pretreatme | the time |
| nt state. from start |  |
| TEAEs | date to the |
| were | date of the |
| defined as | first |
| those with | documenta |
| initial | tion of PD. |
| onset or | PD was |
| increasing | documente |
| in severity | dafter start |



| other | Part A, SD |
| :--- | :--- |
| reason: | was |
| death; | defined as |
| initial or | persistence |
| prolonged | of any non |
| inpatient | target |
| hospitaliza | lesions |
| tion; life- | and/or |
| threatenin | tumor |
| g | marker |
| experience | level above |
| (immediat | the normal |
| e risk of | limits., |
| dying); | Baseline |
| persistent | up to 24 |
| or | months |
| significant | post first |


| disability/ | dose. $\mid$ Kap |
| :--- | :--- |
| incapacity; | lan-Meier |
| congenital | Estimate of |
| anomaly., | Median |
| AEs: The | Duration |
| informed | of |
| consent | Response |
| date up to | (DoR) in |
| the last | Part A, |
| dosing | DoR was |
| date +28 | defined as |
| days or all | the time |
| drug- | from first |
| related | documenta |
| toxicities | tion of |


| The | documenta |
| :--- | :--- |
| informed | tion of PD |
| consent | or death |
| date | due to any |
| through | cause for |
| first dosing | patients |
| date +98 | with an |
| days or up | objective |
| to the last response. |  |
| dosing |  |
| date +60 | CR was |
| days, and | defined as |
| any post- | complete |
| reporting | disappeara |
| period. $\mid \mathrm{N}$ | nce of all |
| umber of | target |
| Participant | lesions |


| s With with the |  |
| :--- | :--- |
| Laboratory | exception |
| Test | of nodal |
| Abnormali | disease |
| ties in Part | and all |
| A, | target |
| Following | nodes |
| parameters | must |
| were | decrease to |
| analyzed | normal |
| for | size (short |
| laboratory | axis $\backslash<10$ |
| examinatio | mm) and |
| n: | all target |
| hematolog | lesions |
| y | must be |
| (hemoglob | assessed. |


| in, |  |
| :--- | :--- |
| hematocrit | PR was |
| , platelet | defined as |
| count, | greater |
| white | than or |
| blood cell | equal to |
| count, total | $30 \%$ |
| neutrophil | decrease |
| s, | under |
| eosinophil | baseline of |
| s, | the sum of |
| monocytes | diameters |
| , basophils, | of all target |
| lymphocyt | measurabl |
| es, partial | e lesions. |
| thrombopl | The short |
| astin time | diameter is |


| (PTT), | used in the |
| :--- | :--- |
| Prothromb | sum for |
| in (PT), PT | target |
| internation | nodes, |
| al ratio); while the |  |
| liver | longest |
| function | diameter is |
| (aspartate | used in the |
| aminotran | sum for all |
| sferase(AS | other |
| T), alanine | target |
| aminotran | lesions and |
| sferase(AL | all target |
| T), total | lesions |
| bilirubin, | must be |
| gamma- | assessed., |
| glutamyl | Baseline |


| transpepti | up to 24 |
| :--- | :--- |
| dase(GT), | months |
| alkaline | post first |
| phosphata | dose.\|Kap |
| se, | lan-Meier |
| albumin, | Estimate of |
| total | Median |
| protein); | Overall |
| renal | Survival |
| function | (OS) in |
| (blood | Part A, OS |
| urea | was |
| nitrogen, | defined as |
| creatinine, | time in |
| uric acid); | months |
| electrolyte | from the |
| s (sodium, | start of |


| potassium, <br> chloride, | study <br> treatment |
| :---: | :---: |
| calcium | to date of |
| phosphate, | death due |
| magnesiu | to any |
| m); clinical | cause. OS |
| chemistry | was |
| (glucose, | calculated |
| creatine | as the |
| kinase, | death date |
| thyroxine | or last |
| (T4), | known |
| thyroid | alive date |
| stimulatin | (if death |
| g | date |
| hormone(T | unavailabl |
| SH)), | e) minus |


| Amylase, | the date of |
| :---: | :---: |
| Lipase), | first dose |
| urinalysis | of study |
| (dipstick | medication |
| $\backslash$ [protein, | plus |
| blood $\backslash$ ], | divided by |
| microscop | 30.44., |
| y \[urine | Baseline |
| red blood | up to 24 |
| cell (RBC), | onth |
| white | post first |
| blood cell | dose. \|Ove |
| (WBC), | rall |
| Epithelial | Survival |
| Cells $\backslash$ ], | Rates |
| miscellane | Months 6, |
| ous | 12, and 24 |


| $\backslash$ [urine casts and | in Part A, Probability |
| :---: | :---: |
| bacteria $\backslash]$ ) | of survival |
| ., The first dosing | $\begin{array}{lr} \text { at } 6, & 12, \\ \text { and } & 24 \end{array}$ |
| date to the | months |
| earlier date | after the |
| between | first dose |
| the last | of study |
| dosing | treatment., |
| date + 35 | Baseline |
| days and | up to 24 |
| the first | months |
| new anti- | post first |
| cancer | dose. \|Max |
| therapy | imum |
| date (if | Serum |


| applicable) | Concentrat |  |
| :--- | :--- | ---: |
| \| Number | ion (Cmax) |  |
| of | of | PF- |
| Participant | 04518600 |  |
| s | With | Following |
| DLTs in | Single |  |
| Part $\quad$ B1, | Dose on |  |
| DLT was | Cycle | 1 |
| defined as | Day | 1 |
| any of the | (C1D1) |  |
| following | and |  |
| adverse | Steady- |  |
| events | State |  |
| occurring | Maximum |  |
| in the first | Serum |  |
| two cycle | Concentrat |  |
| of | ion(Css,Ma |  |


| atment | x) |
| :---: | :---: |
| (28 days), | Following |
| unless | Multiple |
| there was a | Doses on |
| clear | Cycle 3 |
| alternative | Day |
| explanatio | (C3D1) in |
| n : | Part A, |
| hematologi | Cmax was |
| c: grade 4 | defined as |
| neutropeni | maximum |
| a lasting | observed |
| $\backslash>7$ days, | serum |
| febrile | concentrati |
| neutropeni | on and can |
| a; grade | be |
| 鈮 ? | observed |


| neutropeni c infection; | directly <br> from data. |
| :---: | :---: |
| grade 鈮? |  |
| thrombocy | Css,max |
| topenia | was the |
| with | Cmax on |
| clinically | C3D1., For |
| significant | Part A1, |
| bleeding or | pre-dose, |
| requiring | 1, 4, and 24 |
| medical | hours post |
| interventio | dose on |
| n ; grade 4 | C1D1, pre- |
| thrombocy | dose, 1, |
| topenia; | and 4 |
| grade 4 | hours post |
| nemia; | dose on |


| anemia | Cycles 3; |
| :---: | :---: |
| related to | For Par A2, |
| hemolysis | pre-dose, |
| or | 1 , and 4 |
| autoimmu | hours post |
| ne disease. | dose on |
| non | C1D1, pre- |
| hematologi | dose and 1 |
| c: grade | hour post |
| 鈮 | dose |
|  | Day 1 of |
| toxicities | Cycles |
| that were | 3. \| Area |
| considered | Under the |
| clinically | Concentrat |
| significant, | ion-Time |
| including |  |


| cytokine | Profile |  |
| :--- | :--- | :--- |
| release | From Time |  |
| syndrome, | 0 | to Time |
| infusion | Tau |  |
| reactions | (AUCtau) |  |
| and | of PF- |  |
| allergic | 04518600 |  |
| reactions, | Following |  |
| except | Single |  |
| those that | Dose on |  |
| had not | C1D1 and |  |
| been | Following |  |
| maximally | Multiple |  |
| treated or | Doses on |  |
| could be | C3D1 in |  |
| easily | Part A, |  |
| treated. | AUCtau |  |


| The | was |
| :--- | :--- |
| severity of | defined as |
| adverse | area under |
| events was | the |
| graded as | concentrati |
| per | on curve |
| common | from time |
| terminolog | 0 to end of |
| y criteria | dosing |
| for adverse | interval |
| events(CT | where |
| CAE) | dosing |
| version | interval |
| $4.03, ~ a n d ~$ | was $\quad 2$ |
| there were | weeks., For |
| no DLTs | Part A1, |
| reported., | pre-dose, |

The First 2 1, 4, and 24
Cycles of hours post
Treatment dose on
(Day 1 up C1D1, pre-
to Day dose, 1,
28) |Numb and 4
er of hours post
Participant dose on
s With All- Day 1 of
causality Cycles 3;
TEAEs and For Par A2,
SAEs, and pre-dose,
Treatment- 1 , and 4
Related hours post
TEAEs and dose on
SAEs in C1D1, pre-
Part B, dose and 1

| Adverse | hour post |
| :--- | :--- | ---: |
| event (AE) | dose on |
| was | Day 1 of |
| graded by | Cycles |
| the | $3 . \mid$ Area |
| investigato | Under the |
| raccording | Concentrat |
| to CTCAE | ion-Time |
| version | Profile |
| $4.03 \quad$ and | From Time |
| coded | 0 |
| using the | Extrapolat |
| Medical | ed |
| Dictionary | Infinite |
| for | Time |
| Regulatory | (AUCinf) |
| Activities | of PF- |


| (MedDRA) | 04518600 |
| :--- | :--- |
| : Grade 3 | Following |
| (Severe) | Single |
| events=un | Dose on |
| acceptable | C1D1 and |
| or | Following |
| intolerable | Multiple |
| events. | Doses on |
| Grade $\quad 4$ | C3D1 in |
| (Life- | Part A, |
| threatenin | AUCinf |
| g) events | was |
| caused | defined as |
| participant | area under |
| to be in | the plasma |
| imminent | concentrati |
| danger of | on versus |


| death. | time curve |  |
| :--- | :--- | ---: | ---: |
| Grade | (AUC) |  |


| absent | hours post |  |
| :--- | :--- | ---: |
| before | dose on |  |
| treatment | C1D1, pre- |  |
| or that | dose, | 1, |
| worsened | and | 4 |
| relative to | hours post |  |
| pretreatme | dose on |  |
| nt state. | Day | 1 |
| nt of |  |  |
| TEAEs | Cycles | $3 ;$ |
| were | For Par A2, |  |
| defined as | pre-dose, |  |
| those with | 1, and | 4 |
| initial | hours post |  |
| onset or | dose on | on |
| increasing | C1D1, pre- |  |


| first dose | dose on |  |
| :--- | :--- | :--- | :--- |
| of study | Day 1 | of |
| medication | Cycles |  |
| Serious | 3.\|Termin |  |
| adverse | al Half-Life |  |
| event | (t1/2) of |  |
| (SAE) was | PF- |  |
| an AE | 04518600 |  |
| resulting | Following |  |
| in any of | Single |  |
| the | Dose on |  |
| following | C1D1 and |  |
| outcomes | Following |  |
| or deemed | Multiple |  |
| significant | Doses on |  |
| for any | C3D1 in |  |
| other | Part | A, |


| reason: | t1/2 was |
| :--- | :--- |
| death; | defined as |
| initial or | the time |
| prolonged | measured |
| inpatient | for the |
| hospitaliza | serum |
| tion; life- concentrati |  |
| threatenin | on to |
| g | decrease |
| experience | by one half |
| (immediat | of the |
| e risk of | initial |
| dying); | concentrati |
| persistent | on., For |
| or | Part A1, |
| significant | pre-dose, |
| disability/ | 1,4, and 24 |


| incapacity; | hours post |  |
| :--- | :--- | ---: |
| congenital | dose on |  |
| anomaly., | C1D1, pre- |  |
| AEs: The | dose, | 1, |
| informed | and | 4 |
| consent | hours post |  |
| date up to | dose on |  |
| the last | Day | 1 |
| of | of |  |
| dosing | Cycles | $3 ;$ |
| date +60 | For Par A2, |  |
| days or all | pre-dose, |  |
| drug- | 1, and | 4 |
| related | hours post |  |


| informed | dose on |
| :--- | :--- |
| consent | Day 1 of |
| date | Cycles |
| through | $3 . \mid$ Lowest |
| first dosing | Serum |
| date +98 | Concentrat |
| days or up | ion |
| to the last | Observed |
| dosing | During the |
| date + 60 | Dosing |
| days, and | Interval |
| any post- | (Cmin) of |
| reporting | PF- |
| period. $\mid \mathrm{N}$ | 04518600 |
| umber of | Following |
| Participant | Multiple |
| s With | Doses on |


| Laboratory | C3D1 in |
| :--- | :--- |
| Test | Part A., |
| Abnormali | Cmin was |
| ties in Part | defined as |
| B, | Lowest |
| Following | concentrati |
| parameters | on |
| were | observed |
| analyzed | during the |
| for | dosing |
| laboratory | interval |
| examinatio | and can be |
| n: | observed |
| hematolog | directly |
| y | from data., |
| (hemoglob | For Part |
| in, | A1, pre- |


| hematocrit | dose, 1, | 4, |
| :--- | :--- | ---: |
| , platelet | and | 24 |
| count, | hours post |  |
| white | dose | on |
| blood cell | C1D1, pre- |  |
| count, total | dose, | 1, |
| neutrophil | and | 4 |
| s, | hours post |  |
| eosinophil | dose | on |
| s, | Day | 1 |
| of |  |  |
| monocytes | Cycles | $3 ;$ |
| , basophils, | For Par A2, |  |
| lymphocyt | pre-dose, |  |
| es, partial | 1, and | 4 |
| thrombopl | hours post |  |


| Prothromb | dose and 1 |  |
| :--- | :--- | ---: |
| in (PT), PT | hour post |  |
| internation | dose | on |
| al ratio); | Day | 1 |
| of |  |  |
| liver | Cycles |  |
| function | $3 . \mid$ Averag |  |
| (aspartate | e $\quad$ Serum |  |
| aminotran | Concentrat |  |
| sferase(AS | ion Over |  |
| T), alanine | the Dosing |  |
| aminotran | Interval |  |
| sferase(AL | (Cav) of |  |
| T), total | PF- |  |
| bilirubin, | 04518600 |  |
| gamma- | Following |  |
| glutamyl | Multiple |  |
| transpepti | Doses on |  |


| dase(GT), | C3D1 in |
| :--- | :--- |
| alkaline | Part A, Cav |
| phosphata | was |
| se, | defined as |
| albumin, | average |
| total | serum |
| protein); | concentrati |
| renal | on over the |
| function | dosing |
| (blood | interval., |
| urea | For Part |
| nitrogen, | A1, pre- |
| creatinine, | dose, 1, 4, |
| uric acid); | and 24 |
| electrolyte | hours post |
| s (sodium, | dose on |
| potassium, | C1D1, pre- |


| chloride, calcium | $\begin{array}{ll} \text { dose, } & 1, \\ \text { and } & 4 \end{array}$ |
| :---: | :---: |
| phosphate, | hours post |
| magnesiu | dose on |
| m); clinical | Day 1 of |
| chemistry | Cycles 3; |
| (glucose, | For Par A2, |
| creatine | pre-dose, |
| kinase, | 1, and |
| thyroxine | hours post |
| (T4), | dose |
| thyroid | C1D1, pre- |
| stimulatin | dose and 1 |
| g | hour post |
| hormone(T | dose on |
| SH)), | Day 1 of |
| Amylase, | Cycles |


| Lipase), | 3.\|Clearan |
| :--- | :--- |
| urinalysis | ce (CL) of |
| (dipstick | PF- |
| \[protein, | 04518600 |
| blood $\backslash]$, | Following |
| microscop | Multiple |
| y $\backslash$ [urine | Doses on |
| red blood | C3D1 in |
| cell (RBC), Part A, |  |
| white | Drug |
| blood cell clearance |  |
| (WBC), | was a |
| Epithelial | quantitativ |
| Cells $\backslash]$, | e measure |
| miscellane | of the rate |
| ous | at which a |
| $\backslash[$ urine | drug |


| casts and bacteria $\backslash]$ ) | substance is removed |
| :---: | :---: |
| ., The first | from the |
| dosing | blood (rate |
| date to the | at which a |
| earlier date | drug is |
| between | metabolize |
| the last |  |
| dosing | eliminated |
| date + 35 | by normal |
| days and | biological |
| the first | processes). |
| new anti- | CL=Dose/ |
| cancer | AUCss,tau |
| therapy | For Part |
| date (if | A1, pre- |
| applicable) | dose, 1, |

hours post
dose on
C1D1, pre-
dose, 1,
and 4
hours post
dose on
Day 1 of
Cycles 3;
For Par A2,
pre-dose,
1 , and 4
hours post
dose on
C1D1, pre-
dose and 1
hour post
dose on
Day 1 of
Cycles
3. $\mid$ Appare
nt Volume
of
Distributio
n at Steady
State (Vss)
of PF-
04518600
Following
Multiple
Doses on
C3D1 in
Part A.,

Vss was
defined as
volume of
distributio
n at steady
state., For
Part A1,
pre-dose,
1,4 , and 24
hours post
dose on
C1D1, pre-
dose, 1,
and 4
hours post
dose on
Day 1 of

Cycles 3;
For Par A2,
pre-dose,
1 , and 4
hours post
dose on
C1D1, pre-
dose and 1
hour post
dose on
Day 1 of
Cycles
3. |Accum
ulation
Ratio (Rac)
of PF-
04518600

Following
Multiple
Doses on
C3D1 in
Part A,
Accumulat
ion ratio
was
calculated
as, Rac
obtained
from Area
Under the
Concentrat
ion Time
Curve
from Cycle
3 Day 1
divided by
AUC from
Cycle1 Day
1., For Part

A1, pre-
dose, 1, 4,
and 24
hours post
dose on
C1D1, pre-
dose, 1,
and 4
hours post
dose on
Day 1 of
Cycles 3;
For Par A2,
pre-dose,
1 , and 4
hours post
dose on
C1D1, pre-
dose and 1
hour post
dose on
Day 1 of
Cycles
3. Numbe
r ..... of
Participant
s With Anti
Drug
Antibody
(ADA) and
Neutralizi
ng
Antibody
(NAb)
Against
PF-
04518600
in Part A,
ADA
never-
positive
was
defined as
no positive

ADA
results at
any time
point.
ADA ever-
positive
was
defined as
at least one
positive

## ADA

result at
any time
point. nAb
never-
positive
was
defined as
no positive
nAb
results at
any time
point and
nAb ever-
positive
was
defined as
at least one
positive
nAb result
at any time
point.,
Baseline
up to end
treatment
(maximum
of $\quad 14$
weeks). |M
ean
Unbound
Cell
Surface
OX40 in
Part A1,
Mean
unbound
cell surface
OX40 in
peripheral
blood was
engageme
nt (TE) by
PF-
04518600
at baseline
and
multiple
doses., Pre-
dose, 4 and
24 hours
post dose
on Cycle 1
Day 1, and
Day 8 on
Cycles 1 to
3 , then pre-
dose on
Cycles 4
and 7 and
end of
treatment
in Part
A1|ORR
Assessed
by RECIST
Version 1.1
and
irRECIST
in Part B, ORR was
defined as the
percentage
of patients
with best
overall
response
(BOR) of
CR or PR
relative to
the
appropriat
e analysis
set.

Complete
response is
defined
(per
RECIST
1.1) as
disappeara
nce of all
target and
non target
lesions.
Any
pathologic
al lymph
nodes
(whether
non target)
must have
reduction
in short
axis to
$\backslash<10 \mathrm{~mm}$.

PR: Partial
response is
difined
(per
RECIST
1.1) as at
least a $30 \%$
decrease in
the sum of
lesions,
taking as
reference
the
baseline
sum
diameters.

Overall
immune
related
complete
response
(irCR):
Complete
disappeara
nce of all
lesions
(whether
measurabl
e or not)
and no
new
lesions. All
measurabl
e lymph
nodes also
must have
a reduction
in short
axis to
$\backslash<10 \mathrm{~mm}$.

Overall
immune
related
partial
response
(irPR):
Sum of the
diameters
(longest for
non nodal
lesions,
shortest for
nodal
lesions) of
target and
new
e lesions
decreases
鈮 ? $0 \%$.,
Baseline
up to 24
months
post first
dose. |Kap
lan-Meier
Estimate of
Median
PFS in Part
B, PFS was
defined as
the time
from
randomiza
tion date to
date of first
documenta
tion of
progressiv
e
disease(PD
) based on
RECIST,
irRECIST
or death
due to any
cause.

PD was
progressio
documente
d after start
date and
not
qualifying
as $C R, P R$
or SD per
RECIST.,
Baseline
up to 24
months
post first
dose.|Kap
lan-Meier
Estimate of
Median

TTP in Part
B, TTP was
defined as
the time
from start
date to the
date of the
first
documenta
tion of PD.
PD was
documente
d after start
date and
not
qualifying
as $C R, P R$
or SD per
RECIST.,
Baseline
up to 24
months
post first
dose. $\mid \mathrm{Nu}$
mber of
Participant
s Having
SD in Part
B, SD was
defined as
persistence
of any non
target
lesions
and/or
tumor
marker
level above
the normal
limits.,
Baseline
up to 24
months
post first
dose.|Kap
lan-Meier
Estimate of
Median
DoR in
Part B,
DoR was
defined as
the time
from first
documenta
tion of PR
or CR to
date of first
documenta
tion of PD
or death
due to any
cause for
patients
with an
objective
response.
defined as
complete
disappeara
nce of all
target
lesions
with the
exception
of nodal
disease
and all
target
nodes
must
decrease to
normal
size (short
axis $\quad \backslash<10$
mm ) and
all target
lesions
must be
assessed.

PR was
defined as
greater
than or
equal
to
30\%
decrease
under
baseline of
the sum of
diameters
of all target
measurabl
e lesions.
The short
diameter is
used in the
sum for
target
nodes,
while the
longest
diameter is
used in the
sum for all
other
target
lesions and
all target
lesions
must be
assessed.
Baseline
up to 24
months
post first
dose.|Kap
lan-Meier
Estimate of
Median OS
in Part B,
OS was
defined as
months
from the
start of
study
treatment
to date of
death due
to any
cause. OS
was
calculated
as the
death date
or last
known
e) minus
the date of
first dose
of study
medication
plus 1
divided by
7 or 30.44 if
in months.,
Baseline
up to 24
months
post first
dose.|Ove
rall
Survival
Rates at
Months 6,
12 , and 24
in Part B,
Probability
of survival
at 6,12 ,
and 24
months
after the
first dose
of study
treatment.
Baseline

```
up to 24
months
post first
dose.|Cma
x of PF-
04518600
Following
Single
Dose on
C1D1 and
Css,Max
Following
Multiple
Doses on
C3D1 in
Part B,
Cmax was
```

defined as
maximum
observed serum
concentrati
on and can
be
observed
directly
from data.

## Css,max

was the
Cmax on
C3D1., For
Part B1,
pre-dose,
hour post
dose on
Day 1 of
Cycles 3;
For Part
B2, pre-
dose, 1,
and 4
hours post
dose on
C1D1, pre-
dose and 1
hour post
dose on
Day 1 of
Cycles
3. $\mid$ AUCta
u of PF-
04518600
Following
Single
Dose on
C1D1 and
Following
Multiple
Doses on
C3D1 in
Part B,
AUCtau
defined as
area under
the
concentrati
on curve
from time
0 to end of
dosing
interval
where
dosing
interval
was
weeks., For
Part B1,
pre-dose,
hour post
dose on
Day 1 of
Cycles 3;
For Part
B2, pre-
dose, 1,
and 4
hours post
dose on
C1D1, pre-
dose and 1
hour post
dose on
Day 1 of
Cycles
3. $\mid$ AUCinf
of PF-
04518600
Following
Single
Dose on
C1D1 and
Following
Multiple
Doses on
C3D1 in
Part B,
AUCinf
defined as
area under
the plasma
concentrati
on versus
time curve
(AUC)
from time
zero (pre-
dose) to
extrapolate
d infinite
time (0-
inf). It was
obtained
from AUC

| (0-t) | plus |
| :--- | ---: |
| AUC | (t- |
| inf)., | For |
| Part | B1, |
| pre-dose, |  |
| 1,4, | and 24 |
| hours | post |
| dose | on |
| C1D1, pre- |  |
| dose, | 1 |
| hour | post |
| dose | on |
| Day | 1 |
| lr |  |
| Cycles | $3 ;$ |
| For | Part |
| B2, | pre- |
| dose, | 1, |

hours post
dose on
C1D1, pre-
dose and 1
hour post
dose on
Day 1 of
Cycles
3. $\mid \mathrm{t} 1 / 2$ of

PF-
04518600
Following
Single
Dose on
C1D1 and
Following

## Multiple

Doses on
C3D1 in
Part B, t1/2
was
defined as
the time
measured
for the
serum
concentrati
on to
decrease
by one half
of the
initial
concentrati
on., For
Part B1,
pre-dose,
1,4 , and 24
hours post
dose on
C1D1, pre-
dose, 1
hour post
dose on
Day 1 of
Cycles 3;
For Part
B2, pre-
dose, 1 ,
and 4
hours post

Following
Multiple
Doses on
C3D1 in
Part B,
Cmin was
defined as

B1, pre-
dose, 1, 4,
and 24
hours post
dose on

C1D1, pre-
dose, 1
hour post
dose on
Day 1 of
Cycles 3;
For Part
B2, pre-
dose, 1,
and 4
hours post
dose on
C1D1, pre-
dose and 1
hour post
dose on
Day 1 of
Cycles
3. $\mid$ Cav of
PF-
04518600
Following
Multiple
Doses on
C3D1 in
Part B, Cav
was
defined as
average
serum
concentrati
on over the
dosing
interval.,

For Part
B1, pre-
dose, 1, 4,
and 24
hours post
dose on
C1D1, pre-
dose, 1
hour post
dose on
Day 1 of
Cycles 3;
For Part
B2, pre-
dose, 1 ,
and 4
hours post

C1D1, pre-
dose and 1
hour post
dose on
Day 1 of
Cycles
3. $\mid \mathrm{CL}$ of

PF-
04518600
Following
Multiple
Doses on
C3D1 in
Part B,
Drug
clearance
e measure
of the rate
at which a
drug
substance
is removed
from the
blood (rate
at which a
drug is
metabolize
d or
eliminated
by normal
biological

B1, pre-
dose, 1, 4,
and
24
hours post
dose on
C1D1, pre-
dose, 1
hour post
dose on
Day 1 of
Cycles 3;
For Part
B2, pre-
dose, 1,
and 4
hours post
dose on
C1D1, pre-
dose and 1
hour post
dose on
Day 1 of
Cycles
3. |Vss of

PF-
04518600
Following
Multiple
Doses on
C3D1 in

Part B, Vss
was
defined as
volume of
distributio
n at steady
state., For
Part B1,
pre-dose,
1,4 , and 24
hours post
dose on
C1D1, pre-
dose, 1
hour post
dose on
Day 1 of
Cycles ..... 3;
For Part
B2, pre-
dose, 1,
and ..... 4
hours post
dose ..... on
C1D1, pre-dose and 1
hour post
dose onDay 1 ofCycles3. Rac ofPF-04518600
Following
MultipleDoses on
C3D1 in
Part B,
Accumulat
ion ratio
wascalculatedas, Racobtainedfrom AreaUnder theConcentrat
ion Time
Curve
(AUC)from Cycle
3 Day 1
divided by
AUC from
Cycle1 Day
1., For Part
B1, pre-
dose, 1, 4,
and 24
hours post
dose on
C1D1, pre-
dose, 1
hour post
dose on
Day 1 of
Cycles 3;
For Part

B2, pre-
dose, 1,
and 4
hours post
dose on
C1D1, pre-
dose and 1
hour post
dose on
Day 1 of
Cycles
3. | Cmax
of
Utomilum
ab
Following
Single
Dose ..... onC1D1 and
Css,Max
Following
MultipleDoses on
C3D1 in
Part B,Cmax wasdefined as
maximum
observedserumconcentrati
on and canbeobserved
from data.

Css,max
was the
Cmax on
C3D1., For
Part B1,
pre-dose,
1,4 , and 24
hours post
dose on
C1D1, pre-
dose, 1
hour post
dose on
Day 1 of
Cycles ..... 3;
For Part
B2, pre-
dose, ..... 1,
and ..... 4
hours post
dose on
C1D1, pre-
dose and 1
hour post
dose on
Day 1 of
Cycles
3. |AUCta
u

            of
    Utomilum
ab

Following
Single
Dose on
C1D1 and
Following
Multiple
Doses on
C3D1 in
Part B,
AUCtau
was
defined as
area under
the
concentrati
on curve
from time
interval
where
dosing
interval
was
2
weeks., For
Part B1,
pre-dose,
1,4 , and 24
hours post
dose on
C1D1, pre-
dose, 1
hour post
dose on
Day 1 of
Cycles 3;
For Part
B2, pre-
dose, 1,
and 4
hours post
dose on
C1D1, pre-
dose and 1
hour post
dose on
Day 1 of
Cycles
3. |AUCinf
of
Utomilum

Following
Single
Dose on
C1D1 and
Following
Multiple
Doses on
C3D1 in
Part B,
AUCinf
was
defined as
area under
the plasma
concentrati
on versus
time curve
(AUC)
from time
zero (pre-
dose) to
extrapolate
d infinite
time (0-
inf). It was
obtained
from AUC
(0-t) plus
AUC (t-
inf)., For
Part B1,
pre-dose,
1,4 , and 24
hours post
dose on
C1D1, pre-
dose, 1
hour post
dose on
Day 1 of
Cycles 3;
For Part
B2, pre-
dose, 1,
and 4
hours post
dose on
C1D1, pre-
dose and 1
hour post

Day 1 of
Cycles
3. $\mid t 1 / 2$ of

Utomilum
ab
Following
Single
Dose on
C1D1 and
Following
Multiple
Doses on
C3D1 in
Part B, t1/2
was
defined as
for the
serum
concentrati
on to
decrease
by one half
of the
initial
concentrati
on., For
Part B1,
pre-dose,
1,4 , and 24
hours post
dose on

C1D1, pre-
dose, 1
hour post
dose on
Day 1 of
Cycles 3;
For Part
B2, pre-
dose, 1,
and 4
hours post
dose on
C1D1, pre-
dose and 1
hour post
dose on
Day 1 of
Cycles
3. $\mid$ Cmin of
Utomilum
ab
Following
Multiple
Doses on
C3D1 in
Part B,
Cmin was
defined as
Lowest
concentrati
on
observed
during the
dosing
interval
and can be
observed
directly
from data.,
For Part
B1, pre-
dose, 1, 4,
and 24
hours post
dose on
C1D1, pre-
dose, 1
hour post
dose on
Day 1 of
Cycles 3;

B2, pre-
dose, 1,
and 4
hours post
dose on
C1D1, pre-
dose and 1
hour post
dose on
Day 1 of
Cycles
3. |Cav of

Utomilum
ab
Following
Multiple

Part B, Cav
was
defined as
average
serum
concentrati
on over the
dosing
interval.,
For Part
B1, pre-
dose, 1, 4,
and 24
hours post
dose on

C1D1, pre-
dose, 1
hour post
dose on
Day 1 of
Cycles 3;
For Part
B2, pre-
dose, 1,
and 4
hours post
dose on
C1D1, pre-
dose and 1
hour post
dose on
Day 1 of
Cycles
3. $\mid \mathrm{CL}$ of
Utomilumab
Following
Multiple
Doses ..... on
C3D1 ..... in
Part ..... B,Drug
clearance
was ..... a
quantitative measureof the rateat which adrug
is removed
from the
blood (rate
at which a
drug is
metabolize
d or
eliminated
by normal
biological
processes).
CL=Dose/
AUCss,tau
, For Part
B1, pre-
dose, 1, 4,
hours post
dose on
C1D1, pre-
dose, 1
hour post
dose on
Day 1 of
Cycles 3;
For Part
B2, pre-
dose, 1,
and 4
hours post
dose on
C1D1, pre-
dose and 1
dose on
Day 1 of
Cycles
3. |Vss of

Utomilum
ab
Following
Multiple
Doses on
C3D1 in
Part B, Vss
was
defined as
volume of
distributio
n at steady
state., For
Part B1,
pre-dose,
1,4 , and 24
hours post
dose on
C1D1, pre-
dose, 1
hour post
dose on
Day 1 of
Cycles 3;
For Part
B2, pre-
dose, 1 ,
and 4
hours post

Utomilum
ab
Following
Multiple
Doses on
C3D1 in
Part B,
Accumulat
ion ratio
calculated
as, Rac
obtained
from Area
Under the
Concentrat
ion Time
Curve
(AUC)
from Cycle
3 Day 1
divided by
AUC from
Cycle1 Day
1., For Part

B1, pre-
dose, 1, 4,
and 24
hours post
dose on
C1D1, pre-
dose, 1
hour post
dose on
Day 1 of
Cycles 3;
For Part
B2, pre-
dose, 1,
and 4
hours post
dose on
C1D1, pre-
dose and 1
hour post
dose on
Day 1 of
Cycles
3. |Numbe
$r$ of
Participant
s With
ADA and
NAb
Against
PF-
04518600
in Part B,
ADA
never-
defined as
no positive
ADA
results at
any time
point.
ADA ever-
positive
was
defined as
at least one
positive
ADA
result at
any time
point. nAb
never-
positive
was
defined as
no positive
nAb
results at
any time
point and
nAb ever-
positive
was
defined as
at least one
positive
nAb result

Baseline
up to end
of
treatment
(maximum
of $\quad 14$
weeks). |N
umber of
Participant
s With
ADA and
NAb
Against
Utomilum
ab in Part

B, ADA
never-
positive
was
defined as
no positive
ADA
results at
any time
point.
ADA ever-
positive
was
defined as
at least one
positive
ADA
result at
any time
point. nAb
never-
positive
was
defined as
no positive
nAb
results at
any time
point and
nAb ever-
positive
was
defined as
at least one

|  |  |  |  |  |  |  |  | positive |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  |  |  |  |  |  |  |  | $n A b$ result |  |
|  |  |  |  |  |  |  |  | at any time |  |
|  |  |  |  |  |  |  |  | point., |  |
|  |  |  |  |  |  |  |  | Baseline |  |
|  |  |  |  |  |  |  |  | up to end of |  |
|  |  |  |  |  |  |  |  | treatment |  |
|  |  |  |  |  |  |  |  | (maximum |  |
|  |  |  |  |  |  |  |  | of 14 |  |
|  |  |  |  |  |  |  |  |  |  |
| RECRUITIN | Locally | DRUG: PD-1 | PHAS | INTER | Allocation: | 124 | Major | Pathologic | May-21 |
| G | Advanced | antibody | E2 | VENTI | RANDOMI |  | pathologic | al |  |
|  | Gastric | combined |  | ONAL | ZED\|Interv |  | al | complete |  |
|  | Adenocarci | with |  |  | ention |  | response( | response(p |  |
|  | noma | FOLFIRINOX |  |  | Model: |  | MPR), | CR), |  |
|  |  | regimen $\mid$ DR |  |  | PARALLEL |  | Surgery | Surgery ${ }^{\text {D }}$ |  |


| UG: PD-1 | \| Masking: | isease-free |
| :--- | :--- | :--- |
| antibody | SINGLE | survival(D |
| combined | (INVESTIG | FS) rate of |
| with SOX | ATOR) \|Pri | $3 \quad$ years, |
| program | mary | Time to |
|  | Purpose: | relapse or |
|  | TREATME | progressio |
|  |  | nT |
|  |  | disease |
|  |  | (PD) or |
|  |  | death from |
|  |  | any cause |
|  |  | within 3 |
|  | years from |  |
|  |  | subject |
|  |  | screening |

recorded,
progressio
n of
disease
(PD) or
death from
any cause
within 3
years|Dise
ase-free
survival(D
FS) rate of
5 years,
Time to
relapse or
progressio
n
of
(PD) or
death from
any cause
within 5
years from
subject
screening
to first
recorded,
progressio
n of
disease
(PD) or
death from
any cause

|  |  |  |  |  |  |  |  | within 5 <br> years |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| COMPLETE | Gastric | DRUG: ASG- | PHAS | INTER | Allocation: | 51 | Incidence | Best | Jul-10 |
| D | Neoplasms | 5ME | E1 | VENTI | NA \| Interve |  | of adverse | clinical |  |
|  | Pancreatic |  |  | ONAL | ntion |  | events and | response, |  |
|  | Neoplasms |  |  |  | Model: |  | laboratory | Every 2 |  |
|  |  |  |  |  | SINGLE_G |  | abnormalit | months 1 O |  |
|  |  |  |  |  | ROUP \| Mas |  | ies, | verall and |  |
|  |  |  |  |  | king: |  | Through 1 | progressio |  |
|  |  |  |  |  | NONE \| Pri |  | month | n-free |  |
|  |  |  |  |  | mary |  | after last | survival, |  |
|  |  |  |  |  | Purpose: |  | dose | Every |  |
|  |  |  |  |  | TREATME |  |  | month |  |
|  |  |  |  |  | NT |  |  | until death |  |
|  |  |  |  |  |  |  |  | or study |  |
|  |  |  |  |  |  |  |  | closure \|C |  |
|  |  |  |  |  |  |  |  | oncentrati |  |

and
metabolite
s in blood,
Through 1
month
after last
dose Incid
ence of
antitherap
eutic
antibodies
in blood,
Through 1
month


| Cancer 1 Ova | HER2 | HER2 |
| :---: | :---: | :---: |
| rian | cancers., | cancers., |
| Cancer ${ }^{\text {E }}$ End | Evaluated | Defined by |
| ometrium | by the | the time of |
| Cancer \\| Bla | number of | the date of |
| dder | DLTs | first dose |
| Cancer \| Pan | graded | of study |
| creatic | using NCI | drug until |
| Cancer \\| Col | CTCAE | confirmed |
| orectal | v5.0., Up to | disease |
| Cancer ${ }^{\text {No }}$ | 6 | progressio |
| n Small Cell | months \|P | $n$ based on |
| Lung | hase 1 - To | investigato |
| Cancer \\| EG | determine | r |
| F-R Positive | recommen | assessment |
| Non-Small | ded Phase | per |
| Cell Lung | 2 dose | RECIST 1.1 |


| Cancer ${ }^{\text {Hea }}$ | (RP2D) of or death |
| :---: | :---: |
| d and Neck | SNK01 in from any |
| Squamous | combinatio cause, |
| Cell | n with whichever |
| Carcinoma | cetuximab comes |
| Triple | in subjects first., Up to |
| Negative | with 12 |
| Breast | advanced months $\mid P$ |
| Cancer \\| Cer | EGFR hase 2a |
| vical | cancers., To assess |
| Cancer \\| Sarc | Evaluated the |
| oma | by the progressio |
|  | number of n -free |
|  | DLTs survival |
|  | graded (PFS) of |
|  | using NCI SNK01 in CTCAE combinatio |


| v5.0., Up to | with |
| :---: | :---: |
| 6 | cetuximab |
| months \|P | in subjects |
| hase 2a - | with |
| To assess | advanced |
| objective | EGFR |
| response | cancers., |
| rate (ORR) | Defined by |
| of SNK01 | the time of |
| in | the date of |
| combinatio | first dose |
| n with | of study |
| trastuzum | drug until |
| ab in | confirmed |
| subjects | disease |
| with | progressio |
| advanced | n bas |


| HER2 | investigato |
| :--- | :--- |
| cancers., | r |
| Defined by | assessment |
| percentage | per |
| of subjects | RECIST 1.1 |
| with a best or death |  |
| response of | from any |
| complete | cause, |
| response | whichever |
| (CR), | comes |
| partial | first., Up to |
| response | 12 |
| (PR) or | months \|P |
| stable | hase $2 \mathrm{a}-$ |
| disease | To assess |
| (SD) by | the overall |
| investigato | survival |


| r | (OS) of |
| :---: | :---: |
| assessment | SNK01 in |
| per | combinatio |
| RECIST | n with |
| 1.1., Up to | trastuzum |
| 12 | $a b$ in |
| months \| P | subjects |
| hase 2a- | with |
| To assess | advanced |
| objective | HER2 |
| response | cancers., |
| rate (ORR) | Defined as |
| of SNK01 | time from |
| in | first dose |
| combinatio | of study |
| n with | drug to |


| in subjects | to any |
| :---: | :---: |
| with | cause., Up |
| advanced | to 24 |
| EGFR | months \|P |
| cancers., | hase 2 a |
| Defined by | To assess |
| percentage | the overall |
| of subjects | survival |
| with a best | (OS) of |
| response of | SNK01 in |
| complete | combinatio |
| response | with |
| (CR), | cetuximab |
| partial | in subjects |
| response | with |
| (PR) or | advanced |
| stable | EGFR |


| disease | cancers., |
| :---: | :---: |
| (SD) by | Defined as |
| investigato | time from |
| r | first dose |
| assessment | of study |
| per | drug to |
| RECIST | death due |
| 1.1., Up to | to any |
| 12 months | cause., Up |
|  | to 24 |
|  | months \|P |
|  | hase 2 a |
|  | To assess |
|  | the |
|  | duration of |
|  | response |
|  | (DOR) of |

combinatio
n with
trastuzum
ab in
subjects
with
advanced
HER2
cancers.,
Defined as
duration of
time from
initial
response
(complete
response
$\backslash[C R \backslash]$ or
partial
response
$\backslash[\mathrm{PR} \backslash])$ to
first
documenta
tion of
disease
progressio
n or death
from any
cause,
whichever
occurs
first., Up to
12
months |P
hase 2 a -
To assess
the
duration of
response
(DOR) of
SNK01 in
combinatio
n with
cetuximab
in subjects
with
advanced
EGFR
cancers.,
Defined as duration of
time from
initial
response
(complete
response
$\backslash[C R \backslash]$ or
partial
response
$\backslash[\mathrm{PR} \backslash])$ to
first
documenta
tion of
disease
progressio
n or death
from any
cause,
first., Up to
hase 2 a -
To assess
the clinical
benefit rate
(CBR) of
SNK01 in
combinatio
n with
trastuzum
$a b \quad$ in
subjects
with
advanced
HER2
cancers.,
Defined as
proportion
of subjects
who
achieve an
overall
tumor
response
(complete
response
$\backslash[C R \backslash]$ or
partial
response
$\backslash[\mathrm{PR} \backslash]$ or
stable
disease
$\backslash[S D \backslash])$,
Up to 12
months |P
hase 2a -
To assess
the clinical
benefit rate
(CBR) of
SNK01 in
combinatio
n with
cetuximab
in subjects
with
advanced

## EGFR

cancers.,
Defined as
proportion
of subjects
who
achieve an
overall
tumor
response
(complete
response
$\backslash[C R \backslash]$ or
partial
response
$\backslash[\mathrm{PR} \backslash]$ or
stable
trastuzum
ab on
quality of
life in
subjects
with
advanced
HER2

## EORTC

QLQ-C30
questionna
ire consists
of
30
questions,
24 of which
are
grouped
into nine
multi-item
scales (five
functionin
g scales

$$
physical,
role,
cognitive,
```
emotional
and
social
$$,

three
symptom
scales
\fatigue,
pain and
nausea/vo
miting\]

and one
global
health
status
scale). The
remaining
six

```
are single-
item scales
(dyspnea,
appetite
loss, sleep
disturbanc
e,
constipatio
n , diarrhea
and the
financial
impact)
and are
intended
to assess
symptoms.

All of the
scales and
single-item
measures
are scored
on a scale
from 0 to
100. A
better state
of the
patient is
denoted by
a higher
score for
the
functionin
health
status,
while a
worsening
state of the
patient is
denoted by
higher
scores on
the
symptom
and single-
item
scales., Up
to 12
months |P
hase 2 a -
Impact of
SNK01 in
combinatio
n with
cetuximab
on quality
of life in
subjects
with
advanced
EGFR
cancers
evaluated
using
European

\section*{Organizati}
on for
Research
and
Treatment
of Cancer
(EORTC)
Quality of
Life
Questionn
aire Core-
30 (QLQ-
C30)., The
EORTC
QLQ-C30
questionna
ire consists

24 of which
are
grouped
into nine
multi-item
scales (five
functionin
g scales
\(\backslash\) [physical,
role,
cognitive,
emotional
and
social \(\backslash]\),
three
nausea/vo
miting \(\backslash]\)
and one
global
health
status
scale). The
remaining
six
questions
are single-
item scales
(dyspnea,
appetite
loss, sleep
disturbanc
e,
constipatio
n, diarrhea
and the
financial
impact)
and are
intended
to assess
symptoms.

All of the
scales and
single-item
are scored
on a scale
from 0 to
100. A
better state
of the
patient is
denoted by
a higher
score for
the
functionin
g scales
and global
health
status,
worsening
state of the
patient is
denoted by
higher
scores on
the
symptom
and single-
item
scales., Up
to \(\quad 12\)
months |P
hase 2a-
Impact of
SNK01 in
trastuzum
ab on
quality of
life in
subjects
with
advanced
HER2
cancers
evaluated
using
European
Organizati
on for
Research

Treatment
of Cancer
(EORTC)
Quality of
Life
Questionn
aire Lung
Cancer 13
(QLQ-
LC13).,
The
EORTC
QLQ-LC13
is
a
supplemen
tary lung-
questionna
ire and is
used in
conjunctio
n with the
EORTC
QLQ-C30
questionna
ire. It is
comprised
of
13
questions,
3 of which
are
grouped
multi-item
scale to
assess
dyspnea
and 10 of
which are
single-item
scales
assessing
pain,
coughing,
sore
mouth,
dysphagia,
peripheral
neuropath
```

y, alopecia,
and
hemoptysi

```
s.

All of the
scales and
single-item
measures
are scored
on a scale
from 0 to
100. A
better state
of the
patient is
denoted by
a higher
score for
the
functionin
g scales
and global
health
status,
while a
worsening
state of the
patient is
denoted by
higher
scores on
the
symptom
and single-
item
scales., Up
to 12
months |P
hase 2a -
Impact of
SNK01 in
combinatio
n with
cetuximab
on quality
of life in
subjects
with
advanced
EGFR

LC13).,
The
EORTC
QLQ-LC13
is
a
supplemen
tary lung-
cancer
specific
questionna
ire and is
used in
conjunctio
n with the
EORTC
QLQ-C30
questionna
ire. It is
comprised
of 13
questions,
3 of which
are
grouped
into a
multi-item
scale to
assess
dyspnea
and 10 of
which are
single-item
scales
assessing
pain,
coughing,
sore
mouth,
dysphagia,
peripheral
neuropath
y, alopecia,
and
hemoptysi
s.

All of the
scales and
single-item
measures
are scored
on a scale
from 0 to
100. A
better state
of the
patient is
denoted by
a higher
score for
the
functionin
g scales
and global
health
status,
while a
worsening
\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|}
\hline & & & & & & & & state of the patient is & \\
\hline & & & & & & & & denoted by & \\
\hline & & & & & & & & higher & \\
\hline & & & & & & & & scores on & \\
\hline & & & & & & & & the & \\
\hline & & & & & & & & symptom & \\
\hline & & & & & & & & and single- & \\
\hline & & & & & & & & item & \\
\hline & & & & & & & & scales., Up & \\
\hline & & & & & & & & to
\[
12
\] & \\
\hline & & & & & & & & months & \\
\hline RECRUITIN & HER2- & DRUG: ZW25 & PHAS & INTER & Allocation: & 362 & Incidence & Objective & 2019/8/29 \\
\hline G & expressing & (Zanidatama & E2 & VENTI & NON_RAN & & of dose- & response & \\
\hline & Gastrointest & b) |DRUG: & & ONAL & DOMIZED | & & limiting & rate (ORR) & \\
\hline & inal & Capecitabine & & & Intervention & & toxicities & (Part 1), & \\
\hline & Cancers, & | DRUG: & & & Model: & & (DLTs) & Number of & \\
\hline
\end{tabular}
\begin{tabular}{|c|c|c|c|c|}
\hline Including & Cisplatin \(\mid\) DR & PARALLEL & (Part 1), & participant \\
\hline Gastroesoph & UG: & | Masking: & Number of & \(s \quad\) who \\
\hline ageal & Fluorouracil & NONE | Pri & participant & achieved a \\
\hline Adenocarci & DRUG: & mary & s who & best \\
\hline noma, & Leucovorin | & Purpose: & experience & response of \\
\hline Biliary Tract & DRUG: & TREATME & d a DLT. & either \(C R\) \\
\hline Cancer, and & Oxaliplatin | & NT & DLTs & or PR \\
\hline Colorectal & DRUG: & & include & during \\
\hline \multirow[t]{9}{*}{Cancer} & Bevacizumab & & adverse & treatment \\
\hline & | DRUG: & & events & per \\
\hline & Gemcitabine & & considered & RECIST \\
\hline & & & to be & 1.1, Up to \\
\hline & & & related to & 10 \\
\hline & & & study & months | D \\
\hline & & & treatment, & isease \\
\hline & & & including & control \\
\hline & & & the & rate (Parts \\
\hline
\end{tabular}

\begin{tabular}{|c|c|}
\hline chemother
apy & \begin{tabular}{l}
months |D \\
uration of
\end{tabular} \\
\hline regimen., & response \\
\hline Up to 6 & (Parts \\
\hline weeks |Inc & and 2), \\
\hline idence of & Median \\
\hline adverse & duration of \\
\hline events & response \\
\hline (Part 1), & (in \\
\hline Number of & months) \\
\hline participant & and range \\
\hline who & (minimum, \\
\hline experience & maximum) \\
\hline & Up to 2 \\
\hline adverse & years \({ }^{\text {Clin }}\) \\
\hline event, Up & ical benefit \\
\hline to 11 & rate (Parts \\
\hline
\end{tabular}
\begin{tabular}{ll} 
months|In & 1 and 2), \\
cidence of & Number of \\
lab & participant \\
abnormalit & s with SD \\
ies (Part 1), & for 鈮 ?24 \\
Number of & weeks or a \\
participant & confirmed, \\
s who & best \\
experience & overall \\
d a & response of \\
maximum & CR or PR \\
severity of & per \\
Grade 3 or & RECIST \\
higher & 1.1, Up to 2 \\
post- & years |Pro \\
baseline & gression- \\
laboratory & free
\end{tabular}
\begin{tabular}{|c|c|}
\hline abnormalit
y, & \begin{tabular}{l}
survival \\
(Parts
\end{tabular} \\
\hline including & and 2), \\
\hline either & Median \\
\hline hematolog & progressio \\
\hline \(y\) and & n -free \\
\hline chemistry. & survival \\
\hline Grades are & (in \\
\hline defined & months) \\
\hline using & and range \\
\hline National & (minimum, \\
\hline Cancer & maximum) \\
\hline Institute's & , Up to 2 \\
\hline Common & years|Ove \\
\hline Terminolo & rall \\
\hline gy Criteria & survival \\
\hline for & (Parts \\
\hline
\end{tabular}
\begin{tabular}{|c|c|}
\hline Adverse & and 2), \\
\hline Events & Median \\
\hline (CTCAE), & overall \\
\hline version & survival \\
\hline 5.0., Up to & (in \\
\hline 11 & months) \\
\hline months \({ }^{\text {O }}\) & and range \\
\hline bjective & (minimum, \\
\hline response & maximum) \\
\hline rate (ORR) & , Up to 2 \\
\hline (Part 2), & years | Inci \\
\hline Number of & dence \\
\hline participant & anti-drug \\
\hline who & antibodies \\
\hline achieved a & (ADAs) \\
\hline best & (Parts \\
\hline response of & and 2), \\
\hline
\end{tabular}
\begin{tabular}{|c|c|}
\hline either complete & Number of participant \\
\hline response & s who \\
\hline (CR) or & develop \\
\hline partial & ADAs, Up \\
\hline response & to 11 \\
\hline (PR) & months | E \\
\hline during & nd \\
\hline treatment & infusion \\
\hline according & concentrati \\
\hline to the & on \\
\hline Response & ZW25 \\
\hline Evaluation & (Parts 1 \\
\hline Criteria in & and 2), Up \\
\hline Solid & to 11 \\
\hline Tumors & months |M \\
\hline (RECIST) & aximum \\
\hline
\end{tabular}

adverse
events
(Part 2),
Number of
participant
s who
experience
d an
adverse
event, Up
to 11
months | In
cidence of
lab
abnormalit
ies (Part 2),
Number of
baseline
laboratory
abnormalit
y,
including
either
hematolog
y and
\(\left.\begin{array}{lllll} & & \begin{array}{l}\text { chemistry. } \\
\text { Grades are } \\
\text { defined }\end{array} \\
\text { using }\end{array}\right]\)\begin{tabular}{l} 
National \\
Cancer \\
Institute's
\end{tabular}
\begin{tabular}{|c|c|c|}
\hline System & | Masking: & notypic \\
\hline Neoplasms | & NONE | Pri & analysis of \\
\hline Gastrointest & mary & T cells, The \\
\hline inal & Purpose: & number of \\
\hline Diseases & TREATME & CD3+ (or \\
\hline & NT & CD8+ or \\
\hline & & CD4+ or \\
\hline & & CD56+) T \\
\hline & & cell, 1 \\
\hline & & years|Seve \\
\hline & & rity of \\
\hline & & adverse \\
\hline & & events, \\
\hline & & According \\
\hline & & to National \\
\hline & & Cancer \\
\hline & & Institute \\
\hline
\end{tabular}
\begin{tabular}{lllllll} 
& & & & & Common \\
Terminolo \\
gy Criteria
\end{tabular}
\begin{tabular}{ll} 
mary & months |D \\
Purpose: & CR, \\
TREATME & Disease \\
NT & Control \\
& Rate, 9 \\
& months |D \\
& OR, \\
& Duration \\
& of \\
& Response, \\
& 12 \\
& months |A \\
& Es, \\
& Percentage \\
& of \\
& participant \\
& s
\end{tabular}
experienci
ng grade 3-
5 adverse
events, 12
months | Q
ualify of
Life, Based
on Quality
of Life
Questionn
are-Core
30,
evaluate
the quality
of life of
patients, 12
months

ageal
Junction
Adenocarci
noma AJCC
v8 | Clinical
Stage IV
Gastric
Cancer
AJCC
v8|Clinical
Stage IV
Gastroesoph
ageal
Junction
Adenocarci
noma AJCC
v8|Clinical

Stage IVA
Gastric

\section*{Cancer}

AJCC
v8 |Clinical
Stage IVA
Gastroesoph
ageal
Junction
Adenocarci
noma AJCC
v8|Clinical
Stage IVB
Gastric
Cancer
AJCC
v8 |Clinical

Stage IVB
Gastroesoph
ageal
Junction
Adenocarci
noma AJCC
v8 | Metastat
ic Gastric
Adenocarci
noma|Meta
static
Gastroesoph
ageal
Junction
Adenocarci
noma|Path
ologic Stage

\section*{III Gastric}

Cancer
AJCC
v8|Patholo
gic Stage III
Gastroesoph
ageal
Junction
Adenocarci
noma AJCC
v8|Patholo
gic Stage
IIIA Gastric

\section*{Cancer}

AJCC
v8 |Patholo
gic Stage

IIIA
Gastroesoph
ageal
Junction
Adenocarci
noma AJCC
v8 | Patholo
gic Stage
IIIB Gastric
Cancer
AJCC
v8|Patholo
gic Stage
IIIB
Gastroesoph
ageal
Junction

Adenocarci
noma AJCC
v8|Patholo
gic Stage
IIIC Gastric
Cancer
AJCC
v8|Patholo
gic Stage IV
Gastric
Cancer
AJCC
v8|Patholo
gic Stage IV
Gastroesoph
ageal
Junction
Adenocarci
noma AJCC
v8|Patholo
gic Stage
IVA
Gastroesoph
ageal
Junction
Adenocarci
noma AJCC
v8|Patholo
gic Stage
IVB
Gastroesoph
ageal
Junction
Adenocarci
noma AJCC
v8| Postneo
adjuvant
Therapy
Stage III
Gastric
Cancer
AJCC
v8|Postneo
adjuvant
Therapy
Stage III
Gastroesoph
ageal
Junction
Adenocarci
noma AJCC
v8|Postneo
adjuvant
Therapy
Stage IIIA
Gastroesoph
ageal
Junction
Adenocarci
noma AJCC
v8|Postneo
adjuvant
Therapy
Stage IIIB
Gastroesoph
ageal
Junction
Adenocarci
noma AJCC
v8|Postneo
adjuvant
Therapy
Stage IV
Gastric
Cancer
AJCC
v8|Postneo
adjuvant
Therapy
Stage IV
Gastroesoph
ageal
Junction
Adenocarci
noma AJCC
v8|Postneo
adjuvant
Therapy
Stage IVA
Gastroesoph
ageal
Junction
Adenocarci
noma AJCC
v8|Postneo
adjuvant
Therapy
Stage IVB
Gastroesoph
ageal
Junction
Adenocarci
noma AJCC
v8|Unresect
able Gastric
Adenocarci
noma|Unre
sectable
Gastroesoph
ageal
Junction
Adenocarci
noma
\begin{tabular}{lllllllll} 
COMPLETE & Cancer|Soli & DRUG: & PHAS & INTER & Allocation: 38 & Incidence & Peripheral 2017/6/30 \\
D & d Tumor & Fludarabine| & E1 & VENTI & NON_RAN & & of adverse & T-cell
\end{tabular}
\begin{tabular}{|c|c|c|c|}
\hline IMA101 & | Masking: & IMA101 & of T-cells \\
\hline product|BIO & NONE | Pri & alone or in & over time), \\
\hline LOGICAL: & mary & combinatio & up to 18 \\
\hline Recombinant & Purpose: & n with & months |T \\
\hline human & TREATME & atezolizum & umor \\
\hline interleukin- & NT & ab, up to 18 & response \\
\hline 2|DIAGNOS & & months & per \\
\hline TIC_TEST: & & & Response \\
\hline IMADetect & & & Evaluation \\
\hline DRUG: & & & Criteria In \\
\hline Atezolizuma & & & Solid \\
\hline b & & & Tumors \\
\hline & & & (RECIST) \\
\hline & & & \\
\hline & & & immune- \\
\hline & & & related \\
\hline & & & RECIST \\
\hline
\end{tabular}
\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|}
\hline & & & & & & & & \begin{tabular}{l}
(irRECIST) \\
, up to 18 \\
months
\end{tabular} & \\
\hline RECRUITIN & Gastric & DRUG: GEN- & PHAS & INTER & Allocation: & 42 & To assess & Incidence & 2022/4/7 \\
\hline G & Cancer \| Gas & 001|DRUG: & E2 & VENTI & NA | Interve & & the anti- & of Adverse & \\
\hline & troesophage & Avelumab & & ONAL & ntion & & tumor & Events, & \\
\hline & al Junction & & & & Model: & & activity of & Assessed & \\
\hline & Adenocarci & & & & SINGLE_G & & GEN-001, & as per & \\
\hline & noma & & & & ROUP \| Mas & & when & CTCAE & \\
\hline & & & & & king: & & administer & v5.0, 1 & \\
\hline & & & & & NONE | Pri & & ed as & years | Inci & \\
\hline & & & & & mary & & combined & dence of & \\
\hline & & & & & Purpose: & & with & Laboratory & \\
\hline & & & & & TREATME & & avelumab, & abnormalit & \\
\hline & & & & & NT & & Objective & ies, & \\
\hline & & & & & & & Response & Assessed & \\
\hline & & & & & & & (OR) per & as per & \\
\hline
\end{tabular}
\begin{tabular}{|c|c|}
\hline Response & CTCAE \\
\hline Evaluation & v5.0, \\
\hline Criteria in & years |Dur \\
\hline Solid & ation of \\
\hline Tumors & response \\
\hline (RECIST) & (DoR), \\
\hline v1.1, & Assessed \\
\hline years & according \\
\hline & to RECIST \\
\hline & v1.1, \\
\hline & years | Pro \\
\hline & gression- \\
\hline & free \\
\hline & Survival \\
\hline & (PFS), \\
\hline & Assessed \\
\hline & according \\
\hline
\end{tabular}
to RECIST
v1.1, \(\quad 1\)
years |Ove
rall
Survival
(OS), 1
years

G
\begin{tabular}{llllll} 
Stomach & DRUG: & PHAS & INTER & Allocation: & 152 \\
Neoplasms | & Oxaliplatin| & E2 & VENTI & RANDOMI & \\
Esophagoga & DRUG: & & ONAL & ZED|Interv & \\
stric & Tegafur- & & & ention \\
Junction & Gimeracil- & & & Model: \\
Disorder|N & Oteracil|DR & & & PARALLEL \\
eoadjuvant & UG: & & |Masking: \\
Therapy|C & Sintilimab|R & & NONE|Pri \\
hemoradiot & ADIATION: & & mary \\
herapy \(\mid\) Im & Concurrent & & & Purpose:
\end{tabular}

Purpose:

\begin{tabular}{|c|c|c|c|c|}
\hline munotherap & chemoradiati & TREATME & al & of patients \\
\hline y |Gastrecto & on | PROCED & NT & complete & with a \\
\hline my | Adenoc & URE: D2/R0 & & regression & pathologic \\
\hline arcinoma|A & gastrectomy & & ( pCR ) rate: & al \\
\hline djuvant & & & the & response. \\
\hline \multirow[t]{12}{*}{Therapy} & & & proportion & The tumor \\
\hline & & & of patients & regression \\
\hline & & & who & will be \\
\hline & & & achieve & evaluated \\
\hline & & & pCR after & according \\
\hline & & & preoperati & to Ryan's \\
\hline & & & ve therapy. & tumor \\
\hline & & & Patients & regression \\
\hline & & & with a CY0 & grading \\
\hline & & & status at & (TRG). The \\
\hline & & & the time of & pathologic \\
\hline & & & enrollment & al response \\
\hline
\end{tabular}
\begin{tabular}{|c|c|}
\hline should & is defined \\
\hline have no & as TRG0 \\
\hline residual & and TRG1 \\
\hline tumor cells & of the \\
\hline in the & primary \\
\hline primary & lesion after \\
\hline lesion and & preoperati \\
\hline in the & ve \\
\hline dissected & therapy., 6 \\
\hline lymph & months \\
\hline nodes in & after the \\
\hline the & enrollment \\
\hline surgical & of the last \\
\hline specimens & subject \(\mid\) R0 \\
\hline (ypT0N0M & resection \\
\hline \(0)\). Patients & rate, The \\
\hline with a CY & R0 \\
\hline
\end{tabular}

removed,
and no
residual
tumor cells
within 1
mm of the
resection
margin
should be
confirmed
by
postoperat
ive
pathology.
For
patients
with a CY1
status at
the time of
recruitmen
t, an extra
requireme
nt is that
CY0
should be
confirmed
by an
peritoneal
cytological
examinatio
n.,

6
months
enrollment
of the last
subject \(\mid \mathrm{Ob}\)
jective
response
rate (ORR),
The
Objective
response
rate (ORR)
is defined
as the
proportion
of patients
with a
complete
partial
response
(PR) to
preoperati
ve therapy.
The ORR
will be
evaluated
using the
RESIST1.1
protocol., 6
months
after the
recruitmen
t of the last
subject.|E
vent-free
survival
(EFS), The
EFS will be
calculated
from the
date of
randomiza
tion to the
date of any
event or
censoring.
The event
is defined
as below:
(1)
locoregion
al
recurrence;
(2)
peritoneal
seeding;
(3) distant
metastasis;
(4) death of
any reason;
(5) tumor
progressio
n
according
to RESIST
1.1., \(\quad 36\)
months
t of the last
subject.|O
verall
survival
(OS), The
OS will be
calculated
from the
date of
randomiza
tion to the
date of
death or
date of the
last follow-
up., 36
months
after the
recruitmen
t of the last
subject. |Sa
fety of
perioperati
ve therapy
include
chemo(rad
io)therapy
and PD-1
antibody.,
Treatment
related
adverse
to 28 days
after the
last date of
treatment.
Document
ary will
include the
occurrence
time,
severity
and time of
duration.
Common
TRAEs
include
leukopenia
thrombocy
topenia,
anemia,
ALT/AST
increase,
BUN/Scr
increase,
nausea,
vomiting,
diarrhea,
appetite
decrease
pruritus,
rash,
fatigue,
malaise
and
pyrexia.
Additional
TRAEs of
special
interest
include
pneumonit
is,
interstitial
lung
disease,
acute
hepatitis,
hyperthyr
oidism,
autoimmu
ne
thyroiditis,
thyroid
disorder,
hypopituit
arism,
colitis,
maculopap
ular rash
and
epidermal
capillary
hyperplasi
a., One
month
after the
last date of
treatment
grading,
such as
abdominal
or GI tract
bleeding,
anastomoti
c fistula,
pancreatic
fistula of
grade \(B\) or
above, and
incision
complicati
ons
(infection,
bleeding,
rupture).,

\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|}
\hline & & & & & & & & progressio & \\
\hline & & & & & & & & & \\
\hline & & & & & & & n, through study & \begin{tabular}{l}
disease \\
(PD) or
\end{tabular} & \\
\hline & & & & & & & completion & death, & \\
\hline & & & & & & & an & through & \\
\hline & & & & & & & average of & & \\
\hline & & & & & & & 3 years & completion & \\
\hline & & & & & & & & an & \\
\hline & & & & & & & & average of & \\
\hline & & & & & & & & 3 years & \\
\hline COMPLETE & Advanced & DRUG: & PHAS & INTER & Allocation: & 37 & The & Objective- & 2019/2/15 \\
\hline D & Solid & FT500|DRU & E1 & VENTI & NON_RAN & & incidence & response & \\
\hline & Tumors \| Ly & G: & & ONAL & DOMIZED | & & of & rate (ORR), & \\
\hline & mphoma|G & Nivolumab & & & Intervention & & participant & ORR is & \\
\hline & astric & DRUG: & & & Model: & & s with & defined as & \\
\hline & Cancer \({ }^{\text {Col }}\) & Pembrolizum & & & PARALLEL & & Dose & the & \\
\hline
\end{tabular}
\begin{tabular}{|c|c|c|c|c|}
\hline orectal & ab|DRUG: & | Masking: & Limiting & proportion \\
\hline Cancer \| Hea & Atezolizuma & NONE | Pri & Toxicities & of \\
\hline d and Neck & b|DRUG: & mary & (DLTs) & participant \\
\hline Cancer \({ }^{\text {Squ }}\) - & Cyclophosph & Purpose: & within & who \\
\hline amous Cell & amide|DRU & TREATME & each dose & achieve \\
\hline Carcinoma & G: & NT & level & immune \\
\hline EGFR & Fludarabine & & cohort., & partial \\
\hline Positive & DRUG: IL-2 & & The & reponse/p \\
\hline Solid & & & incidence & artial \\
\hline Tumor | HE & & & of & response \\
\hline R2-positive & & & participant & (iPR/PR) \\
\hline Breast & & & s with & or immune \\
\hline Cancer \({ }^{\text {He }}\) & & & DLTs & complete \\
\hline patocellular & & & within & response/c \\
\hline Carcinoma & & & each & omplete \\
\hline Small Cell & & & assessed & response \\
\hline Lung & & & dose level & (iCR/CR). \\
\hline
\end{tabular}
\begin{tabular}{|c|c|c|}
\hline Cancer 1 Ren & cohort to & Tumor \\
\hline al Cell & determine & response \\
\hline Carcinoma & the & will be \\
\hline Pancreas & maximum & assessed \\
\hline Cancer \| Mel & tolerated & using \\
\hline anoma|NS & dose & modified \\
\hline CLC|Uroth & (MTD) or & Response \\
\hline elial & maximum & Evaluation \\
\hline Carcinoma | & assessed & Criteria in \\
\hline Cervical & dose & Solid \\
\hline Cancer \| Mic & (MAD)., & Tumors \\
\hline rosatellite & Day 29 & (iRECIST) \\
\hline Instability | & & or \\
\hline Merkel Cell & & Response \\
\hline Carcinoma & & Evaluation \\
\hline & & Criteria in \\
\hline & & Lymphom \\
\hline
\end{tabular}
a (RECIL), as
applicable.
, Day 29
and every
8 weeks
thereafter
through
Day
366|Durati
on of
FT500
persistence
, Duration
of FT500
response is
defined as
\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|}
\hline & & & & & & & & duration & \\
\hline & & & & & & & & from Day 1 & \\
\hline & & & & & & & & to & \\
\hline & & & & & & & & undetectab & \\
\hline & & & & & & & & le levels of & \\
\hline & & & & & & & & FT500 cells & \\
\hline & & & & & & & & per uL & \\
\hline & & & & & & & & blood., & \\
\hline & & & & & & & & Day
\[
1
\] & \\
\hline & & & & & & & & through & \\
\hline & & & & & & & & Day 366 & \\
\hline ACTIVE_NO & Gastric & DRUG: & PHAS & INTER & Allocation: & 60 & R0 & Near & 2019/7/24 \\
\hline T_RECRUITI & Cancer & SHR1210 & E2 & VENTI & NA | Interve & & resection & pathologic & \\
\hline NG & & combined & & ONAL & ntion & & rate, The & al & \\
\hline & & with FOLFOX & & & Model: & & & complete & \\
\hline & & & & & SINGLE_G & & of patients & response & \\
\hline & & & & & ROUP | Mas & & who have & (near-pCR) & \\
\hline
\end{tabular}
\begin{tabular}{lll} 
king: & no residual rate, Near- \\
NONE |Pri & cancer cells & pCR rate is \\
mary & (gross or & defined as \\
Purpose: & microscopi & the \\
TREATME & cally) at the & percentage \\
NT & resection & of patients \\
& margins., & with grade \\
& Up to & \(0-1\) tumors \\
& approxima per NCCN \\
& tely 16 & tumor \\
& weeks \(\mid\) pat & regression \\
& hological & grading \\
& complete & (TRG)., Up \\
& response & to \\
& (pCR) rate, & approxima \\
& The & tely 16 \\
& percentage & weeks \(\mid O v\)
\end{tabular}
\begin{tabular}{|c|c|}
\hline \multicolumn{2}{|l|}{of patients erall} \\
\hline with no & survival(O \\
\hline residual & S), OS is \\
\hline cancer cells & defined as \\
\hline at the & the time \\
\hline primary & from the \\
\hline cancer site & first dose \\
\hline and \(\mathrm{N}(-)\) & to all-cause \\
\hline per & death., \\
\hline histologica & From \\
\hline 1 & randomiza \\
\hline \multicolumn{2}{|l|}{evaluation. tion to the} \\
\hline Up to & date \\
\hline approxima & death (up \\
\hline tely 16 & to \\
\hline weeks & approxima \\
\hline & tely \\
\hline
\end{tabular}
```

years)|Pro
gression-
free
survival(P
FS), PFS is
defined as
the time
from the
first dose
to objective
disease
progressio
n or death.,
up to 2
years|Dise
ase-free
survival

```
as the time
from the
postoperat
ive
baseline
imaging
evaluation
to disease
recurrence
or death in
subjects
who are
disease-
free after
surgery.,
From
randomiza
tion to the
date of
recurrence
or death
(up
to
approxima
tely \(\quad 4\)
years)|Per
centage of
Participant
s Who
Experience
One or
More
Adverse

\section*{Events}
(AEs), The
incidence
and grade
of adverse
events
(including
serious
adverse
events and immune-
related
adverse
events)
will be
determine
d per NCI-
\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|}
\hline & & & & & & & & CTCAE & \\
\hline & & & & & & & & 4.0., up to approxima & \\
\hline & & & & & & & & tely 1 years & \\
\hline UNKNOWN & Metastatic & DRUG: & PHAS & INTER & Allocation: & 40 & margin- & pathologic & Aug-20 \\
\hline & Gastric & Camrelizuma & E2 & VENTI & | Interventio & & free-(R0) & al & \\
\hline & Cancer \({ }^{\text {Loc }}\) & b plus & & ONAL & \(n\) Model: & & resection & complete & \\
\hline & ally & mFLOT & & & SEQUENTI & & rate, R0 & response & \\
\hline & Advanced & regimen \(\mid\) PR & & & AL|Maskin & & resection & (pCR), 6-9 & \\
\hline & Gastric & OCEDURE: & & & g : & & was & weeks after & \\
\hline & Adenocarci & R0 surgery & & & NONE | Pri & & defined as & immunoch & \\
\hline & noma & & & & & & no tumor & emotherap & \\
\hline & & & & & Purpose: & & identified & \(y\) and R0 & \\
\hline & & & & & TREATME & & on & surgery|o & \\
\hline & & & & & NT & & microscopi & verall & \\
\hline & & & & & & & c & response & \\
\hline & & & & & & & examinatio & rate (ORR), & \\
\hline
\end{tabular}
\begin{tabular}{|c|c|}
\hline \multicolumn{2}{|l|}{n of up to 24} \\
\hline proximal, & months \({ }^{\text {N }}\) \\
\hline distal,or & umber of \\
\hline circumfere & participant \\
\hline ntial & s with \\
\hline margins., & treatment- \\
\hline 6-9 weeks & related \\
\hline after & adverse \\
\hline immunoch & events as \\
\hline emotherap & assessed \\
\hline \multirow[t]{7}{*}{y} & by CTCAE \\
\hline & v5.0, up to \\
\hline & 24 \\
\hline & months \({ }^{\text {su }}\) \\
\hline & gery \\
\hline & complicati \\
\hline & ons, sugery \\
\hline
\end{tabular}
complicati
ons, up to 2
months
after the
period of
surgery|p
rogression
free
survival
(PFS),
randomisa
tion to
disease
progressio
n , relapse,
or death;
surgical
\begin{tabular}{llllll} 
& & & \begin{tabular}{l} 
morbidity \\
and
\end{tabular} \\
mortality,
\end{tabular}
\begin{tabular}{|c|c|c|}
\hline mary & RECIST & any cause \\
\hline Purpose: & 1.1, The & 锛 审 \\
\hline TREATME & Percent of & ssessed up \\
\hline \multirow[t]{14}{*}{NT} & patinets & to 2 \\
\hline & after first & years ]|PF \\
\hline & progressio & S2, \\
\hline & n until & Progressio \\
\hline & disease & n-free \\
\hline & progressio & survival by \\
\hline & \[
\mathrm{n} \text { in } 6
\] & IRRC \\
\hline & months & assessment \\
\hline & & per \\
\hline & & RECIST \\
\hline & & 1.1, From \\
\hline & & date of \\
\hline & & randomiza \\
\hline & & tion until \\
\hline
\end{tabular}
the date of second-
line
treatment
progressio
n or date of
death from
any cause,
whichever
came
first|PFS1,
Progressio
n-free
survival by
IRRC
assessment
per
1.1, From
date of
randomiza
tion until
the date of
first
documente
d
progressio
nor date of
death from
any cause,
whichever
came first
\begin{tabular}{|c|c|c|c|c|c|}
\hline UNKNOWN & Colorectal & BIOLOGICA & PHAS & INTER & Allocation: \\
\hline & Cancer \| Tri & L: Adoptive & E1 & VENTI & | Interventio \\
\hline & ple Negative & Cell Transfer & & ONAL & n Model: \\
\hline & Breast & of NKG2DL- & & & SEQUENTI \\
\hline & Cancer \| Sarc & targetting & & & AL|Maskin \\
\hline & oma | Nasop & Chimeric & & & g : \\
\hline & haryngeal & Antigen & & & NONE | Pri \\
\hline & Carcinoma & Receptor- & & & mary \\
\hline & Prostate & grafted & & & Purpose: \\
\hline & Cancer \| Gas & Gamma Delta & & & OTHER \\
\hline & tric Cancer & T cell & & & \\
\hline
\end{tabular}
\begin{tabular}{ll} 
Number of & Occurence \(2019 / 12 / 1\) \\
Patients & of adverse \\
with Dose & events \\
Limiting & during \\
Toxicity, & therapy, A \\
The & secondary \\
primary & outcome is \\
endpoint & to observe \\
of this & for the \\
dose- & occurence \\
escalation & of any \\
study will & adverse \\
be the & events \\
occurrence & (AEs) and \\
of dose- & serious \\
limiting & adverse \\
toxicities & events
\end{tabular}
\begin{tabular}{|c|c|}
\hline (DLTs) & (SAEs) \\
\hline during 4 & during 4 \\
\hline cycles of & cycles of \\
\hline treatment & treatment \\
\hline and the & and the \\
\hline week after & week after \\
\hline treatment., & treatment, \\
\hline 6 months & 6 \\
\hline & months \({ }^{\text {O }}\) \\
\hline & bservation \\
\hline & of clinical \\
\hline & efficacy, A \\
\hline & secondary \\
\hline & outcome is \\
\hline & to observe \\
\hline & for the \\
\hline & occurrence \\
\hline
\end{tabular}
of objective
clinical
response at
d31, M3,
M6, M9,
M12, M18
and M24
after the
start of 1st
cycle of
treatment
(assessed
according
to RECIST
criteria,
version
1.1), 6
months to
2
years|Obs
ervation
for
progressio
n-free
survival, A
secondary
outcome is
to observe
for
progressio
n-free
survival
(PFS) and
after the
start of 1st
cycle of
treatment,
up to 2
years|Obs
ervation
for
duration of
response,
A
secondary
outcome is
to observe
the
duration of
response in
patients
\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|}
\hline & & & & & & & & with objective response up to M24, After the start of 1st cycle of treatment, Up to 2 years & \\
\hline RECRUITIN & Gastric & DRUG: KK- & PHAS & INTER & Allocation: & 42 & Maximum & Adverse & 2022/9/26 \\
\hline G & Cancer \| Bre & LC-1 TCR-T & E1 & VENTI & NA | Interve & & tolerated & events of & \\
\hline & ast & cells|DRU & & ONAL & ntion & & dose & KK-LC-1 & \\
\hline & Cancer \| Cer & Aldesleukin & & & Model: & & (MTD) of & TCR T & \\
\hline & vical & 720,000 & & & SEQUENTI & & KK-LC-1 & cells, & \\
\hline & Cancer \(/\) Lun & IU/kg IV & & & AL|Maskin & & TCR-T & Adverse & \\
\hline & g Cancer & & & & g: & & cells, The & & \\
\hline
\end{tabular}
\begin{tabular}{|c|c|c|c|}
\hline every eight & NONE | Pri & highest & determinat \\
\hline \multirow[t]{16}{*}{hours} & mary & dose level & ion as \\
\hline & Purpose: & achieved & measured \\
\hline & TREATME & according & by \\
\hline & NT & to the & National \\
\hline & & protocol- & Cancer \\
\hline & & defined & Institute \\
\hline & & criteria for & ( NCI ) \\
\hline & & DLTs and & Common \\
\hline & & determinat & 5.0Termin \\
\hline & & ion of & ology \\
\hline & & MTD., 30 & Criteria for \\
\hline & & days & Adverse \\
\hline & & & Events \\
\hline & & & (CTCAE) \\
\hline & & & Criteria \\
\hline & & & Version \\
\hline
\end{tabular}
5.0, \(\quad 30\)
days|Tum
or
response
rate,
Tumor
response
will be
determine
d by
RECIST
criteria as
per the
protocol
description
, 6
weeks|Tu
duration
Tumor
response
duration
will be
determine
d by
RECIST
criteria as
per the
protocol
description
, Through
study
completion
\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|}
\hline \multirow[b]{2}{*}{RECRUITIN} & \multirow[b]{2}{*}{Advanced} & \multirow[b]{2}{*}{DRUG:} & \multirow[b]{2}{*}{PHAS} & \multirow[b]{2}{*}{INTER} & \multirow[b]{2}{*}{Allocation:} & \multirow[b]{2}{*}{365} & \multicolumn{3}{|c|}{, up to 5 years} \\
\hline & & & & & & & Phase 1 & Phase 1 & 2023/1/4 \\
\hline \multirow[t]{14}{*}{G} & Solid & STAR0602 & E1|PH & VENTI & NON_RAN & & (Dose & and 2 & \\
\hline & Tumors \| Ge & & ASE2 & ONAL & DOMIZED | & & Escalation) & (Dose & \\
\hline & nital & & & & Intervention & & :Number & Escalation & \\
\hline & Neoplasm, & & & & Model: & & of & and & \\
\hline & Female | Uro & & & & SEQUENTI & & Participant & Expansion) & \\
\hline & genital & & & & AL|Maskin & & s with & : & \\
\hline & Neoplasms | & & & & g : & & Dose- & Percentage & \\
\hline & Lung & & & & NONE | Pri & & limiting & of & \\
\hline & Neoplasm| & & & & mary & & Toxicities & Participant & \\
\hline & Neoplasms & & & & Purpose: & & (DLTs) in & \(s \quad\) with & \\
\hline & by & & & & TREATME & & Cycle 1, & ORR, Up to & \\
\hline & Site | Papillo & & & & NT & & Cycle 1 & 3 & \\
\hline & mavirus & & & & & & (Cycle & years |Pha & \\
\hline & Infection \(\mid\) E & & & & & & length \(=28\) & se 1 and 2 & \\
\hline
\end{tabular}
\begin{tabular}{|c|c|c|}
\hline pstein-Barr & days)|Pha & (Dose \\
\hline Virus & se 1 and 2 & Escalation \\
\hline Infections & (Dose & and \\
\hline Carcinoma | & Escalation & Expansion) \\
\hline Neoplasms | & and & Duration \\
\hline Vulvar & Expansion) & of \\
\hline Neoplasms | & : Number & Responses \\
\hline Vulvar & of & (DOR), Up \\
\hline Diseases \| A & Participant & to 3 \\
\hline bdominal & s with & years |Pha \\
\hline Neoplasm & Adverse & se 1 and 2 \\
\hline & Events & (Dose \\
\hline & (AEs) and & Escalation \\
\hline & Serious & and \\
\hline & Adverse & Expansion) \\
\hline & Events & : \\
\hline & (SAEs), Up & Percentage \\
\hline
\end{tabular}
\begin{tabular}{|c|c|}
\hline to 3 & of \\
\hline years | Pha & Participant \\
\hline se 2 (Dose & with \\
\hline Expansion) & Disease \\
\hline : & Control \\
\hline Percentage of & (CR, PR, and Stable \\
\hline Participant & Disease), \\
\hline with & Up to 3 \\
\hline Overall & years |Pha \\
\hline Objective & se 2 (Dose \\
\hline Tumor & Expansion) \\
\hline Responses & \\
\hline (ORR), & Progressio \\
\hline Complete & Free \\
\hline response & Survival \\
\hline (CR) and & (PFS), Up \\
\hline
\end{tabular}
\begin{tabular}{ll} 
partial & to \(\quad 3\) \\
response & years \(\mid\) Pha \\
\((\mathrm{PR})\), Up to & se 2 (Dose \\
3 years & Expansion) \\
& : Overall \\
& Survival \\
& \((\mathrm{OS}), \mathrm{Up}\) to
\end{tabular}
years \(\mid\) Pha
se 1 and 2
(Dose
Escalation
and
Expansion)

Maximum
Observed

\section*{Plasma}

Concentrat
ion (Cmax)
for
STAR0602,
Dose
Escalation:
Cycle
and Cycle
6
at
predefined
intervals
up to 1
year; Dose
Expansion:
Cycle 1,
Cycle 3,
and Cycle
6
at
predefined
intervals
up to 3
years
(Cycle
length \(=28\)
days)|Pha
se 1 and 2
(Dose
Escalation
and
Expansion)
Time
(Tmax) to
Reach the
MaximumPlasma
Concentration (Cmax)forSTAR0602,
Dose
Escalation
Cycle ..... 1
and Cycle
6 ..... at
predefinedintervals
up to 1
year; Dose
Expansion:
Cycle ..... 1,
```

Cycle 3,
and Cycle
6 at
predefined
intervals
up to 3
years
(Cycle
length= 28
days)|Pha
se 1 and 2
(Dose
Escalation
and
Expansion)
: Area
Under the

```

\section*{Plasma}

Concentrat
ion (AUC)
Versus
Time
Curve for
STAR0602,
Dose
Escalation:
Cycle 1
and Cycle
6
at
predefined
intervals
up to 1
year; Dose
Expansion:
Cycle ..... 1,
Cycle ..... 3 ,and Cycle
6 ..... atpredefinedintervals
up to 3years(Cyclelength \(=28\)
days)|Pha
se 1 and 2
(Dose
EscalationandExpansion)- Terminal

Eliminatio
n Half-life
( \(\mathrm{t} 1 / 2\) ) for
STAR0602,
Dose
Escalation:
Cycle 1
and Cycle
6
at
predefined
intervals
up to 1
year; Dose
Expansion:
Cycle
1,
Cycle 3,
and Cycle
predefined
intervals
up to 3
years
(Cycle
length \(=28\)
days)|Pha
se 1 and 2
(Dose
Escalation
and
Expansion)
: Apparent
Total Body
Clearance
(CL) for

Escalation:
Cycle 1
and Cycle
6
at
predefined
intervals
up to 1
year; Dose
Expansion:
Cycle 1,
Cycle 3,
and Cycle
6 at
predefined
intervals
years
(Cycle
length \(=28\)
days)|Pha
se 1 and 2
(Dose
Escalation
and
Expansion)
: Apparent
Volume of
Distributio
n (Vd) for
STAR0602,
Dose
Escalation:
Cycle 1
and Cycle
6 at
predefined
intervals
up to 1
year; Dose
Expansion:
Cycle 1,
Cycle 3,
and Cycle
6 at
predefined
intervals
up to 3
years
(Cycle
length \(=28\)
days)|Pha
se 1 and 2
(Dose
Escalation
and
Expansion)
: Anti-drug
Antibody
(ADA)
formation,
Dose
Escalation
and
Expansion:
Day 1 of
predetermi
\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|}
\hline & & & & & & & & \begin{tabular}{l}
ned cycles \\
up to 3 \\
years \\
(Cycle \\
length \(=28\) \\
days)
\end{tabular} & \\
\hline RECRUITIN & Advanced & DRUG: AU- & PHAS & INTER & Allocation: & 69 & Evaluate & Magnitude & 2022/4/4 \\
\hline G & Solid & 007|DRUG: & E1|PH & VENTI & NON_RAN & & the safety & of & \\
\hline & Tumor \| Met & Aldesleukin & ASE2 & ONAL & DOMIZED | & & and & Pharmaco & \\
\hline & astatic & & & & Intervention & & tolerability & kinetic & \\
\hline & Cancer & & & & Model: & & of AU-007, & changes in & \\
\hline & & & & & SEQUENTI & & Measured & the blood & \\
\hline & & & & & AL|Maskin & & & & \\
\hline & & & & & g : & & & dosing & \\
\hline & & & & & NONE | Pri & & of DLTs & determine & \\
\hline & & & & & mary & & & d by area & \\
\hline & & & & & Purpose: & & limiting & under the & \\
\hline
\end{tabular}
\begin{tabular}{|c|c|c|}
\hline TREATME & Toxicity) & curve \\
\hline \multirow[t]{16}{*}{NT} & and safety & (AUC) of \\
\hline & profile, & AU-007, \\
\hline & Day 1 thru & The AUC \\
\hline & EOT visit & of AU-007 \\
\hline & (28) days & will be \\
\hline & after last & measured \\
\hline & dose)|Esta & at different \\
\hline & blish the & timepoints \\
\hline & maximum & after AU- \\
\hline & tolerated & 007 \\
\hline & dose & administra \\
\hline & (MTD) and & tion, Day 1 \\
\hline & or/ & thru EOT \\
\hline & recommen & visit (28 \\
\hline & ded Phase & days after \\
\hline & 2 dose & last \\
\hline
\end{tabular}
\begin{tabular}{|c|c|}
\hline (RP2D), & dose)|Mag \\
\hline With AU- & nitude of \\
\hline 007 alone & Pharmaco \\
\hline or in & kinetic \\
\hline combinatio & anges in \\
\hline n with & the blood \\
\hline aldesleuki & after \\
\hline n & dosing \\
\hline measured & determine \\
\hline by PK, PD, & by \\
\hline and & maximum \\
\hline Biomarker & concentrati \\
\hline s, Day 1 & on (Cmax) \\
\hline thru EOT & of AU-007, \\
\hline visit (28 & The Cmax \\
\hline days after & of AU-007 \\
\hline last dose) & will be \\
\hline
\end{tabular}
```

measured
at different
timepoints
after AU-
007
administra
tion, Day 1
thru EOT
visit (28
days after
last
dose)|Mag
nitude of
Pharmaco
kinetic
changes in
the blood

```
maximum
concentrati
on (Tmax),
The Tmax
of AU-007
will be
measured
at different
timepoints
after AU-
007
administra
tion, Day 1
thru EOT
visit (28
days after
last
dose)|Mag
nitude of
Pharmaco
kinetic
changes in
the blood
after
dosing
determine
d by Half-
life (T1/2)
of AU-007,

The T1/2
of AU-007
will be
measured
at different
timepoints
after AU-
007
administra
tion, Day 1
thru EOT
visit (28
days after
last
dose)|Mag
nitude of
cytokine
changes in
the blood
after
dosing,
Day 1 thru
EOT visit
\((28 \quad\) days
after last
dose) \(\mid\) Mag
nitude of
immunoge
nicity after
dosing
with AU-
007 alone
or in
combinatio
aldesleuki
n,
Assessed
by
summarizi
ng the
number of
patients
who
develop
detectable
anti-drug
antibodies
(ADAs) at
different
timepoints
or
in
combinatio
n with
aldesleuki
n, Day 1
thru EOT
visit (28
days after
last
dose)|Eval
uate the
preliminar
\(y\) anti-
tumor
activity of

AU-007
alone or in
combinatio
n with
aldesleuki
n in
patients
with
unresectab
le locally
advanced
or
metastatic
cancer,
Clinical
anti-tumor
activity
will be
evaluated
using
convention
al
Response
Evaluation
Criteria in
Solid
Tumors
version 1.1
(RECIST
v1.1) and
modified
RECIST
v1.1., Day
1 thru EOT

\begin{tabular}{lllllll} 
SUSPENDED & Metastatic & GENETIC: & PHAS & INTER & Allocation: 48 \\
& Cancers & Gene & E2 & VENTI & NA|Interve
\end{tabular}
and severity
of
treatment-related
adverse events, Grade and type of toxicity per dose level; fraction of patients who experience
a DLT at a given dose level, and number and grade of each type of DLT, From time of cell infusion to two weeks after cell infusion

Efficacy, Safety, Oct-12
Monitorin Monitorin
g of CEA g and
levels, pre recording
and post of all

\begin{tabular}{|c|c|c|}
\hline mary & toxicities & CT \\
\hline Purpose: & until four & measurem \\
\hline TREATME & weeks after & ent of \\
\hline \multirow[t]{14}{*}{NT} & combined & SUVmax, \\
\hline & radio- & After 6 \\
\hline & chemo- & weeks of \\
\hline & immunoth & chemo- \\
\hline & erapy & immunoth \\
\hline & & erapy \(\mid\) Sec \\
\hline & & ondary \\
\hline & & resectabilit \\
\hline & & y, Decided \\
\hline & & by a \\
\hline & & multidisci \\
\hline & & plinary \\
\hline & & team 3-5 \\
\hline & & weeks after \\
\hline
\end{tabular}
the end of neoadjuva
nt
treatment |
Major
histopatho
logical
response
rate, at
surgery 4-6
weeks after
end of
neoadjuva
nt
therapy \(\mid R\)
-0 resection
rate, at
surgery 4-6
weeks after
the end of neoadjuva
nt
therapy \(\mid S\)
urgical
morbidity,
within 30
days after
surgery|O
verall
survival,
Measured
by median,
\(1-\) - 2-, and
3- year
survival
rates | Time
to local
and
systemic
progressio
n after R0-
resection, 5
years after
completion
of the trial
treatement
|Feasibilit
y, Defined
as
completion
of
tumors)
and being
alive 30
days
postoperat
ively.|Toxi
city
(according
to NCI-

CTCAE,
Version
4.0),

Within 30
days after
completion
of the trial treatement
RECRUITIN Gastric DRUG: PHAS INTER Allocation: 35

G
\begin{tabular}{llll} 
Cancer \(\mid\) Peri & Sintilimab in E2 & VENTI & NA | Interve \\
toneal & Combination & ONAL & ntion \\
Metastases | & With S- & & Model: \\
Ascites, & 1/oxaliplatin & & SINGLE_G \\
Malignant & With nab- & ROUP |Mas \\
& paclitaxel & king: \\
& intraperitone & NONE |Pri \\
& al & mary
\end{tabular}
\begin{tabular}{|c|c|c|c|}
\hline infusion | OT & Purpose: & calculated & year 1 Prog \\
\hline HER: Blood & TREATME & as a & ress free \\
\hline samples, & NT & summed & survival \\
\hline tumor biopsy & & ratio of & (PFS), PFS \\
\hline specimens, & & patients & is defined \\
\hline ascites, and & & with & as the time \\
\hline feces samples & & disappeare & from the \\
\hline will be & & d and & date of \\
\hline collected & & decreased & treatment \\
\hline & & ascites to the total & to the first date \\
\hline & & number of patients., 1 & \begin{tabular}{l}
disease, 1 \\
year|12
\end{tabular} \\
\hline & & & months os \\
\hline & & & rate, The definition \\
\hline & & & of 12- \\
\hline
\end{tabular}
months OS
rate is the
percentage
of patients
who had
NOT has
an event
before or at
12 months,
1
year |Obie
ctive
response
rate of
Solid
tumor
lesion (if
```

exists),
Number of
participant
s with
partial
response
or
complete
response
treating by
anloitnib
according
to RESIST
criteria
v1.1, 1
year|Safet
y

```
, Number
and
percentage
of
participant
s with
Adverse
Events
(any Grade
and Grade
3/4), \(\quad 1\)
year |Chan
ges of
ascite cell
subsets in
patients,

Changes in
ascites cell
subsets in
patients
before and
after
treatment.
Difference
\(s\) in the
proportion
of
subpopula
tions and
gene
expression
levels of
ascites cells

\begin{tabular}{|c|c|c|}
\hline mary & adverse & maximum \\
\hline Purpose: & events that & tolerated \\
\hline TREATME & are & dose \\
\hline \multirow[t]{14}{*}{NT} & considered & (MTD) or \\
\hline & study drug & maximum \\
\hline & related can & administer \\
\hline & be & ed dose \\
\hline & reported at & (MAD) (if \\
\hline & any time & no MTD is \\
\hline & after Study & defined) of \\
\hline & Day 50 or & margetuxi \\
\hline & 28 days & mab, up to \\
\hline & after the & Study Day \\
\hline & last & 28 for \\
\hline & infusion., & weekly \\
\hline & Up to 28 & dosing \(/ \mathrm{N}\) \\
\hline & days after & umber of \\
\hline
\end{tabular}
\begin{tabular}{ll} 
last & participant \\
infusion & s with dose \\
& limiting \\
& toxicities \\
& every 3- \\
& week \\
& dosing, \\
& Characteri \\
& ze \\
& maximum \\
& tolerated \\
& dose \\
& (MTD) or \\
& maximum \\
& administer \\
& ed dose \\
& (MAD) (if
\end{tabular}
no MTD is
defined) of
margetuxi
mab, Up to
Study Day
21 day for
every 3-
week
dosing|Co
ncentratio
n of
Margetuxi
mab at
Steady
State once-
weekly
doses of
margetuxi
mab, Study
Day 1, 2, 4,
\(5,8,15,22\),
29 ,36, 50,
every 4
weeks
thereafter
throughou
t study
completion
, average 2
months.|
Number of
patients
who
develop
```

treatment-
emergent
anti-drug
antibodies
to
margetuxi
mab
(Immunog
enicity),
Study Day
1, 22, 50,
every 4
weeks
thereafter
throughou
t study
completion

```
, average 2
months.|
Maximum
Concentrat
ion of
Margetuxi
mab at
Steady
State once
every 3
weeks
schedule,
Study Day
1, 2, 4, 5, 22,
29 ,36, 50,
every 3
weeks
thereafter
throughou
t study
completion
, average
10
months. |A
rea Under
the
Concentrat
ion Time
Curve at
Steady
State (AUC
ss) once
every
3
weeks

\section*{schedule,}

AUC is a
mathemati
cal
calculation
that
describes
the drug
concentrati
on in the
blood over
time.,
Study Day
1 through
Day
22 | Area
Under the

\section*{Concentrat}
ion Time
Curve at
Steady
State (AUC
ss) weekly
dosing
schedule,
AUC is a
mathemati
cal
calculation
that
describes
the drug
concentrati
on in the
blood over
time.,
Study Day
1 through
Day
8|Clearanc
e once
every 3
weeks
schedule,
Drug
clearance
is the
amount of
drug
removed
from the
\(1,2,4,5,22\),
29 ,36, 50,
every 3
weeks
thereafter
through
study
completion
, average
10
months | V
olume of
Distributio
\(n\) at Steady
State once
every 3
weeks, The
volume of
distributio
n is related
to a
whether
how much
drug is
distributed
to body
tissues or
remains in
the
bloodstrea

Day 1, 2, 4,
5, 22,
29 ,36, 50,
every 3
weeks
thereafter
through
study
completion
, average
10
months |T
erminal
Half-life
once every
3 weeks

\section*{schedule,}

Terminal
half-life is
the time
required to
divide the
plasma
concentrati
on by two
after
reaching
pseudo-
equilibriu
m., Study

Day 1
through
Day
22 |Termin
al Half-life
once every
weekly
dosing
schedule,
Terminal
half-life is
the time
required to
divide the
plasma
concentrati
on by two
after
reaching
pseudo-
equilibriu
m., Study

Day 1
through
Day
8|Number
of Patients
Who
Develop
Treatment-
emergent
Anti-drug
Antibodies
to
Margetuxi
mab once
every 3
weeks
schedule,
Study Day
\(1,2,4,5,22\),
29 ,36, 50,
every 3
weeks
thereafter
through
study
completion
, average
10
months \(\mid \mathrm{N}\)
umber of
Patients
with aCompleteResponse
(CR) ..... orPartialResponse(PR) to
Treatment,Investigatethepreliminar
y anti-
tumor
activity asmeasuredbyresponse totreatment
mab, using
convention
al
Response
Evaluation
Criteria in
Solid
Tumors
(RECIST)
1.1,

Assessed
at \(6,18,30\),
42 , and 54
weeks,
they every
treatment
discontinu
ation,
average 10
months |D
uration of
response,
Duration
of response
is
calculated
at the time
from \(C R\) or
PR to
relapse or
n,
Assessed
at \(6,18,30\),
42 , and 54
weeks,
they every
24 weeks
until
treatment
discontinu
ation,avera
ge \(\quad 10\)
months \(\mid \mathrm{Pr}\)
ogression
free

The
interval
between
the first
dose of
study
medication
and
progressio
n of
disease or
death from
any cause,
Assessed
at \(6,18,30\),
42 , and 54
```

weeks,
they every
24 weeks
until
treatment
discontinu
ation,
average 10
months|N
umber of
patients
with
complete
response,
partial
response,
stable

```
disease, or
progressiv
e disease
according
to each
CD16A-
158
genotype
(FF, FV,
VV), \(\quad \mathrm{Fc}\)
Receptor
polymorph
isms may
affect
responsive
ness to
immunoth
erapies, Fc
receptor
genotypes
assessed
prior to
study
treatment.
Response
to
treatment
assessed at
\(6,18,30\),
42 , and 54
weeks,
then every
24 weeks
until
discontinu
ation,
average 10
months \(\mid C\)
hanges in
immune
cell
subsets,
Changes in immune
cell subsets
may affect
responsive
ness to
immunoth erapies,

Before
infusion
and 1 hour
after
infusion on
Study Day
1, Study
Day 2,
before
infusion on
Study Day
22 and
50|Serum
cytokines
in the
blood,
Changes in
the levels
of
cytokines
in the
blood may
be related
to an
immune
response to
treatment.,
Study Day
\(1,2,4,5,22\),
29 ,36, 50,
every 3
weeks
thereafter
through
study
completion
, average
10
months |A
mount
HER2 in
the blood,
Levels of
HER2 in
the
bloodstrea
m may
indicate
response to
treatment.,
Before
infusion
and 1 hour
after
infusion on
Study Day
1, Study
Day 2,
before
infusion on
Study Day
22 and
50|Antibo
dy
dependent
cellular
cytotoxicit
y (ADCC)
activity,
ADCC
activity is
the ability
of immune
cells (like
lymphocyt
es) to kill
cells that
have
immune
markers
(like
HER2) on
the cell
surface,
Before
infusion
and 1 hour
after
infusion on
Study Day
1, Study
Day 2,
before
infusion on
Study Day
22 and
50 |Fc
receptor
occupancy,
Fc receptor
occupancy
is the
amount of
time that
the
receptor is
bound to
an immune
marker
(like
HER2) on
the cell
surface.,
Before
infusion
and 1 hour
after
infusion on
Study Day
\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|}
\hline & & & & & & & & 1, Study & \\
\hline & & & & & & & & \[
\text { Day } \quad 2,
\] & \\
\hline & & & & & & & & before & \\
\hline & & & & & & & & infusion on & \\
\hline & & & & & & & & Study Day & \\
\hline & & & & & & & & 22 and 50 & \\
\hline RECRUITIN & Upper & BIOLOGICA & PHAS & INTER & Allocation: & 20 & Tumor & Tumor & 2022/1/17 \\
\hline G & Digestive & L: & E2 & VENTI & NA | Interve & & uptake of & heterogene & \\
\hline & Tract Cancer & Radiopharma & & ONAL & ntion & & 68Ga- & ity, & \\
\hline & & ceutical 68Ga- & & & Model: & & PSMA, & Proportion & \\
\hline & & PSMA & & & SINGLE_G & & Proportion & of tumor & \\
\hline & & & & & ROUP | Mas & & & lesions & \\
\hline & & & & & king: & & participant & identified & \\
\hline & & & & & NONE | Pri & & s with & on CT that & \\
\hline & & & & & mary & & tumor & accumulat & \\
\hline & & & & & Purpose: & & uptake & e 68Ga- & \\
\hline & & & & & & & equal to or & PSMA in & \\
\hline
\end{tabular}
\begin{tabular}{|c|c|c|}
\hline DIAGNOST & greater & each \\
\hline \multirow[t]{16}{*}{IC} & than 1.5 & participant \\
\hline & times the & , At 1 hour \\
\hline & mean & post- \\
\hline & hepatic & injection \\
\hline & uptake & acquisition \\
\hline & (SUVmean & | Tumor \\
\hline & ) on 68Ga- & lesions that \\
\hline & PSMA PET & do not \\
\hline & according & accumulat \\
\hline & to the & e 68Ga- \\
\hline & criteria & PSMA, \\
\hline & suggested & Proportion \\
\hline & by the & of patients \\
\hline & European & with CT- \\
\hline & Associatio & identified \\
\hline & n of & tumor \\
\hline
\end{tabular}
\begin{tabular}{|c|c|}
\hline Nuclear & lesions that \\
\hline Medicine & do not \\
\hline (EANM), & accumulat \\
\hline At 1 hour & e 68Ga- \\
\hline post- & PSMA, At \\
\hline injection & 1 hour \\
\hline acquisition & post- \\
\hline & injection \\
\hline & acquisition \\
\hline & | Effective \\
\hline & half-life of \\
\hline & 68Ga- \\
\hline & PSMA, \\
\hline & Compariso \\
\hline & n of \\
\hline & uptakes of \\
\hline & 68Ga- \\
\hline
\end{tabular}
lesions and
healthy
tissue at
each time
points, At
30
minutes,
60 minutes
and, 120
minutes
post-
injection |
Radiation
dose
(mGy),

\section*{Estimated}
radiation
dose
(mGy)
delivered
to healthy
and tumor
tissues
from
177Lu-
PSMA
extrapolate
d from
68Ga-
PSMA
results, At
30


resulting
from any
cause., 3
years. |R0
resection
rate,
Proportion
of patients
who
achieved
R0
resection.,
Within 4
weeks
following
the
operation.
\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|}
\hline SUSPENDED & Oesophagea & DRUG: & PHAS & \begin{tabular}{l}
INTER \\
VENTI
\end{tabular} & Allocation: & 90 & Tumor & Proportion & 2022/3/22 \\
\hline & 1 & Capmatinib & & & NON_RAN & & response, & & \\
\hline & Adenocarci & DRUG: & & ONAL & DOMIZED & & Overall & unaccepta & \\
\hline & noma |Gastr & Spartalizuma & & & Intervention & & response & ble toxicity & \\
\hline & ic & b & & & Model: & & rate & of the & \\
\hline & Adenocarci & & & & SINGLE_G & & defined as & regimen & \\
\hline & noma & & & & ROUP | Mas & & the & during the & \\
\hline & & & & & king: & & proportion & first and & \\
\hline & & & & & NONE | Pri & & of patients & second & \\
\hline & & & & & mary & & with at & cycles of & \\
\hline & & & & & Purpose: & & least one & administra & \\
\hline & & & & & TREATME & & objective & tion, & \\
\hline & & & & & NT & & tumour & Presence of & \\
\hline & & & & & & & response & at least one & \\
\hline & & & & & & & (complete & of & \\
\hline & & & & & & & or partial) & (composite & \\
\hline & & & & & & & according & endpoint): & \\
\hline
\end{tabular}

concomita
nt
medication
s
* Non-
hematologi
cal AE
grade 鈮?
* Recurring
grade
2
pneumonit
is,
Myocarditi
s grade
鈮?
*

\section*{Autoimmu}
ne
hemolytic
anemia,
hemolytic
uremic
syndrome,
acquired
hemophili
a grade
鈮?
* Guillain-

Barre,
severe
peripheral
or
autonomic
```

neuropath
y,
transverse
myelitis,
encephaliti
s, aseptic
meningitis
*
Laboratory
abnormalit
y grade
鈮 ? for
\>7days
(except
nephritis
grade 3-4,
combined

```
elevations
of
aspartate
or alanine
transamina
se and total
bilirubin,
hyperglyce
mia, serum
electrolyte
s/enzymes
changes
without
clinical
impact)
* Febrile
neutropeni
documente
d infection
with
absolute
neutrophil
count \(\backslash 10\)
\^9/L,
grade 3
neutropeni
a \>7days,
grade 4
neutropeni
a or
thrombocy
topenia, or
bleeding
with
platelet
transfusion
* AE with
discontinu
ation
\>21days
*
Significant
drug-
related AE ,
Day
42 | Propor
tion of
unaccepta
ble toxicity
of the
regimen
during the
whole
treatment
course,
Presence of
at least one
of
(composite
endpoint):
* Adverse
event (AE)
grade \>3
(NCI-
CTCAE
v5), at least
unrelated
to disease,
progressio
n,
intercurren
t illness,
concomita
nt
medication
s
* Non-
hematologi
cal AE
grade 鈮?
* Recurring
grade 2
pneumonit
is,
Myocarditi
s grade
鈮?
*
Autoimmu
ne
hemolytic
anemia,
hemolytic
uremic
syndrome,
* Guillain-

Barre,
severe
peripheral
or
autonomic
neuropath
y,
transverse
myelitis,
encephaliti
s, aseptic
meningitis

Laboratory
abnormalit
y grade
鈮 ? for
\>7days
(except
nephritis
grade 3-4,
combined
elevations
of
aspartate
or alanine
transamina
se and total
bilirubin,
hyperglyce
mia, serum
electrolyte
s/enzymes
changes
without
clinical
impact)
* Febrile
neutropeni
a,
documente
d infection
with
absolute
neutrophil
count \(\backslash<10\)
\^9/L,
grade 3
neutropeni
a \>7days, grade 4
neutropeni
a or
thrombocy
topenia, or
bleeding
with
platelet
transfusion
* AE with
discontinu
ation
\>21days
Significant drug-
related AE,
12 months or
treatment
discontinu
ation \(\mid\) Prop
ortion of
patients
with
adverse
events
during the
whole
treatment
course, All
adverse
events
during the
whole
treatment
course, 12
months or
treatment
discontinu
ation | Dur
ation of
overall
response,
Time
between
the first
objective
response,
partial or
complete
(RECIST
1.1) and
the first
radiologica
1
progressio
n, with
response
assessment
every 9
weeks, up
months, 24
months \(\mid \mathrm{Ti}\)
me to
response,
Time
between
inclusion
and the
first
occurrence
of tumor
objective
response
(complete
or partial,
according
to RECIST
1.1) or the
end of the
study, with
response
assessment
every 9
weeks, up
to 24
months, 24
months \(\mid \mathrm{Pr}\)
ogression-
free
survival,
Time
between
inclusion
date of the
first
radiologica
1
progressio
n
(according
to RECIST
1.1), death
(any
cause), or
last follow-
up
(maximum
\(=24\)
months),
occurs
first., 24
months |O
verall
survival,
Time
between
inclusion
and death
(any cause)
or
last
follow-up
(maximum
\(=24\)
months),
whichever
\begin{tabular}{|c|c|c|c|c|c|c|c|c|}
\hline & & & & & & & \begin{tabular}{l}
occurs \\
first, \(\quad 24\) \\
months
\end{tabular} & \\
\hline ACTIVE_NO & Stomach & PROCEDURE: & OBSER & Observation & 3000 & 1-year & The & 2010/1/1 \\
\hline T_RECRUITI & Neoplasms & Gastrectomy; & VATI & al Model: & & overall & incidence & \\
\hline NG & Neoplasm & Hepatectomy & ONAL & | Time & & survival, & of gastric & \\
\hline & Metastasis & & & Perspective: & & The & cancer & \\
\hline & & & & p & & proportion & liver & \\
\hline & & & & & & & metastasis & \\
\hline & & & & & & gastric & cases, The & \\
\hline & & & & & & cancer & rate of & \\
\hline & & & & & & liver & gastric & \\
\hline & & & & & & metastasis & & \\
\hline & & & & & & patients & liver & \\
\hline & & & & & & that & metastasis & \\
\hline & & & & & & survived & cases & \\
\hline & & & & & & beyond & divided by & \\
\hline
\end{tabular}
\begin{tabular}{ll} 
one-year & all gastric \\
follow-up & cancer \\
period., & cases in the \\
\(2011 / 01 / 0\) & study \\
\(1-\) & period., \\
\(2020 / 12 / 3\) & \(2010 / 01 / 0\) \\
\(1 \mid 3-\) year & 1 - \\
overall & \(2019 / 12 / 3\) \\
survival, & \(1 \mid\) The \\
The & proportion \\
proportion & for \\
(\%) & of synchrono \\
gastric & us and \\
cancer & metachron \\
liver & ous liver \\
metastasis & metastases \\
patients & cases, The
\end{tabular}
\begin{tabular}{|c|c|}
\hline that & proportion \\
\hline survived & (\%) of \\
\hline beyond & synchrono \\
\hline three-year & us or \\
\hline follow-up & metachron \\
\hline period., & ous gastric \\
\hline 2011/01/0 & cancer \\
\hline 1- & liver \\
\hline 2021/12/3 & metastases \\
\hline 1|5-year & cases in all \\
\hline overall & gastric \\
\hline survival, & cancer \\
\hline The & cases, \\
\hline proportion & 2010/01/0 \\
\hline (\%) of & 1- \\
\hline gastric & 2019/12/3 \\
\hline cancer & 1|The \\
\hline
\end{tabular}
\begin{tabular}{ll} 
liver & survival of \\
metastasis & patients \\
patients & that \\
that & recieved \\
survived & different \\
beyond & therapeuti \\
five-year & c methods, \\
follow-up & The \\
period., & proportion \\
\(2011 / 01 / 0\) & (\%) of \\
\(1-\) & patients \\
\(2021 / 12 / 3\) & under \\
1 & different \\
& therapies \\
& that \\
& survived
\end{tabular}
beyond
specific
follow-up
period.,
2010/01/0
1 -
2019/12/3
1 |The
prognostic
predictive
value for
patients
with
different
C-GCLM
classificati
on, The
proportion
\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|}
\hline & & & & & & & & (\%) & \\
\hline & & & & & & & & patients & \\
\hline & & & & & & & & different & \\
\hline & & & & & & & & classificati & \\
\hline & & & & & & & & on th & \\
\hline & & & & & & & & survived & \\
\hline & & & & & & & & beyond & \\
\hline & & & & & & & & specific & \\
\hline & & & & & & & & follow-up & \\
\hline & & & & & & & & period., & \\
\hline & & & & & & & & 2010/01/0 & \\
\hline & & & & & & & & 1- & \\
\hline & & & & & & & & 2019/12/3 & \\
\hline & & & & & & & & 1 & \\
\hline RECRUITIN & Stage IV & RADIATION: & NA & INTER & Allocation: & 28 & Overall & ORR by & 2020/8/7 \\
\hline G & Esophageal & Radiation & & VENTI & NA | Interve & & response & immune- & \\
\hline & Adenocarci & Therapy (RT) & & ONAL & ntion & & rate (ORR), & Modified & \\
\hline
\end{tabular}
\begin{tabular}{lllll} 
noma \(\mid\) Stage & Model: & Proportion & Response \\
IV & SINGLE_G & of patients & Evaluation \\
Esophageal & ROUP|Mas & who & Criteria in \\
Squamous & king: & achieve as & Solid \\
Cell & NONE |Pri & their best & Tumors \\
Carcinoma & mary & overall & (iRECIST), \\
Stage IV & Purpose: & response & Will be \\
Gastric & TREATME & according & determine \\
Cancer |Sta & NT & & to & d \\
ge IV & & Response & immune- \\
Adenocarci & & Evaluation & Modified \\
noma of the & & Criteria in & Response \\
Gastroesoph & & Solid & Evaluation \\
ageal & & Tumors & Criteria in \\
Junction St & & (RECIST) & Solid \\
age IVA & & criteria: & (iRECIST).
\end{tabular}
\begin{tabular}{|c|c|c|}
\hline Adenocarci & Stable & Immune \\
\hline noma|Stage & disease & Complete \\
\hline IVA & (SD), & Response \\
\hline Esophageal & partial & (iCR), \\
\hline Squamous & response & Partial \\
\hline Cell & (PR), & Response \\
\hline Carcinoma & confirmed & (iPR), or \\
\hline Stage IVA & Complete & Stable \\
\hline Gastric & Response & Disease \\
\hline Cancer | Sta & (CR), or & (iSD) per \\
\hline ge IVA & progressiv & definitions \\
\hline Adenocarci & e disease & of CR, PR, \\
\hline noma of the & (PD). & and SD, \\
\hline Gastroesoph & Correspon & but \\
\hline ageal & ding exact & occurring \\
\hline Junction \(\mid\) St & confidence & after initial \\
\hline age IVB & intervals & immune \\
\hline
\end{tabular}
\begin{tabular}{|c|c|c|}
\hline Esophageal & will be & unconfirm \\
\hline Adenocarci & reported & ed \\
\hline noma|Stage & for the & progressiv \\
\hline IVB & entire & e disease \\
\hline Esophageal & cohort and & (iUPD). \\
\hline Squamous & stratified & The same \\
\hline Cell & by & definition \\
\hline Carcinoma | & histologic & will be \\
\hline Stage IVB & subtype, & used for \\
\hline Gastric & programm & per lesion \\
\hline Cancer \({ }^{\text {S }}\) Sa & ed cell & analysis. \\
\hline ge IVB & death & PD will be \\
\hline Gastroesoph & protein & designated \\
\hline ageal & (PD- & for all \\
\hline Junction & 1)/progra & patients \\
\hline Adenocarci & mmed & with PD \\
\hline noma|Meta & death- & determinat \\
\hline
\end{tabular}
\begin{tabular}{|c|c|c|}
\hline static Anal & ligand & ion by \\
\hline Canal & (PD-L1) & RECIST \\
\hline Carcinoma & status, & v1.1 or \\
\hline Metastatic & microsatell & immune- \\
\hline Colorectal & ite & confirmed \\
\hline Carcinoma & instability & progressiv \\
\hline Metastatic & (MSI), and & e disease \\
\hline Esophageal & organs & (iCPD) by \\
\hline Carcinoma & treated if & iRECIST. \\
\hline Metastatic & sample & Unconfirm \\
\hline Gastric & size & ed \\
\hline Carcinoma & allows. & response \\
\hline Metastatic & Patients & for all \\
\hline Gastroesoph & with & patients \\
\hline ageal & unevaluabl & designated \\
\hline Junction & e or & as iUPD. \\
\hline Adenocarci & unknown & Will be \\
\hline
\end{tabular}
\begin{tabular}{|c|c|c|}
\hline noma | Meta & response & reported as \\
\hline static & status will & proportion \\
\hline Hepatocellu & be & of response \\
\hline lar & considered & and \\
\hline Carcinoma & nonrespon & correspon \\
\hline Metastatic & ders., Up & ding exact \\
\hline Malignant & to 8 weeks & confidence \\
\hline Digestive & & intervals. \\
\hline System & & Patients \\
\hline Neoplasm| & & with \\
\hline Metastatic & & unevaluabl \\
\hline Small & & or \\
\hline Intestinal & & unknown \\
\hline Carcinoma | & & response \\
\hline Pancreatobil & & status will \\
\hline iary & & be \\
\hline Carcinoma & & considered \\
\hline
\end{tabular}
\begin{tabular}{ll} 
Pathologic & nonrespon \\
Stage IV & ders., \begin{tabular}{l} 
Up
\end{tabular} \\
Gastric & to \\
Cancer & weeks \(\mid\) Pro \\
AJCC & gression \\
v8|Patholo & free \\
gic Stage & survival \\
IVA & (PFS), PFS \\
Esophageal & is defined \\
Adenocarci & as \\
noma AJCC & duration of \\
v8|Patholo & time from \\
gic Stage & start \begin{tabular}{l} 
of \\
IVA
\end{tabular} \\
Esophageal & radiation \\
Squamous & treatment \\
Cell & to time of
\end{tabular}
\begin{tabular}{ll} 
Carcinoma & n or death \\
AJCC & a \\
v8|Patholo & proportion \\
gic Stage & with exact \\
IVB & confidence \\
Esophageal & intervals \\
Adenocarci & and will be \\
noma AJCC & reported \\
v8|Patholo & for \\
gic Stage & entire \\
IVB & cohort and \\
Esophageal & stratified \\
Squamous & by \\
Cell & histologic \\
Carcinoma & subtype, \\
AJCC & PD1/PDL1 \\
v8|Patholo & status,
\end{tabular}
\begin{tabular}{ll} 
gic Stage & MSI, and \\
IVB & organs \\
Gastroesoph & treated if \\
ageal & sample \\
Junction & size \\
Adenocarci & allows. \\
noma AJCC & Time to \\
v8|Postneo & local \\
adjuvant & progressio \\
Therapy & n will be \\
Stage & described \\
Esophageal & using the \\
Squamous & cumulative \\
Cell & incidence \\
Carcinoma & method \\
AJCC & and \\
v8|Postneo & compariso
\end{tabular}
\begin{tabular}{ll} 
adjuvant & ns between \\
Therapy & strata via \\
Stage IV & Gray's test, \\
Gastric & if sample \\
Cancer & size \\
AJCC & allows; \\
v8|Postneo & Otherwise, \\
adjuvant & Kaplan- \\
Therapy & Meier \\
Stage & methodolo \\
Gastroesoph & gy will be \\
ageal & used and \\
Junction & compariso \\
Adenocarci & ns will be \\
noma AJCC & made via \\
v8|Postneo & log-rank \\
adjuvant & test; and
\end{tabular}
\begin{tabular}{ll} 
Therapy & Cox \\
Stage IVA & proportion \\
Esophageal & al hazards \\
Adenocarci & analysis, if \\
noma AJCC & possible., \\
v8|Postneo & Up to 36 \\
adjuvant & months O \(^{\prime}\) \\
Therapy & verall \\
Stage IVA & survival \\
Esophageal & (OS), OS \\
Squamous & will \\
Cell be \\
Carcinoma & measured \\
AJCC & from the \\
v8|Postneo & date \(\quad\) of \\
adjuvant & initiation \\
Therapy & of RT. OS is
\end{tabular}
\begin{tabular}{ll} 
Stage IVA & the time \\
Gastroesoph & from the \\
ageal & date of \\
Junction & initiation \\
Adenocarci & of RT to the \\
noma AJCC & date of \\
v8|Postneo & death due \\
adjuvant & to \\
Therapy & cause. \\
Stage IVB & Censoring \\
Esophageal & will be \\
Adenocarci & performed \\
noma AJCC & using the \\
v8|Postneo & date of last \\
adjuvant & known \\
Therapy & contact for \\
Stage IVB & those who
\end{tabular}
\begin{tabular}{ll} 
Esophageal & are alive at \\
Squamous & the time of \\
Cell & analysis. \\
Carcinoma & OS will be \\
AJCC & reported \\
V8|Postneo & for \\
adjuvant & entire \\
Therapy & cohort and \\
Stage IVB & stratified \\
Gastroesoph & by \\
ageal & histologic \\
Junction & subtype, \\
Adenocarci & PD1/PDL1 \\
noma AJCC & status, \\
v8|Stage IV & MSI, and \\
Anal Cancer & organs \\
AJCC & treated if
\end{tabular}
\begin{tabular}{ll} 
v8|Stage IV & sample \\
Colorectal & size \\
Cancer & allows., Up \\
AJCC & to \\
v8|Stage IV & months |D \\
Hepatocellu & etermine \\
lar & local \\
Carcinoma & control in \\
AJCC & radiated \\
v8|Stage & lesion(s), \\
IVA & Local \\
Colorectal & control \\
Cancer & will be \\
AJCC & defined as \\
v8|Stage & absence of \\
IVA & per-lesion \\
Hepatocellu & PD in an
\end{tabular}
\begin{tabular}{|c|c|}
\hline lar & irradiated \\
\hline Carcinoma & lesion (as \\
\hline AJCC & defined \\
\hline v8|Stage & above, a \\
\hline IVB & 20\% \\
\hline Colorectal & increase in \\
\hline Cancer & the longest \\
\hline AJCC & diameter \\
\hline v8 | Stage & since the \\
\hline IVB & treatment \\
\hline Hepatocellu & started or a \\
\hline lar & 5 mm \\
\hline Carcinoma & increase \\
\hline AJCC & over the \\
\hline v8|Stage & nadir \\
\hline IVC & longest \\
\hline Colorectal & diameter \\
\hline
\end{tabular}
Cancer from
AJCC v8 initiation
of
radiation
therapy to
time of
progressio
n of
radiated
lesion(s),
Up to 36
months |T
umor
measurem
ent change
by RECIST
or

Abscopal
response
rate is
defined as
present for
all patients
for whom
an
unirradiate
d target or
non-target
lesion
previously
determine
d to be a
progressin
described
proportion
with exact
confidence
intervals
and will be
reported
for the
cohort,
reported
for RECIST
and
iRECIST
definitions,
and
stratified
by
histologic
subtype,
PD1/PDL1
status,
MSI, and
organs
treated if
sample
size
allows, Up
to 8
weeks|Inc
idence of
New
metastatic
lesions,
From
initiation
of
radiation
therapy to
first
imaging
scan after
radiation
therapy
completion
, time to
new
metastatic
lesions will
be
described
using the
cumulative
incidence
method
and
compariso
ns between
strata via
Gray's test,
if sample
size
allows;
Kaplan-
Meier
methodolo
gy will be
used and
compariso
ns will be
made via
log-rank
test; and
Cox
proportion
al hazards
analysis, if
possible.,
Up to 8
weeks \(\mid\) Fre
quency of
grade 3 or
higher
adverse
events,
Common
Terminolo
gy Criteria
for
Adverse
Events
(CTCAE
v.5.0) will
be used to
determine
frequency
of grade 3
or higher
adverse
events
reported as
a
proportion
with
correspon
ding exact
confidence
intervals.,
Up to 36
months |Ti
me to new
systemic
therapy,
Time to
new
systemic
therapy
from
initiation
of
radiation
therapy to
initiation
of new
systemic
therapy
will be
\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|}
\hline & & & & & & & & described using & \\
\hline & & & & & & & & Kaplan- & \\
\hline & & & & & & & & Meier & \\
\hline & & & & & & & & product & \\
\hline & & & & & & & & limit & \\
\hline & & & & & & & & estimators, & \\
\hline & & & & & & & & and Cox & \\
\hline & & & & & & & & proportion & \\
\hline & & & & & & & & al hazards & \\
\hline & & & & & & & & analysis, if & \\
\hline & & & & & & & & possible., & \\
\hline & & & & & & & & Up to 36 months & \\
\hline COMPLETE & Advanced & BIOLOGICA & PHAS & INTER & Allocation: & 116 & Incidence & Proportion & 2019/2/26 \\
\hline D & Solid & L: ALKS & E1|PH & VENTI & NON_RAN & & of Adverse & of subjects & \\
\hline & Tumors & 4230 | BIOLO & ASE2 & ONAL & DOMIZED| & & Events & with & \\
\hline
\end{tabular}
\begin{tabular}{llll} 
GICAL: & Intervention & (AEs), and objective \\
Pembrolizum & Model: & identify & evidence of \\
ab & PARALLEL & the RP2D & Complete \\
& | Masking: & of ALKS & Response \\
& NONE |Pri & \(4230 \quad\) in & (CR)/imm
\end{tabular}
\begin{tabular}{ll} 
days after & hic images, \\
last dose of & From time \\
study & of \\
drug, & initiation \\
assessed & of therapy \\
up to 24 & until the \\
months \(\mid \mathrm{N}\) & date of first \\
umber of & documente \\
subjects & d tumor \\
experienci & progressio \\
ng \(\quad\) AEs & n, assessed \\
that are & up to 24 \\
both & months \(\mid\) Pr \\
serious & oportion of \\
and drug- & subjects \\
related in & with \\
Part & B, objective
\end{tabular}
\begin{tabular}{ll} 
Includes & evidence of \\
AEs that & Partial \\
are both & Response \\
serious & \((\mathrm{PR}) / \mathrm{imm}\) \\
and drug- & une PR \\
related, & (iPR), ORR \\
From time & will be \\
of & based on \\
initiation & investigato \\
of therapy & r review of \\
until 30 & radiograph \\
days after & ic or \\
last dose of & photograp \\
study & hic images, \\
drug, & From time \\
assessed & of \\
up to 24 & initiation
\end{tabular}
\begin{tabular}{ll} 
months \(\mid \mathrm{Cl}\) & of therapy \\
inical & until the \\
Activity of & date of first \\
combinatio & documente \\
\(n\) & d tumor \\
treatment & progressio \\
with ALKS & n, assessed \\
4230 and & up to 24 \\
pembroliz & months |D \\
umab in & uration of \\
each Part B response in \\
tumor & subjects \\
type., & with \\
Overall & CR/iCR, \\
Response & \(C R / i C R\)
\end{tabular} \begin{tabular}{ll} 
rate (ORR) & duration, \\
will be & Time from
\end{tabular}
based on the first
investigato documenta
r review of tion of
radiograph complete
ic and response,
photograp measured
hic images, approxima
From time tely every 6
of therapy weeks, to
until the the first
date of first documenta
documente tion of
d tumor objective
progressio tumor
n , assessed progressio
up to 24

\title{
up to 24
}
months)|
Duration
of response
in subjects
with
PR/iPR,
PR/iPR
duration,
Time from
the first
documenta
tion of
complete
response,
measured
approxima
tely every 6
weeks, to
the first
documenta
tion of
objective
tumor
progressio
n or death
due to any
cause
(estimated
up to 24
months)|
Non-
n for Part
B, Time
from first
dose of SC
ALKS 4230
to the time
of
progressio
n or death,
Assessed
up to 24
months \(\mid \mathrm{O}\)
verall
survival
for Part B,
Time from
first dose of SC

ALKS 4230
to the time
of death,
Assessed
up to 24
months |Se
rum
concentrati
ons of
ALKS 4230
will be
determine
d at
various
time
points,
Concentrat
ion vs time
and
standard
pharmacok
inetic (PK)
parameters
will be
summarize
d by dose
level, From
time of
initiation
of therapy
until the
last
treatment
cycle (each
cycle is 21
days),
assessed
up to 24
months \(\mid \mathrm{Se}\)
rum will be
assayed for
the
presence of
anti-ALKS
4230
antibodies,
Results
will be
summarize
treatment
cycle (each
cycle is 21
days),
assessed
up to 24
months |I
mmunoph
enotyping
of
mononucle
ar cells will
be
performed
by flow
cytometry
at various
time
points,
Results
will be
summarize
d by dose
level, From
time of

\section*{initiation}
of therapy
until the
last
treatment
cycle (each
cycle is 21
days),
assessed
up to 24
months|Se
rum
concentrati
ons of
proinflam
matory
cytokines
will be
assessed
using a
multiplex
method at
various
time
points,
Results
will be
summarize
d by dose
level, From
time of
initiation
of therapy
until the
\begin{tabular}{|c|c|c|c|c|c|c|c|c|}
\hline & & & & & & & last treatment cycle (each cycle is 21 days), assessed up to 24 months & \\
\hline COMPLETE & Melanoma & DRUG: Dose & PHAS & INTER & Allocation: & 557 & Part 1 Dose Escalation: & 2016/12/19 \\
\hline D & Renal Cell & Escalation & E1|PH & VENTI & NON_RAN & & Incidence of Dose- & \\
\hline & Carcinoma & Doublet: & ASE2 & ONAL & DOMIZED | & & limiting Toxicity (DLT) & \\
\hline & Non Small & Combination & & & Intervention & & During the DLT & \\
\hline & Cell Lung & of NKTR-214 & & & Model: & & Evaluation Window, & \\
\hline & Cancer \| Uro & + & & & PARALLEL & & Part 1of the study was a & \\
\hline & thelial & nivolumab| & & & | Masking: & & dose-escalation phase & \\
\hline & Carcinoma & DRUG: Dose & & & NONE | Pri & & that evaluated the safety & \\
\hline & Triple & Expansion & & & mary & & and tolerability and & \\
\hline
\end{tabular}
\begin{tabular}{llll} 
Negative & Doublet: & Purpose: & defined the maximum \\
Breast & Combination & TREATME & tolerated dose or \\
Cancer \(\mid\) HR & of NKTR-214 & NT & recommended Phase 2 \\
+/HER2- & + & & dose of the NKTR- \\
Breast & nivolumab & & \(214 /\) nivolumab doublet \\
Cancer \(\mid\) Gas & DRUG: & across
\end{tabular}
\begin{tabular}{|c|c|}
\hline Combination & dosing). Patients were \\
\hline of NKTR- & counted only once under \\
\hline 214+ & each preferred \\
\hline nivolumab+ & term.|Part 3 Schedule \\
\hline \multirow[t]{10}{*}{ipilimumab} & Finding: Incidence of \\
\hline & Dose-limiting Toxicity (DLT) During the DLT \\
\hline & Evaluation Window, \\
\hline & Part 3 of the study was a schedule finding phase \\
\hline & to establish the \\
\hline & recommended phase 2 \\
\hline & dosing schedules for \\
\hline & Part 4 and assess the safety and tolerability \\
\hline & for the NKTR- \\
\hline & 214/nivolumab/ipilimu \\
\hline
\end{tabular}
mab triplet combination.
The results presented
are for the DLT
Population., Dose-
limiting toxicities (DLTs)
were assessed during a
3-week (21-day) DLT
evaluation period
beginning with the first
dose
of
ipilimumab.|Part 2 and
Part 4: Objective
Response Rate (ORR)
Per RECIST 1.1 at
Recommended Phase 2
Dose (RP2D), Objective
Response Rate (ORR)
per Response Evaluation Criteria in Solid Tumors version 1.1 (RECIST 1.1) at Recommended Phase 2 Dose (RP2D).

ORR is defined as the percentage of enrolled participants who achieved a Best Overall
Response (BOR) of Complete Response (CR) or Partial Response (PR). CR is defined as disappearance of all target lesions. Any pathological lymph
nodes (whether target or non-target) had to have reduction in short axis to \(\backslash<10 \mathrm{~mm}\). PR is defined as at least a \(30 \%\) decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters. ORR is calculated as the sum of CR and PR., Tumor assessment at Screening then every 8 weeks (卤 7 days) from Cycle 1 Day 1 and end of treatment (unless scan done within
4 weeks) up to
\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|}
\hline \multirow[b]{2}{*}{RECRUITIN} & \multirow[b]{2}{*}{Malignant} & \multirow[b]{2}{*}{BIOLOGICA} & \multirow[b]{2}{*}{PHAS} & \multirow[b]{2}{*}{INTER} & \multirow[b]{2}{*}{Allocation:} & \multirow[b]{2}{*}{30} & \multicolumn{2}{|l|}{\begin{tabular}{l}
approximately
\[
27
\] \\
months.
\end{tabular}} & \\
\hline & & & & & & & Number of & Response & Jul-16 \\
\hline \multirow[t]{14}{*}{G} & Neoplasm & L: EpCAM & E1 & VENTI & NA | Interve & & participant & rate of & \\
\hline & of & CAR-T cells & & ONAL & ntion & & s with & participant & \\
\hline & Nasopharyn & & & & Model: & & treatment- & s treated & \\
\hline & \(x \quad\) TNM & & & & SINGLE_G & & related & with & \\
\hline & Staging & & & & ROUP | Mas & & adverse & EpCAM & \\
\hline & Distant & & & & king: & & events/do & CAR-T & \\
\hline & Metastasis & & & & NONE | Pri & & se limiting & cells & \\
\hline & (M) | Breast & & & & mary & & toxicity as & assessed & \\
\hline & Cancer & & & & Purpose: & & assessed & by RECIST & \\
\hline & Recurrent | & & & & TREATME & & by CTCAE & v1.1, & \\
\hline & Gastric & & & & NT & & v4.0, & Determine & \\
\hline & Cancer With & & & & & & Determine & whether & \\
\hline & Metastasis & & & & & & the largest & there is & \\
\hline & & & & & & & dose of & therapeuti & \\
\hline
\end{tabular}
\begin{tabular}{ll} 
EpCAM & c efficacies \\
CAR-T & of the safe \\
cells for & dose \\
patients & infusion of \\
with & EpCAM \\
nasophary & CAR-T \\
ngeal & cells for \\
carcinoma, & patients \\
breast & with solid \\
cancer and & tumors., 24 \\
other & months \\
tumors & after \\
expressing & infusion of \\
EpCAM., 6 & the CAR-T \\
weeks after & cells |Persi \\
infusion & stence of
\end{tabular}
\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|}
\hline & & & & & & & & CAR-T & \\
\hline & & & & & & & & & \\
\hline & & & & & & & & correlation & \\
\hline & & & & & & & & with the & \\
\hline & & & & & & & & Response & \\
\hline & & & & & & & & \[
\text { rate, } \quad 24
\] & \\
\hline & & & & & & & & months & \\
\hline & & & & & & & & post CAR- & \\
\hline & & & & & & & & T infusion & \\
\hline RECRUITIN & Gastric & DRUG: & PHAS & INTER & Allocation: & 100 & major & complete & 2022/7/1 \\
\hline G & Cancer & camrelizuma & E1|PH & VENTI & RANDOMI & & pathologic & pathologic & \\
\hline & & b+chemother & ASE2 & ONAL & ZED|Interv & & response & response & \\
\hline & & apy |DRUG: & & & ention & & rate, & rate, & \\
\hline & & Chemotherap & & & Model: & & complete & complete & \\
\hline & & y & & & PARALLEL & & or subtotal & regression & \\
\hline & & & & & | Masking: & & regression & (no & \\
\hline & & & & & NONE | Pri & & ( \(\backslash<10 \%\) & residual & \\
\hline
\end{tabular}
\begin{tabular}{lll} 
mary & residual & tumor per \\
Purpose: & tumor per & tumor \\
TREATME & tumor & bed), one \\
NT & \begin{tabular}{l} 
bed), one \\
month \\
after
\end{tabular} & after \\
& surgery & 0 resection \\
& & rate, \\
& & surgically \\
& & removed \\
& & tissue \\
& & without \\
& & residual \\
& & cancer \\
& & cells, one \\
& & month \\
& &
\end{tabular}
surgery \({ }^{\mathrm{O}}\)
verall
survival,
the time
from the
start of
randomiza
tion to
death due
to any
cause., 3
years|Dise
ase-free
survival,
the time
from the
start of
randomiza
tion to the
incurable
resection,
local
recurrence
or
metastasis,
or death
from any
cause., 3
years \(\mid\) peri
operative
complicati
ons,
perioperati
ve
\(\left.\begin{array}{llllll} & & & \begin{array}{l}\text { complicati } \\ \text { ons, } \\ \text { the }\end{array} \\ \text { time from }\end{array}\right)\)
\begin{tabular}{|c|c|c|c|c|}
\hline oglioma|Est & Analysis |OT & mary & fusion & covariance \\
\hline rogen & HER: & Purpose: & protein & (ANCOVA \\
\hline Receptor & Pharmacologi & TREATME & CDX-1401 & model \\
\hline Negative |E & cal & NT & with and & with post- \\
\hline strogen & Study | DRU & & without & treatment \\
\hline Receptor & G: Sirolimus & & sirolimus, & levels \\
\hline Positive |Gli & & & as & modeled \\
\hline oblastoma | & & & evaluated & as a \\
\hline Hormone- & & & according & function \\
\hline Resistant & & & to the NCI & pretreatme \\
\hline Prostate & & & CTCAE & nt levels \\
\hline Cancer \({ }^{\text {M }}\) Met & & & scale & and main \\
\hline astatic & & & version 4.0, & effects \\
\hline Prostate & & & The safe & correspon \\
\hline Carcinoma & & & schedule of & ding to the \\
\hline Metastatic & & & the & \(3+3\) \\
\hline Renal Cell & & & combinato & design., \\
\hline
\end{tabular}

Cancer \(\mid\) Rec
urrent Adult
Brain
Neoplasm |
Recurrent
Bladder
Carcinoma
Recurrent
Breast
Carcinoma
Recurrent
Colorectal
Carcinoma |
Recurrent
Esophageal
Carcinoma |
Recurrent
rial \(\quad U p\) to 12
regimen is months
established post-
at the dose treatment |
before 2/6 NY-ESO-1
patients specific
experience humoral
dose- immunity,
limiting ANCOVA
toxicity. model
Estimated with post-
using a treatment
one-sided, levels
\(95 \%\), exact modeled
binomial as a
confidence function
interval pretreatme

Gastric
Carcinoma |
Recurrent
Hepatocellu
lar
Carcinoma |

\section*{Recurrent}

Lung
Carcinoma |
Recurrent
Melanoma
Recurrent
Ovarian
Carcinoma|
Recurrent
Prostate
Carcinoma |
\begin{tabular}{ll} 
(Clopper- & nt levels \\
Pearson)., & and main \\
Up to 12 & effects \\
months & correspon \\
post- & ding to the \\
treatment & \(3 \quad+\quad 3\) \\
& \begin{tabular}{ll} 
design., \\
& Up to 12 \\
& months \\
& post- \\
& treatment
\end{tabular}
\end{tabular}
Recurrent
Renal Cell
Carcinoma
Recurrent
Uterine
Corpus
Carcinoma
Resectable
Hepatocellu
lar
Carcinoma
Sarcoma|St
age ..... IA
Breast
Cancer Sta
ge IA
Ovarian
Cancer |Sta
ge ..... IA
Uterine
Corpus
Cancer |Sta
ge IB Breast
Cancer \({ }^{\text {Sta }}\)
ge ..... IB
Ovarian
Cancer |Sta
ge ..... IB
Uterine
Corpus
Cancer |Sta
ge ..... IC
Ovarian
Cancer | Sta

\section*{ge II Uterine}

\section*{Corpus}

Cancer |Sta
ge IIA Breast
Cancer |Sta
ge IIA Lung
Carcinoma|
Stage IIA
Ovarian
Cancer \| Sta
ge IIB Breast
Cancer |Sta
ge IIB
Esophageal
Cancer \({ }^{\text {Sta }}\)
ge IIB Lung
Carcinoma
Stage IIB
Ovarian
Cancer |Sta
ge IIB Skin
Melanoma
Stage IIC
Ovarian
Cancer |Sta
ge IIC Skin
Melanoma
Stage IIIA
Breast
Cancer | Sta
ge IIIA
Esophageal
Cancer | Sta
ge IIIA Lung
Carcinoma
Stage IIIA
Ovarian
Cancer |Sta
ge IIIA Skin
Melanoma
Stage IIIAUterine
Corpus
Cancer | Sta
ge ..... IIIB
Breast
Cancer | Sta
ge ..... IIIB
Esophageal
Cancer |Sta
ge ..... IIIB

Ovarian
Cancer |Sta
ge IIIB Skin
Melanoma
Stage IIIB
Uterine
Corpus
Cancer | Sta
ge IIIC
Breast
Cancer \| Sta
ge IIIC
Esophageal
Cancer | Sta
ge IIIC
Ovarian
Cancer | Sta
ge IIIC Skin
Melanoma |
Stage IIICUterineCorpus
Cancer | Sta
ge ..... IVBladderUrothelial
Carcinoma
Stage IVEsophageal
Cancer |Sta
ge ..... IVOvarianCancer \({ }^{\text {Sta }}\)
ge ..... IV
\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|}
\hline & Prostate & & & & & & & & \\
\hline & Cancer \| Sta & & & & & & & & \\
\hline & ge IV Skin & & & & & & & & \\
\hline & Melanoma & & & & & & & & \\
\hline & Stage IVA & & & & & & & & \\
\hline & Uterine & & & & & & & & \\
\hline & Corpus & & & & & & & & \\
\hline & Cancer \({ }^{\text {Sta }}\) & & & & & & & & \\
\hline & ge IVB & & & & & & & & \\
\hline & Uterine & & & & & & & & \\
\hline & Corpus & & & & & & & & \\
\hline & Cancer & & & & & & & & \\
\hline RECRUITIN & Chemothera & DRUG: & PHAS & INTER & Allocation: & 70 & pathologic & rate of & 2021/6/25 \\
\hline G & py|Immune & delayed & E2 & VENTI & RANDOMI & & al & adverse & \\
\hline & Checkpoint & toripalimab| & & ONAL & ZED|Interv & & complete & events, rate & \\
\hline & Inhibitor | L & DRUG: & & & ention & & response & of adverse & \\
\hline & ocally & control & & & Model: & & rate, the & events, 3 & \\
\hline
\end{tabular}
\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|}
\hline & Advanced & & & & PARALLEL & & proportion & months \({ }^{\text {di }}\) & \\
\hline & Gastric & & & & | Masking: & & of patients & sease-free & \\
\hline & Carcinoma & & & & NONE | Pri & & with no & survival, & \\
\hline & & & & & mary & & tumor cells & the rate of & \\
\hline & & & & & Purpose: & & in the & patients & \\
\hline & & & & & TREATME & & postoperat & who keep & \\
\hline & & & & & NT & & & from & \\
\hline & & & & & & & specimens, & disease at & \\
\hline & & & & & & & 6 months & three & \\
\hline & & & & & & & & years, 3 years & \\
\hline ACTIVE_NO & Solid & BIOLOGICA & PHAS & INTER & Allocation: & 96 & Occurrenc & BNT141 & 2022/1/18 \\
\hline T_RECRUITI & Tumor \| Gas & L: & E1|PH & VENTI & NON_RAN & & e of & pharmacok & \\
\hline NG & tric & BNT141 \({ }^{\text {DR }}\) & ASE2 & ONAL & DOMIZED & & treatment- & inetic: Area & \\
\hline & Cancer \| Gas & UG: Nab- & & & Intervention & & emergent & under the & \\
\hline & troesophage & paclitaxel|D & & & Model: & & adverse & concentrati & \\
\hline & al Junction & & & & SEQUENTI & & events & on time & \\
\hline
\end{tabular}
\begin{tabular}{|c|c|c|c|c|}
\hline Adenocarci & RUG: & AL|Maskin & (TEAEs) & curve \\
\hline noma|Esop & Gemcitabine & g : & within a & (AUC), \\
\hline hageal & & NONE | Pri & patient & pre-dose \\
\hline Adenocarci & & mary & including & until 60 \\
\hline noma | Panc & & Purpose: & Grade & days after \\
\hline reatic & & TREATME & 鈮 ? 3 , & last \\
\hline Cancer | Bili & & NT & serious, & dose | \(\mathrm{BNT}^{\text {d }}\) \\
\hline ary Tract & & & fatal TEAE & 141 \\
\hline Cancer \| Cho & & & by & pharmacok \\
\hline langiocarcin & & & relationshi & inetic: \\
\hline oma | Metast & & & p, TEAEs & Clearance \\
\hline atic Cancer & & & will be graded & \begin{tabular}{l}
(CL), pre- \\
dose until
\end{tabular} \\
\hline & & & according & \\
\hline & & & & after last \\
\hline & & & National & dose | \(\mathrm{BNT}^{\text {a }}\) \\
\hline & & & Cancer & 141 \\
\hline
\end{tabular}
\begin{tabular}{ll} 
Institute & pharmacok \\
Common & inetic: \\
Terminolo & Volume of \\
gy Criteria & distributio \\
for & \(\mathrm{n} \quad\) (VD), \\
Adverse & pre-dose \\
Events & until 60 \\
(NCI- & days after \\
CTCAE) v & last \\
\(5.0 .\), up to & dose|BNT \\
36 & 141 \\
months |O & pharmacok \\
ccurrence & inetic: \\
of dose & Maximum \\
reductions & concentrati \\
and & on of the \\
discontinu & drug
\end{tabular}
\begin{tabular}{lll} 
ation of & (Cmax), \\
BNT141 & pre-dose \\
due to & until & 60 \\
TEAEs & days after \\
throughou & last \\
\(t\) the study & dose & BNT \\
and up to & 141 \\
\(60 \quad\) days & pharmacok \\
after last & inetic: \\
subject last & Time to \\
treatment, & maximum \\
up to 36 & concentrati \\
months \(\mid O\) & on (Tmax), \\
ccurrence & pre-dose \\
of dose- & until 60 \\
limiting & days after \\
toxicities & last
\end{tabular}
\begin{tabular}{ll} 
(DLTs) & dose|BNT \\
within a & 141 \\
patient & pharmacok \\
during the & inetic: \\
DLT & Concentrat \\
evaluation & ion prior to \\
period, & next dose \\
DLTs are & (Ctrough), \\
assessed & pre-dose \\
during the & until 60 \\
first cycle & days after \\
(21 days) & last \\
in each & dose|BNT \\
cohort to & 141 \\
determine & pharmacok \\
maximum & inetic: \\
tolerated & Eliminatio
\end{tabular}
\begin{tabular}{|c|c|}
\hline dose & n half-life \\
\hline (MTD) & ( t half), \\
\hline and/or & pre-dose \\
\hline recommen & until 60 \\
\hline ded phase & days after \\
\hline 2 dose & last \\
\hline (RP2D)., & dose | BNT \\
\hline assessed & 141 \\
\hline during the & Objective \\
\hline first cycle & response \\
\hline (21 days) & rate (ORR), \\
\hline in each & ORR is \\
\hline cohort & defined as \\
\hline & the \\
\hline & proportion \\
\hline & of patients \\
\hline & in whom \\
\hline
\end{tabular}
complete
response
(CR) or
partial
response
(PR), per
Response
Evaluation
Criteria in
Solid
Tumors
(RECIST) v
1.1 is
confirmed
as best
overall
response.,
months | B
NT141
Disease
control
rate (DCR),
DCR is
defined as
the
proportion
of patients
in whom a
CR or PR
or stable
disease
(SD) (per
RECIST v
assessed at
least
weeks after
first dose)
is observed
as best
overall
response.,
up to 36
months |B
NT141
Duration
of response
(DOR),
DOR is
defined as
from first
objective
response
(CR or PR
per
RECIST v
1.1) to first
occurrence
of objective
tumor
progressio
n
(progressi
ve disease
per
RECIST v
\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|}
\hline & & & & & & & & 1.1) or & \\
\hline & & & & & & & & death from & \\
\hline & & & & & & & & & \\
\hline & & & & & & & & whichever & \\
\hline & & & & & & & & occurs & \\
\hline & & & & & & & & first., up to & \\
\hline & & & & & & & & 36 months & \\
\hline COMPLETE & Biomarkers & & & OBSER & & 116 & Overall s & al, Overall & 2017/1/1 \\
\hline D & & & & VATI & al Model: & & survival of & patients with & \\
\hline & & & & ONAL & | Time & & gastric canc & two years & \\
\hline & & & & & Perspective: & & & & \\
\hline & & & & & p & & & & \\
\hline ACTIVE_NO & Gastric & DRUG: & PHAS & INTER & Allocation: & 44 & Pathologic & Number of & 2017/7/31 \\
\hline T_RECRUITI & Adenocarci & FLOT-A & E2 & VENTI & NA | Interve & & al & participant & \\
\hline NG & noma |Oeso & & & ONAL & ntion & & complete & s with & \\
\hline & phageal & & & & Model: & & response & grade 3 or & \\
\hline & & & & & SINGLE_G & & rate of & 4 & \\
\hline
\end{tabular}

\begin{tabular}{ll} 
the pCR & rates as \\
rate after & proportion \\
peri- & s., Within 2 \\
operative & years |Rad \\
treatment & iological \\
from 10\% & response \\
(minimum & rate using \\
expected & RECIST 1.1 \\
path CR & criteria, \\
rate for & Radiologic \\
peri- & al response \\
operative & rate \\
FLOT & assessed at \\
chemother & the pre- \\
apy), to a & operative \\
superior & scan using \\
pCR rate of & RECIST 1.1
\end{tabular}
\begin{tabular}{|c|c|}
\hline \begin{tabular}{l}
\(\backslash>25 \%\), by \\
adding
\end{tabular} & \begin{tabular}{l}
criteria. \\
Radiologic
\end{tabular} \\
\hline Avelumab & al tumour \\
\hline to FLOT. & response \\
\hline & before \\
\hline Complete & surgery \\
\hline histopatho & will be \\
\hline logic & defined as \\
\hline response is & partial \\
\hline defined by & response \\
\hline no vital & or \\
\hline tumour & complete \\
\hline cells & response., \\
\hline neither in & Within 3 \\
\hline the & years |Med \\
\hline oesophagu & ian \\
\hline s, the & progressio \\
\hline
\end{tabular}
\begin{tabular}{ll}
\begin{tabular}{l} 
stomach
\end{tabular} n free \\
nor in the & survival by \\
regional & Kaplan \\
lymph & Meir \\
nodes. In & method, \\
cases of & PFS will be \\
residual & summarise \\
tumour, & d using \\
the & Kaplan \\
response & Meier \\
assessment & methods, \\
will follow & presenting \\
criteria & median \\
described & survival \\
by & with \(95 \%\) \\
Mandard & confidence \\
et al., & intervals.
\end{tabular}
\begin{tabular}{lrl} 
Within & 2 & PFS is \\
years & of & defined as \\
study & & time from \\
opening & registratio
\end{tabular}
n to
clinical/ra
diological
progressio
n or death
from any
cause.
Patients
event free
at time of
analysis
will be
censored at
last follow-
up date., Within 5
years \(\mid\) Med
ian overall
survival by
Kaplan
Meir
method,
OS will be
summarise
d using
Kaplan
Meier
method,
presenting
median
survival
with 95\%
confidence
intervals
OS is
defined as
time from
registratio
n to date of
death of
any cause.

\section*{Patients}
event free
at time of
analysis
will be
censored at
\begin{tabular}{|c|c|c|c|c|c|c|c|c|}
\hline & & & & & & & last followup date. Within 5 years & \\
\hline NOT_YET_R & Diffuse & DRUG: & PHAS & INTER & Allocation: & 134 & Phase 1: safety and & 2023/10/1 \\
\hline ECRUITING & Astrocytom & NEO212 Oral & E1|PH & VENTI & NON_RAN & & tolerability of increasing & \\
\hline & a, IDH- & Capsule \({ }^{\text {DR }}\) & ASE2 & ONAL & DOMIZED & & dose levels of orally & \\
\hline & Mutant | Gli & UG: & & & Intervention & & administered NEO212 & \\
\hline & oblastoma, & Ipilimumab | & & & Model: & & alone in patients with & \\
\hline & IDH- & DRUG: & & & PARALLEL & & Astrocytoma IDH- & \\
\hline & wildtype|B & Pembrolizum & & & | Masking: & & mutant, Glioblastoma & \\
\hline & rain & ab|DRUG: & & & NONE | Pri & & IDH-wildtype or & \\
\hline & Metastases, & Nivolumab & & & mary & & patients with select solid & \\
\hline & Adult | Cerv & DRUG: & & & Purpose: & & tumors with & \\
\hline & ical & Regorafenib | & & & TREATME & & uncontrolled metastases & \\
\hline & Cancer 1 Col & DRUG: & & & NT & & to the brain, As & \\
\hline & orectal & Carboplatin & & & & & determined by incidence & \\
\hline
\end{tabular}
\begin{tabular}{|c|c|c|}
\hline Cancer \({ }^{\text {Eso }}\) & DRUG: & and severity of adverse \\
\hline phageal & Paclitaxel|D & events according to \\
\hline Cancer \({ }^{\text {Eso }}\) & RUG: & National Cancer \\
\hline phageal & FOLFIRI & Institute Common \\
\hline Squamous & Protocol|DR & Terminology Criteria for \\
\hline Cell & UG: & Adverse Events (NCI \\
\hline Carcinoma & Bevacizumab & CTCAE v5.0, 6 \\
\hline Gastric & & months|Phase 1: \\
\hline Cancer \| Gas & & Identify the maximum \\
\hline troesophage & & tolerated dose (MTD) of \\
\hline al Junction & & NEO212, Maximum \\
\hline Adenocarci & & Tolerated Dose of \\
\hline noma | Head & & NEO212 as determined \\
\hline and Neck & & by the dose escalation \\
\hline Squamous & & rules., 6 months|Phase \\
\hline Cell & & 1: Determine the \\
\hline Carcinoma & & recommended Phase 2 \\
\hline
\end{tabular}

Melanoma
Merkel Cell
Carcinoma
Microsatellit
e Instability-
High Solid
Malignant
Tumor|Mis
match
Repair
Deficient
Solid
Malignant
Tumor | Mic
rosatellite
Instability-
High
dose (RP2D) of NEO212,
Determine the
recommended Phase 2
dose (RP2D) of NEO212,
6 months|Phase 2a:
Assess the safety and
tolerability of orally
administered NEO212 in
combination with select
SOC regimens following
a standard 3+3 design in
patients with select solid
tumors with
uncontrolled metastases
to the brain, Determined
by incidence and
severity of adverse
\begin{tabular}{|c|c|}
\hline Colorectal & events determined \\
\hline Cancer \| Mis & according to National \\
\hline match & Cancer Institute \\
\hline Repair & Common Terminology \\
\hline Deficient & Criteria for Adverse \\
\hline Colorectal & Events (NCI CTCAE \\
\hline Cancer \| No & v5.0)., 6 months |Phase \\
\hline n-small Cell & 2b: Determine the \\
\hline Lung & intracranial progression- \\
\hline Cancer \| Ren & free survival rate at six \\
\hline al Cell & months (PFS6) of orally \\
\hline Carcinoma & administered NEO212 \\
\hline Small Cell & alone in patients with \\
\hline Lung & Astrocytoma IDH- \\
\hline Cancer 1 Squ & mutant, Glioblastoma \\
\hline amous Cell & IDH-wildtype., \\
\hline Carcinoma & Determine the \\
\hline
\end{tabular}
\begin{tabular}{|c|c|}
\hline Urothelial & intracranial progression- \\
\hline \multirow[t]{16}{*}{Carcinoma} & free survival rate at six \\
\hline & months (PFS6) of orally \\
\hline & administered NEO212 \\
\hline & alone in patients with \\
\hline & Astrocytoma IDH- \\
\hline & mutant, Glioblastoma \\
\hline & IDH-wildtype., 6 \\
\hline & months |Phase 2 b : \\
\hline & Determine the \\
\hline & intracranial progression- \\
\hline & free survival rate at six \\
\hline & months (PFS6) of orally \\
\hline & administered NEO212 in \\
\hline & combination with select \\
\hline & SOC regimens in \\
\hline & patients with select solid \\
\hline
\end{tabular}
uncontrolled metastases
to the brain., Determine
the
intracranial
progression-free
survival rate at six
months (PFS6) of orally
administered NEO212 in
combination with select
SOC regimens in
patients with select solid
tumors (see Appendix 2)
with uncontrolled
metastases to the brain.,
6 months
\begin{tabular}{|c|c|c|c|c|c|c|c|c|}
\hline RECRUITIN & Adenocarci & DIAGNOSTIC_TEST: & OBSER & Observation & 100000 & Best & Overall & 2021/5/5 \\
\hline \multirow[t]{16}{*}{G} & noma | Aden & Biomarker Testing & VATI & al Model: & & overall & survival & \\
\hline & ocystic & (L)|DRUG: Systemic & ONAL & | Time & & response & (OS), The & \\
\hline & Carcinoma & Treatment & & Perspective: & & (BOR) - 1st & overall & \\
\hline & Anal & (T) |OTHER: Patient & & p & & line of & survival of & \\
\hline & Cancer \| Ap & Reported Outcomes (P) & & & & therapy, & a patient & \\
\hline & pendix & & & & & The best & from the & \\
\hline & Cancer - Brai & & & & & overall & time of & \\
\hline & n & & & & & response & being & \\
\hline & Tumor | Glio & & & & & for 1st line & diagnosed & \\
\hline & blastoma \({ }^{\text {A }}\) & & & & & of therapy & with & \\
\hline & strocytoma | & & & & & as & advanced & \\
\hline & Bile Duct & & & & & determine & disease & \\
\hline & Cancer \| Cho & & & & & by & until & \\
\hline & langiocarcin & & & & & physician & death, & \\
\hline & oma | Bladd & & & & & assessment & through & \\
\hline & er & & & & & , 1st line of & study & \\
\hline
\end{tabular}

\section*{Cancer | Bon}
e
Cancer|Syn
ovial
Sarcoma |C
hondrosarco
ma|Liposar
coma|Sarco
ma,
Kaposi|Sarc
oma,Soft
Tissue |Sarc
oma|Osteos
arcoma \(\mid \mathrm{CN}\)
S
Cancer \({ }^{\text {Brai }}\)
n Stem
therapy, completion
on average , on
less than 1 average
year|Best less than 3
overall years
response
(BOR)
2nd line of
therapy,
The best
overall
response
for 2nd line
of therapy
as
determine
d by
\begin{tabular}{ll} 
Neoplasms & physician \\
Breast & assessment \\
Cancer | Cer & , 2nd line \\
vical & of therapy, \\
Cancer \(\mid\) Col & on average \\
orectal & less than 1 \\
Cancer |Rec & year |Best \\
tal & overall \\
Cancer |Col & response \\
on & (BOR) -3rd \\
Cancer |Eso & line \\
phageal of \\
Cancer |Eso & therapy, \\
phagus & The best \\
Cancer \(\mid\) Can & overall \\
cer & response \\
Colon \(\mid\) Panc & for 3rd line
\end{tabular}
\begin{tabular}{ll} 
reatic & as \\
Cancer \(\mid\) Can & determine \\
cer of & d by \\
Pancreas |T & physician \\
estis & assessment \\
Cancer |Test & ,3rd line of \\
icular & therapy, \\
Cancer |Ure & on average \\
ter & less than 1 \\
Cancer |Ren & year |Best \\
al & overall \\
Carcinoma & response \\
Kidney & (BOR) -4 th \\
Cancer |Ges & line \\
tational & therapy, \\
Trophoblast & The best \\
ic & overall
\end{tabular}
\begin{tabular}{ll} 
Tumor \(\mid\) Hea & response \\
d and Neck & for 4th line \\
Neoplasms | & of therapy \\
Parotid & as \\
Tumor | Lar & determine \\
ynx & d \(\quad\) by \\
Cancer |Ton & physician \\
gue & assessment \\
Cancer |Pha &, 4 th line of \\
rynx & therapy, \\
Cancer |Sali & on average \\
vary Gland & less than 1 \\
Cancer |Acu & year |Best \\
te Myeloid & overall \\
Leukemia & response \\
Chronic & (BOR) -5th \\
Myeloid & line
\end{tabular}
\begin{tabular}{ll} 
Leukemia & therapy, \\
Acute & The best \\
Lymphoblas & overall \\
tic & response \\
Leukemia & for 5 th line \\
Multiple & of therapy \\
Myeloma | & as \\
Non & determine \\
Hodgkin & d \\
Lymphoma & physician \\
\(\mid\) Carcinoid & assessment \\
Tumor |Lun & , 5th line of \\
g & therapy, \\
Cancer \(\mid\) Ne & on average \\
uroendocrin & less than 1 \\
e & year \(\mid\) Prog \\
Tumors |Me & ression-
\end{tabular}
\begin{tabular}{ll} 
sothelioma & free \\
Thyroid & survival \\
Cancer |Par & \((\) PFS \()-1\) st \\
athyroid & line of \\
Neoplasms | & therapy, \\
Adrenal & The \\
Cancer |Sm & progressio \\
all Bowel & n free \\
Cancer |Sto & survival \\
mach & for 1st line \\
Cancer |Liv & of therapy \\
er & as \\
Cancer | He & determine \\
patic & d \\
Cancer |Mel & physician \\
anoma |Skin & assessment \\
Cancer |Un & , 1st line of
\end{tabular}
\begin{tabular}{ll} 
known & therapy, \\
Primary & on average \\
Tumors |Ut & less than 1 \\
erine & year | Prog \\
Cancer |Fall & ression- \\
opian Tube & free \\
Cancer |Ova & survival \\
rian & (PFS) - 2nd \\
Cancer |Pro & line of \\
state & therapy, \\
Cancer |Vag & The \\
inal & progressio \\
Cancer |Pen & n \\
ile & survival \\
Cancer |Vul & for 2nd line \\
var & of therapy \\
Cancer | Wal & as
\end{tabular}
\begin{tabular}{ll} 
denstrom & determine \\
Macroglobu & d by \\
linemia \(\mid \mathrm{Ca}\) & physician \\
ncer, & assessment \\
Advanced & , 2nd line \\
Thymus & of therapy, \\
Cancer |Nas & on average \\
opharyngeal & less than 1 \\
Carcinoma & year |Prog \\
Multiple & ression- \\
Endocrine & free \\
Neoplasia & survival \\
Pheochrom & (PFS) - 3rd \\
ocytoma S & line \\
mall of \\
Carcinoma & therapy, \\
& The \\
\hline
\end{tabular}
PulmonaryCarcinoma
\(n\) free
survival
for 3rd line
of therapy
as
determine
d by
physician
assessment
, 3rd line of
therapy,
on average
less than 1
year |Prog
ression-
free
survival
(PFS) - 4th
line of
therapy,
The
progressio
n free
survival
for 4th line
of therapy
as
determine
d by
physician
assessment
, 4th line of
therapy,
on average
less than 1
year \(\mid\) Prog
ression-
free
survival
(PFS) - 5th
line of
therapy,
The
progressio
n free
survival
for 5th line
of therapy
as
determine
d by
\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|}
\hline & & & & & & & physician & & \\
\hline & & & & & & & assessment & & \\
\hline & & & & & & & , 5th line of & & \\
\hline & & & & & & & therapy, & & \\
\hline & & & & & & & on average & & \\
\hline & & & & & & & \begin{tabular}{l}
less than 1 \\
year
\end{tabular} & & \\
\hline RECRUITIN & Gastric & DRUG: & PHAS & INTER & Allocation: & 31 & Primary & Patients \({ }^{\prime}\) & 2021/4/1 \\
\hline G & Cancer \| Mic & Durvalumab & E2 & VENTI & NON_RAN & & outcome of & quality of & \\
\hline & rosatellite & |DRUG: & & ONAL & DOMIZED & & Cohort 1: & life, & \\
\hline & Instability & Tremelimum & & & Intervention & & Pathologic & Quality of & \\
\hline & & ab & & & Model: & & al & life will be & \\
\hline & & & & & SINGLE_G & & complete & assessed & \\
\hline & & & & & ROUP \| Mas & & response & through & \\
\hline & & & & & king: & & (ypT0N0) & Patient & \\
\hline & & & & & NONE | Pri & & and & reported & \\
\hline & & & & & mary & & negative & outcomes & \\
\hline
\end{tabular}
\begin{tabular}{lll} 
Purpose: & ctDNA & (PRO) \\
TREATME & status, & instrument \\
NT & Rate of & EORTC \\
& patients & QLQ-C30 \\
& \((\%)\) & For \\
& achieving & questions \\
& both & \(1-28 \quad\) of \\
& pathologic & EORTC \\
& al & QLQ-C30 a \\
& complete & 4-point \\
& response & scale is \\
& (ypT0N0) & used. It \\
& and & scores \\
& negative & from 1 to 4: \\
& ctDNA & \(1 \quad\) ("Not at \\
& status after & all"), 2 ("A \\
& neoadjuva & little"), 3
\end{tabular}
\begin{tabular}{|c|c|}
\hline nt & ("Quite \\
\hline immunoth & bit") and 4 \\
\hline erapy in & ("Very \\
\hline the & much"). \\
\hline intention- & Half points \\
\hline to-treat & are not \\
\hline population & allowed. \\
\hline of Cohort & The range \\
\hline 1, From the & is 3 . For the \\
\hline enrollment & raw score, \\
\hline of the first & less points \\
\hline patient in & are \\
\hline Cohort 1 & considered \\
\hline up to & to have a \\
\hline months & better \\
\hline from the & outcome. \\
\hline \(1 m e n t\) & For \\
\hline
\end{tabular}
\begin{tabular}{|c|c|}
\hline of the last patient in & \begin{tabular}{l}
questions \\
29 and 30
\end{tabular} \\
\hline Cohort & of EORTC \\
\hline 1|Primary & QLQ-C30 a \\
\hline outcome of & 7-points \\
\hline Cohort 2: & scale is \\
\hline 2-year & used. It \\
\hline complete & scores \\
\hline response & from 1 to 7: \\
\hline rate, 2-year & ("very \\
\hline complete & poor") to 7 \\
\hline response & ("excellent" \\
\hline rate, & Half \\
\hline defined as & points are \\
\hline the & not \\
\hline absence of & allowed. \\
\hline macroscop & The range \\
\hline
\end{tabular}
\begin{tabular}{llr} 
ic or & is 6 . First of \\
microscopi & all, & raw \\
c residual & score & has \\
disease & to & be \\
(locally, & calculated \\
regionally & with mean \\
and & values. \\
distantly) & Afterward \\
at & s linear \\
radiologica & transforma \\
l & tion & is \\
examinatio & performed \\
ns, tissue & to & be \\
and liquid & comparabl \\
biopsy, in & e. & More \\
absence & of & points
\end{tabular}
gastrectom to have a
y., From better
the
enrollment For each
of the first Cohort,
patient in from the
Cohort 2 enrollment
up to 2 of the first
years from patient up
the end of to
pre-
operative from the
treatment last patient
of the last starting the
patient
phase |Pati
ents'
quality of
life,
Quality of
life will be
assessed
through
Patient
reported
outcomes
(PRO)
instrument
. EORTC
QLQ-
STO22.

For
questions
31-52 of
EORTC
QLQ-
STO22 a 4-
point scale
is used. It
scores
from 1 to 4:
1 ("Not at all"), 2 ("A
little"), 3
("Quite a
bit") and 4
("Very
much").

Half points
are not
allowed.
The range
is 3 . For the
raw score,
less points
are
considered
to have a
better
outcome.,
For each
Cohort,
from the
enrollment
of the first
months
from the
last patient
starting the
pre-
operative
treatment
phase|Pati
ents'
quality of
life,
Quality of
life will be
assessed
through

Patient
reported
outcomes
(PRO)
instrument
EuroQol
EQ-5D-5L.

The EQ-
5D-5L uses
for first 5
questions
qualitative
multiple
choice
answers
with NO

SCALE.
For the last
questions,
a score
from 0 to
100
indicates
from the
worst to
the best
outcome.,
For each
Cohort,
from the
enrollment
of the first
patient up
months
from the
last patient
starting the
pre-
operative
treatment
phase \({ }^{3-}\)
year
disease-
free
survival,
time from
the
enrollment
in the
the
occurrence
of disease
relapse
(local
and/or
distant),
second
gastric or
gastroesop
hageal
junction
cancer
primary, or
death from
any cause.,

For each
Cohort,
from the
enrollment
of the first
patient up
to 3 years
from the
enrollment
of the last
patient|5-
year
overall
survival,
time from
the
enrollment
the
occurrence
of death.,
For each
Cohort,
from the
enrollment
of the first
patient up
to 5 years
from the
enrollment
of the last
patient \(\mid M\)
etastases-
survival,
time from
the
enrollment
in the
study to
the first
evidence of
metastases
or death
from any
cause., For
each
Cohort
from the
enrollment
of the first
patient up
to 5 years
from the
enrollment
of the last
patient \(\mid G a\)
strectomy-
free
survival
(Cohort 2
only), time
from the
inclusion
in the
study to
the
gastrectom
y or death
from any
cause.,
From the
enrollment
of the first
patient up
to 5 years
from the
enrollment
of the last
patient | In
cidence of
Treatment-
Emergent
Adverse
Events
[Safety and
Tolerabilit
y],
incidence
of adverse
events
during the
treatment
and
follow-up
phases,
assessed
according
to CTCAE
```

v5.0., For
each
Cohort
from the
enrollment
of the first
patient up
to 5 years
from the
enrollment
of the last
patient|Po
st
gastrectom
y
complicati
ons, Rate

```
complicati
ons
following
tremelimu
mab and
durvaluma
\(b\) as pre-
operative
treatment
strategy.,
For each
Cohort,
from the
enrollment
\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|}
\hline & & & & & & & & of the first patient up to 1 year from the enrollment of the last patient & \\
\hline RECRUITIN & Gynecologic & RADIATION: & NA & INTER & Allocation: & 200 & Overall & Progressio & 2021/6/10 \\
\hline G & Cancer \({ }^{\text {Ski }}\) & Stereotactic & & VENTI & RANDOMI & & survival, & n-free & \\
\hline & n & & & ONAL & ZED|Interv & & Overall & survival, 9 & \\
\hline & Cancer \({ }^{\text {/ }}\) Hea & radiotherapy & & & ention & & survival is & years from & \\
\hline & d and Neck & | RADIATIO & & & Model: & & the time & first & \\
\hline & Cancer \| Sarc & N : Palliative & & & PARALLEL & & interval & patient & \\
\hline & oma|Renal & RT & & & | Masking: & & from the & in | Disease & \\
\hline & Cancer \| Bla & & & & NONE | Pri & & date of & -specific & \\
\hline & dder & & & & mary & & randomiza & survival, 9 & \\
\hline & Cancer \| Up & & & & Purpose: & & tion to the & years from & \\
\hline
\end{tabular}
\begin{tabular}{|c|c|c|c|}
\hline per Urinary & TREATME & date of & first \\
\hline Tract & NT & death & patient \\
\hline Carcinoma & & whatever & in |Time to \\
\hline Pancreatic & & the cause & disease \\
\hline Cancer \({ }^{\text {He }}\) & & of death. & progressio \\
\hline patobiliary & & Patients & \(n\), Disease- \\
\hline Cancer \| Gas & & who are & specific \\
\hline tric & & alive are & survival is \\
\hline Cancer \({ }^{\text {Sm }}\) & & censored at & the time \\
\hline all Bowel & & the last & interval \\
\hline Cancer \| Eso & & date & from the \\
\hline phageal & & known to & date of \\
\hline Cancer 1 Mel & & be alive., & randomiza \\
\hline anoma \(\mid \mathrm{Col}\) & & 7.5 years & tion to the \\
\hline on & & from first & date of \\
\hline Cancer \({ }^{\text {Oli }}\) & & patient in & cancer- \\
\hline & & & related \\
\hline
\end{tabular}
gometastasi
S
death., 9
years from
first
patient
in |Time to
developme
nt of new
metastatic
lesions,
Time to
developme
nt of new
metastatic
lesions is
the time
interval
from the
tion to the
date of first
occurrence
of any of
the
following
events:

Developm
ent new
metastatic
lesions,
* Cancer-
related
years from
first
patient
in |Time to
developme
nt of
polymetast
atic
disease,
Time to
developme
nt of
polymetast
atic disease
is the time
interval
randomiza
tion to the
date of first occurrence
of any of the
following
events:
* Presence
of more
than 5
metastases
at a specific
timepoint
during
follow-up,

Developm
ent
of
metastases
that
preclude
treatment
with SBRT
(e.g. due to
large size
or locating
in
previously
irradiated
region
where
irradiation
is not
possible),
* Cancer-
related
death., 9
years from
first
patient
in | Advers
e events
graded
according
to the
National
Cancer

\section*{Institute}

Common
Terminolo
gy Criteria
for adverse
events
(NCI-
CTCAE)
version 5.0,
9 years
from first
patient
in |Health-
related
quality of
life
evaluated
using self-
administer
ed EORTC
QLQ-C30
questionna
ires, \(\quad 9\)
years from
first
patient
in |Health-
related
quality of
life
evaluated
using self-
administer
ed EQ-5D-
\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|}
\hline & & & & & & & & 5L questionna & \\
\hline & & & & & & & & ires, \(\quad 9\) & \\
\hline & & & & & & & & years from & \\
\hline & & & & & & & & first & \\
\hline & & & & & & & & patient in & \\
\hline RECRUITIN & Gastric & DRUG: & PHAS & INTER & Allocation: & 35 & 3-year & Major & 2019/9/26 \\
\hline G & Cancer & Toripalimab | & E2 & VENTI & NA | Interve & & Disease- & pathologic & \\
\hline & & DRUG: & & ONAL & ntion & & Free & al & \\
\hline & & Docetaxel|D & & & Model: & & Survival & (complete & \\
\hline & & RUG: & & & SINGLE_G & & Rate, The & and nearly & \\
\hline & & Fluorouracil | & & & ROUP | Mas & & primary & complete) & \\
\hline & & DRUG: & & & king: & & end point & response & \\
\hline & & Leucovorin | & & & NONE | Pri & & of the & (MPR), & \\
\hline & & DRUG: & & & mary & & study is the & Proportion & \\
\hline & & Oxaliplatin & & & Purpose: & & effect of & of patients & \\
\hline & & & & & & & perioperati & & \\
\hline
\end{tabular}
\begin{tabular}{lll} 
TREATME & ve time flot & gastric \\
NT & regimen & cancer who \\
& combined & received \\
& with & Toripalima \\
& Toripalima & b \\
& b and D2 & combined \\
& radical & with FLOT \\
& operation & regimen \\
& on the 3- & after \\
& year & cycles of \\
disease- & neoadjuva \\
& free & nt therapy \\
survival & and \\
time of & postoperat \\
resectable & ive \\
& gastric & pathologic \\
cancer., Up & al
\end{tabular}
\begin{tabular}{ll} 
to & examinatio \\
years|Path & n TRG1a or \\
ological & \(1 b .\), Up to 6 \\
complete & months|A \\
response & dverse \\
rate (pCR), & Events, For \\
Proportion & any \\
of patients & adverse \\
with & reactions, \\
gastric & the \\
cancer who & researchers \\
received & refer to the \\
Toripalima & National \\
b & Cancer \\
combined & Institute \\
with FLOT & (NCI) \\
regimen & standard
\end{tabular}
\begin{tabular}{|c|c|}
\hline after & of common \\
\hline cycles of & toxicity \\
\hline neoadjuva & (CTC), Up \\
\hline nt therapy & to 6 \\
\hline and & months |5- \(^{\text {- }}\) \\
\hline postoperat & year \\
\hline ive & Disease- \\
\hline pathologic & Free Rate, \\
\hline al & The \\
\hline examinatio & proportion \\
\hline \(n\) TRG1a, & of patients \\
\hline Up to 6 & with \\
\hline months & resectable \\
\hline & gastric \\
\hline & cancer who \\
\hline & have no \\
\hline & recurrence \\
\hline
\end{tabular}
metastasis
after 5
years of
perioperati
ve
treatment,
Up to 5
years|5-
year
Survival
Rate,
Proportion
of patients
with
resectable
gastric

\begin{tabular}{llr} 
Cancer|Ski & Therapy & Epidermal \\
n & Growth & Factor \\
Cancer \(\mid\) Mel & Inhibitors 18 Item) \\
anoma \(\mid\) Hea & \\
\(\mathrm{d} \quad\) Neck & \\
Cancer &
\end{tabular}
\begin{tabular}{ll} 
kinase ole of \\
(CDK) & therapy, \\
inhibitors., & To \\
To & describe \\
investigate & differences \\
the & in quality \\
correlation & of life \\
between & based on \\
the skin & type of \\
toxicity & therapy \\
related to & received \\
the use of & (Immunot \\
monoclona & herapy vs \\
l antibody & CDK \\
against the & inhibitors). \\
PD1/PDL1 & , 18 months \\
/CTLA4 or
\end{tabular}
to cyclin-
dependent
kinase
(CDK)
inhibitors
and the
quality of
life., 18
months \(\mid Q\)
uality of
life during
therapy
with anti-
PD1/PDL1
/CTLA4 or
cyclin-
dependent
kinase
(CDK)
inhibitors.,
To
evaluate
the
correlation
between
skin
toxicity
and
quality of
life over
three
months of
treatment
in patients
\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|}
\hline & & & & & & & initially na & & \\
\hline & & & & & & & 茂 ve for & & \\
\hline & & & & & & & monoclona & & \\
\hline & & & & & & & 1 antibody anti- & & \\
\hline & & & & & & & PD1/PDL1 & & \\
\hline & & & & & & & /CTLA4 or & & \\
\hline & & & & & & & with & & \\
\hline & & & & & & & cyclin- & & \\
\hline & & & & & & & dependent & & \\
\hline & & & & & & & kinase & & \\
\hline & & & & & & & (CDK) & & \\
\hline & & & & & & & inhibitors., & & \\
\hline & & & & & & & 18 months & & \\
\hline RECRUITIN & Gastric & OTHER: & non- & OBSER & Observation & 169 & Major & Pathologic & 2021/5/25 \\
\hline G & Adenocarci & intervention & & VATI & al Model: & & pathologic & al & \\
\hline & noma |Gastr & & & ONAL & | Time & & response & complete & \\
\hline
\end{tabular}
\begin{tabular}{|c|c|c|c|}
\hline oesophageal & Perspective: & (MPR) & response \\
\hline Junction & p & rate, & (pCR) rate, \\
\hline Adenocarci & & Defined as & Defined as \\
\hline noma & & \<10\% & the \\
\hline & & residual & percentage \\
\hline & & viable & of \\
\hline & & tumor cells & participant \\
\hline & & in the & \(s\) having a \\
\hline & & resection & pathologic \\
\hline & & specimen & al \\
\hline & & after & complete \\
\hline & & neoadjuva & response., \\
\hline & & nt drug & From the \\
\hline & & treatment., & initiation \\
\hline & & From the & date of first \\
\hline & & initiation & cycle to the \\
\hline & & date of first & date of \\
\hline
\end{tabular}

surgery, an
average of
10
weeks | Dis
ease-free
Survival
(DFS),
Defined as
the time
from post-
surgery
baseline
scan until
the first
occurrence
of
local/dista
\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|}
\hline & & & & & & & & & \\
\hline & & & & & & & & recurrence & \\
\hline & & & & & & & & or death & \\
\hline & & & & & & & & from any & \\
\hline & & & & & & & & cause and & \\
\hline & & & & & & & & is based on & \\
\hline & & & & & & & & RECIST 1.1 & \\
\hline & & & & & & & & as assessed & \\
\hline & & & & & & & & by the & \\
\hline & & & & & & & & investigato & \\
\hline & & & & & & & & r., 3 years & \\
\hline UNKNOWN & Gastric & DRUG: & PHAS & INTER & Allocation: & 30 & Identificati & Objective & 2019/1/17 \\
\hline & Cancer & MCS110/PD & E2 & VENTI & NA | Interve & & on of & response & \\
\hline & & R001 & & ONAL & ntion & & potential & rate, & \\
\hline & & combination & & & Model: & & biomarker & According & \\
\hline & & & & & SINGLE_G & & s of & to RECIST & \\
\hline & & & & & ROUP \| Mas & & MCS110 in & v1.1 & \\
\hline
\end{tabular}
\begin{tabular}{lll} 
king: & combinatio & criteria, \\
NONE |Pri & \(\mathrm{n} \quad\) with & 6weeks|I \\
mary & PDR001, & mmune- \\
Purpose: & The & related \\
TREATME & current & response \\
NT & study & rate, \\
& explores & According \\
& potential & to RECIST \\
& biomarker & v1.1 \\
& s of & criteria, \\
& MCS110 in & 6 6eeks |Pr \\
& combinatio & ogression- \\
& \(\mathrm{n} \quad\) with & free \\
& PDR001 & survival, \\
& that & Time from \\
& predict & randomiza \\
& tumor & tion until
\end{tabular}
\begin{tabular}{|c|c|}
\hline \begin{tabular}{l}
response in \\
the tumor
\end{tabular} & \begin{tabular}{l}
disease \\
progressio
\end{tabular} \\
\hline tissue and & n or death, \\
\hline blood of & 6weeks |D \\
\hline patients & uration of \\
\hline with & response, \\
\hline gastric & Time from \\
\hline cancer., & documenta \\
\hline 3weeks & tion of \\
\hline & tumor \\
\hline & response to \\
\hline & disease \\
\hline & progressio \\
\hline & n, \\
\hline & 6weeks \({ }^{\text {Di }}\) \\
\hline & sease \\
\hline & control \\
\hline
\end{tabular}
rate, The
percentage
of patients
who have
achieved
complete
response,
partial
response
and stable
disease,
6weeks|O
verall
survival,
Time from
randomiza
tion until

\begin{tabular}{|c|c|c|}
\hline Perspective: & with & presented \\
\hline \multirow[t]{16}{*}{p} & gastric & by HLA-I, \\
\hline & cancer, The & Computati \\
\hline & analysis of & onal \\
\hline & tumor & pipelines \\
\hline & DNA and & will be \\
\hline & RNA & employed \\
\hline & sequencing & to predict \\
\hline & data will & the pairing \\
\hline & provide & of \\
\hline & the & neoantigen \\
\hline & mutational & \(s\) and HLA \\
\hline & distributio & molecules. \\
\hline & n of & Subsequen \\
\hline & patients & tly, the \\
\hline & with & ratio of \\
\hline & gastric & those \\
\hline
\end{tabular}
\begin{tabular}{ll} 
cancer, & \multicolumn{1}{l}{ predicted } \\
which & neoantigen \\
could give & s will be \\
rise & to \\
neoantigen & by co- \\
s. Of those, & immunopr \\
neoantigen & ecipitation \\
s derived & with anti- \\
from & HLA \\
hotspot & antibodies \\
mutations & and mass \\
in & spectromet \\
Vietnames & ry analysis \\
e gastric & for their \\
cancer & binding to \\
patients & correspon \\
will & be
\end{tabular}

neoantigen
s ..... thatcould
activate
CD4 ..... and
CD8 T cells
to kill
tumor cells
and serveas putativecandidates
forimmunoth
erapy., 12
months
from the
beginning
\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|}
\hline & & & & & & & & of the study & \\
\hline RECRUITIN & HER2- & BIOLOGICA & PHAS & INTER & Allocation: & 48 & Assess the & Estimate & 2021/2/2 \\
\hline G & positive \({ }^{\text {Ad }}\) & L: CT- & E1 & VENTI & NON_RAN & & safety and & the & \\
\hline & enocarcino & 0508 \| BIOLO & & ONAL & DOMIZED | & & tolerability & objective & \\
\hline & ma|Bile & GICAL: & & & Intervention & & of CT-0508 & response & \\
\hline & Duct & Pembrolizum & & & Model: & & by & rate (ORR), & \\
\hline & Cancer \| Bili & ab & & & PARALLEL & & estimating & according & \\
\hline & ary Tract & & & & | Masking: & & the & to RECIST & \\
\hline & Cancer \| Bla & & & & NONE | Pri & & frequency & v1.1, of at & \\
\hline & dder & & & & mary & & and & least 1 dose & \\
\hline & Cancer \| Bre & & & & Purpose: & & severity of & of CT-0508 & \\
\hline & ast & & & & TREATME & & adverse & among & \\
\hline & Cancer \| Bre & & & & NT & & events in & subjects & \\
\hline & ast & & & & & & subjects & with HER2 & \\
\hline & Neoplasm| & & & & & & with HER2 & overexpres & \\
\hline & Carcinoma, & & & & & & overexpres & sing solid & \\
\hline
\end{tabular}

\section*{Ductal|Carc}
inoma,
Hepatocellu
lar | Cancer |
Lung
Cancer,
Non-Small-
Cell | Carcin
oma,
Ovarian
Epithelial|C
arcinoma,
Small
Cell | Carcin
oma,
Squamous |
Carcinoma,
\begin{tabular}{ll} 
sing solid & tumors., \\
tumors., & Proportion \\
Frequency & of subjects \\
and & with an \\
severity of objective \\
adverse & response \\
events & (either a \\
including, & complete \\
but not & response \\
limited to, & \(\backslash[C R \backslash]\) or \\
estimating & partial \\
frequency & response \\
and & \(\backslash[P R \backslash]\) in \\
severity of & subjects \\
Cytokine & who \\
Release & received at \\
Syndrome & least 1 dose
\end{tabular}
\begin{tabular}{|c|c|}
\hline Transitional & (CRS), 14 of CT-0508 \\
\hline Cell | Colore & months \(\mid\) A and at least \\
\hline ctal & ssess the the 8-week \\
\hline Cancer \({ }^{\text {Eso }}\) & feasibility tumor \\
\hline phagogastri & of evaluation \\
\hline c Junction & manufactu as \\
\hline Neoplasms | & ring CT- determine \\
\hline Inflammator & 0508 by d by the \\
\hline y Breast & describing investigato \\
\hline Cancer \({ }^{\text {Sto }}\) & the \(r\) using \\
\hline mach & percentage RECIST \\
\hline Neoplasms | & of v1.1., 24 \\
\hline Malignant & products months|Es \\
\hline Neoplasms & passing timate \\
\hline Ovarian & release progressio \\
\hline Neoplasms | & criteria., \(\quad \mathrm{n}\)-free \\
\hline Pancreatic & Percentage survival \\
\hline
\end{tabular}

Cancer | HE
R2-positive
Solid
Tumors | HE
R2-positive
Breast
Cancer 1 HE
R2-positive
Gastric
Cancer 1 HE
R-2 Protein
Overexpress
ion|HER-2

\section*{Gene}

Amplificatio
n | Prostate
Cancer|Hea
\begin{tabular}{ll} 
of & (PFS)., \\
products & Defined as \\
that pass & the time \\
release & between \\
criteria & the date of \\
among all & first dose \\
manufactu & and the \\
red & date of first \\
products., & documente \\
12 & d disease \\
months \(|\)\begin{tabular}{ll} 
A & progressio
\end{tabular} \\
ssess the & n \\
safety and & determine \\
tolerability & d by the \\
of CT-0508 & investigato \\
in & r using \\
combinatio & RECIST
\end{tabular}
\begin{tabular}{|c|c|c|}
\hline d and Neck & \(n \quad\) with & v1.1 or \\
\hline Cancer \| End & pembroliz & death due \\
\hline ometrial & umab by & to any \\
\hline Cancer / Lun & estimating & cause, \\
\hline g Cancer, & the & whichever \\
\hline Small Cell & frequency & occurs \\
\hline & and & first. \\
\hline & severity of & \\
\hline & adverse & Defined as \\
\hline & events in & the time \\
\hline & subjects & between \\
\hline & with HER2 & the date of \\
\hline & overexpres & first dose \\
\hline & sing solid & and the \\
\hline & tumors & date of first \\
\hline & (CT-0508 & documente \\
\hline & and & d disease \\
\hline
\end{tabular}
\begin{tabular}{lll} 
pembroliz & \multicolumn{1}{l}{ progressio } \\
umab & n & as \\
substudy & determine \\
only), & d & by \\
Frequency & investigato \\
and & r & using
\end{tabular}
\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|}
\hline & & & & & & & Release & & \\
\hline & & & & & & & Syndrome & & \\
\hline & & & & & & & \begin{tabular}{l}
\[
\text { (CRS), } 14
\] \\
months
\end{tabular} & & \\
\hline ACTIVE_NO & Metastatic & DRUG: & PHAS & INTER & Allocation: & 49 & Dose & Progressio & 2018/2/6 \\
\hline T_RECRUITI & Esophageal & Olaparib|BI & E1|PH & VENTI & NA | Interve & & limiting & n free & \\
\hline NG & Carcinoma & OLOGICAL: & ASE2 & ONAL & ntion & & toxicity & survival, & \\
\hline & Metastatic & Ramuciruma & & & Model: & & and & Will be & \\
\hline & Gastric & b & & & SINGLE_G & & maximum & compared & \\
\hline & Carcinoma & & & & ROUP \| Mas & & tolerated & for & \\
\hline & Metastatic & & & & king: & & dose of & duration of & \\
\hline & Gastroesoph & & & & NONE | Pri & & olaparib & response & \\
\hline & ageal & & & & mary & & (Phase I), & survival & \\
\hline & Junction & & & & Purpose: & & Will be & with & \\
\hline & Adenocarci & & & & TREATME & & assessed & Kaplan- & \\
\hline & noma|Recu & & & & NT & & by & Meier & \\
\hline & rrent & & & & & & National & estimates & \\
\hline
\end{tabular}

Esophageal
Carcinoma |
Recurrent
Gastric
Carcinoma |
Recurrent
Gastroesoph
ageal
Junction
Adenocarci
noma|Stage
III
Esophageal
Cancer
AJCC
v7|Stage III
Gastric

Cancer
and log-
Institute rank tests.
(NCI) The
Common Rothman
Terminolo CI will be
gy Criteria reported.
(CTCAE) In
for addition,
Adverse the
Events possible
version risk factors
5.0., Up to will be

14 compared
days|Obje for
ctive survival
response with log-
rate (Phase rank test.
\begin{tabular}{|c|c|c|}
\hline Cancer & II), Will be & For \\
\hline AJCC & defined as & multivariat \\
\hline v7|Stage IV & complete & e analysis, \\
\hline Esophageal & or partial & the \\
\hline Cancer & response & proportion \\
\hline AJCC & assessed & al hazards \\
\hline v7|Stage IV & by & Cox model \\
\hline Gastric & Response & will be \\
\hline Cancer & Evaluation & applied to \\
\hline AJCC & Criteria in & investigate \\
\hline v7|Unresect & Solid & potential \\
\hline able & Tumors & prognostic \\
\hline Esophageal & version 1.1. & factors, \\
\hline Carcinoma | & Will be & such as age \\
\hline Unresectabl & estimated & and stage \\
\hline e Gastric & using the & of disease \\
\hline Carcinoma & 95\% & of the PFS \\
\hline
\end{tabular}

\section*{Unresectabl}
e
Gastroesoph
ageal
Junction
Adenocarci
noma
\begin{tabular}{|c|c|}
\hline interval & adjusted p - \\
\hline (CI) based & values of \\
\hline on & the hazard \\
\hline Wilson's & ratios and \\
\hline method. A & the \\
\hline 5\% 2-sided & adjusted \\
\hline alpha will & 95\% \\
\hline be used. & confidence \\
\hline The & interval \\
\hline Wilcoxon & will be \\
\hline rank sum & reported., \\
\hline test and & From start \\
\hline Fisher's & of \\
\hline exact test & treatment \\
\hline will be & to time of \\
\hline applied to & progressio \\
\hline
\end{tabular}
interval adjusted p-
(CI) based values of
Wilson's ratios and
method. A the
5\% 2-sided adjusted
alpha will 95\%
be used. confidence
The interval
will be
rank sum reported.,
test and From start
Fisher's of
exact test treatment
will be to time of
applied to progressio
\begin{tabular}{|c|c|}
\hline association & whichever \\
\hline between & occurs \\
\hline the & first, \\
\hline response & assessed \\
\hline status and & up to 6 \\
\hline the & years |Ove \\
\hline continuous & rall \\
\hline and & survival, \\
\hline categorical & Will be \\
\hline variables, & compared \\
\hline respectivel & for \\
\hline \(y\). The & duration of \\
\hline generalize & response \\
\hline d non- & survival \\
\hline linear & with \\
\hline model and & Kaplan- \\
\hline
\end{tabular}
\begin{tabular}{ll} 
logistic & Meier \\
regression & estimates \\
will be & and log- \\
applied for & rank tests. \\
multivaria & The \\
ble data & Rothman \\
analysis. & CI will be \\
The & reported. \\
adjusted p- & In \\
value and & addition, \\
95\% CI of & the \\
the odds & possible \\
ratio will & risk factors \\
be & will be \\
reported., & compared \\
Up to 6 & for \\
years & survival
\end{tabular}
with log-
rank test.
The
adjusted p-
values of
the hazard
ratios and
the
adjusted
95\%
confidence
interval
will be
reported.,
Up to 6
years \(\mid B R\)
OCA-HR
status, Will
compared
for
duration of
response
survival
with
Kaplan-
Meier
estimates
and log-
rank tests.
The
Rothman
CI will be
reported.
the
possible
risk factors
will be
compared
for
survival
with log-
rank test.
The
adjusted p -
values of
the hazard
ratios and
the
adjusted
95\%
confidence
interval
will be
reported.,
Up to 6
years | Inci
dence of
adverse
events,
Will be
assessed
by NCI
CTCAE
version 5.0.
Will be

\section*{tabulated}
by type
and grade
and
compared
to
established
rates for
ramucirum
ab
monothera
py. Ninety-
five
percent
confidence
intervals
will be
\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|}
\hline & & & & & & & & calculated for each of these., Up to 30 days of last dose administra tion & \\
\hline ACTIVE_NO & Localized & DRUG: & PHAS & INTER & Allocation: & 160 & Rate of & Safety & 2021/10/18 \\
\hline T_RECRUITI & Resectable & Pembrolizum & E2 & VENTI & NON_RAN & & complete & the & \\
\hline NG & Tumor \| MSI & ab & & ONAL & DOMIZED| & & pathologic & perioperati & \\
\hline & /dMMR or & & & & Intervention & & al response & ve & \\
\hline & EBV- & & & & Model: & & (pCR) after & treatment, & \\
\hline & positive & & & & PARALLEL & & & Safety & \\
\hline & Gastric & & & & | Masking: & & complete & profile, & \\
\hline & Cancers & & & & NONE | Pri & & pathologic & determine & \\
\hline & & & & & mary & & al response & d using the & \\
\hline & & & & & Purpose: & & will be & National & \\
\hline
\end{tabular}
\begin{tabular}{|c|c|c|}
\hline TREATME & defined as & Cancer \\
\hline \multirow[t]{16}{*}{NT} & 0\% viable & Institute \\
\hline & tumor & Common \\
\hline & cells., 6 & Terminolo \\
\hline & weeks after & gy Criteria \\
\hline & first & for \\
\hline & injection & Adverse \\
\hline & & Event \\
\hline & & (NCI-CTC \\
\hline & & AE) \\
\hline & & grading \\
\hline & & scale \\
\hline & & version 5. \\
\hline & & Adverse \\
\hline & & events will \\
\hline & & be \\
\hline & & described \\
\hline
\end{tabular}
and
severity, 36
Months
(over the
whole
study)|Rat
e of
surgical
complicati
ons (post-
operative
morbidity)
, The rate
of surgical
complicati
morbidity)
will be
assessed
according
to
modified
Clavien
Dindo
scoring, 1
Month
after
sugery \(\mid \mathrm{Ra}\)
te of
patients
with the R0
resection,
Percentage
of patients
with the R0
resection,
36
Months | M
ajor
pathologic
al response
rate,
Percentage
of patients
with major
pathologic
al response
( 鈮 ? 10\%
residual
viable
tumor), 36
Months |R
ecurrence-
free
survival
(RFS), RFS
defined as
the time
from the
date of first
study
treatment
administra
tion to the
date of first
recurrence,

Months|O
verall
response
rate (ORR)
at 4 weeks
after the
injection of
neodjuvan
t
pembroliz
umab,
Percentage
of patients
with
objective
response at
1 month
(complete
or partial
response)
after
neoadjuva
nt
pembroliz
umab,
according
to RECIST
v1.1., \(\quad 4\)
weeks after
first study
treatment
injection |
Rate of
second
cancer in
the Lynch
syndrom
spectrum,
Percentage
of patients
with
second
cancer, 36
Months |T
he overall
survival
(OS), OS,
defined
from the
date of first
study
treatment
administra
tion to the
date of
death due
to any
cause.,
From 36
months \(\mid \operatorname{Pr}\)
ogression-
free
survival
(PFS) after
recurrence,
PFS,
defined
from the
date of first
documente
d
recurrence
to the date
of
documente
d
progressio
n., \(\quad 36\)
months |Q
uality of
life (QoL),

QoL,
assessed
using the
EORTC
QLQ-C30,
Baseline,
before
surgery
and at 5
months
post
inclusion |
The
prognostic
value
of
lung
immune
\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|}
\hline & & & & & & & & \begin{tabular}{l}
prognostic \\
index \\
（LIPI）， 36 \\
months
\end{tabular} & \\
\hline COMPLETE & Breast & OTHER：虏 & PHAS & INTER & Allocation： & 18 & Safety and & Immunoge & Jul－11 \\
\hline D & Neoplasms & & E1 & VENTI & NA｜Interve & & tolerability & nicity：To & \\
\hline & Peritoneal & 鹿 虏 Pb & & ONAL & ntion & & ：To & characteriz & \\
\hline & Neoplasms｜ & TCMC－ & & & Model： & & measure & e the & \\
\hline & Ovarian & Trastuzumab & & & SINGLE＿G & & the & human & \\
\hline & Neoplasms｜ & ｜BIOLOGIC & & & ROUP｜Mas & & number of & immune & \\
\hline & Pancreatic & AL: & & & king： & & participant & response & \\
\hline & Neoplasms｜ & trastuzumab & & & NONE｜Pri & & s who & against 虏 & \\
\hline & Stomach & & & & mary & & experience & 鹿虏 Pb－ & \\
\hline & Neoplasms & & & & Purpose： & & adverse & & \\
\hline & & & & & TREATME & & events & TCMC－ & \\
\hline & & & & & NT & & after & Trastuzum & \\
\hline & & & & & & & intraperito & ab given & \\
\hline & & & & & & & & via IP & \\
\hline
\end{tabular}
\begin{tabular}{|c|c|}
\hline \begin{tabular}{l}
neal（IP） \\
administra
\end{tabular} & \begin{tabular}{l}
infusion．， \\
Assessed
\end{tabular} \\
\hline tion of 虏 & at six \\
\hline 鹿 虏 Pb－ & \begin{tabular}{l}
weeks \\
visit｜Anti－
\end{tabular} \\
\hline TCMC－ & \\
\hline Trastuzum ab．， & effects：To monitor \\
\hline Adverse events & for anti－ tumor \\
\hline \begin{tabular}{l}
considered \\
dose
\end{tabular} & effects as assessed \\
\hline limiting toxicity： & by physical examinatio \\
\hline \begin{tabular}{l}
＊Grade 3 \\
elevations \\
of ALP，
\end{tabular} & n， radiograph ic imaging， \\
\hline
\end{tabular}
\begin{tabular}{ll} 
bilirubin, & and tumor \\
ALT, or & marker \\
AST & studies., \\
lasting 鈮? & Assessed \\
days & after six \\
* Grade 3 & and twelve \\
elevations & weeks, and \\
of serum & then at \\
creatinine & twelve- \\
within 6 & week \\
weeks of & intervals \\
treatment & until \\
* Grade 2 & progressio \\
elevations & n. \(\mid\) Pharma \\
of serum & cokinetics: \\
creatinine & To \\
lasting 鈮? &
\end{tabular}
\begin{tabular}{ll} 
days that the plasma \\
occur after & pharmacok \\
6 weeks & inetics and \\
* Grade 3 & assess the \\
proteinuri & extent of \\
a & exit of \\
* Any & radioactivi \\
other & ty from the \\
Grade 3 or & peritoneal \\
4 & non- cavity by \\
hematologi & 纬 -camera \\
c toxicity & imaging., \\
* Grade 4 & Up to 3 \\
neutropeni & days post- \\
a lasting & injection \\
鈮? days or & \\
febrile
\end{tabular}
neutropeni
a of any
duration
* Grade 3
thrombocy
topenia
that fails to
recover to
鈮?Grade 2
at 6 weeks
* Grade 4
thrombocy
topenia
lasting 鈮?
days or
thrombocy
topenia
\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|}
\hline & & & & & & & accompani & & \\
\hline & & & & & & & ed by & & \\
\hline & & & & & & & bleeding, & & \\
\hline & & & & & & & Assessed & & \\
\hline & & & & & & & periodicall & & \\
\hline & & & & & & & y during & & \\
\hline & & & & & & & study & & \\
\hline & & & & & & & treatment & & \\
\hline & & & & & & & follow-up, & & \\
\hline & & & & & & & up to five & & \\
\hline & & & & & & & years. & & \\
\hline TERMINATE & Solid & BIOLOGICA & PHAS & INTER & Allocation: & 6 & Safety and & Anti- & 2019/3/13 \\
\hline D & Tumor | HE & L: ACTR T & E1 & VENTI & NA | Interve & & tolerability & tumor & \\
\hline & R-2 Protein & Cell & & ONAL & ntion & & of ACTR T & activity as & \\
\hline & Overexpress & Product \({ }^{\text {DR }}\) & & & Model: & & cell & measured & \\
\hline & ion & UG: & & & SINGLE_G & & product & by overall & \\
\hline & & Trastuzumab & & & ROUP \| Mas & & with & response & \\
\hline
\end{tabular}
\begin{tabular}{lll} 
king: & trastuzum & rate (ORR) \\
NONE |Pri & ab as & per \\
mary & assessed & iRECIST, \\
Purpose: & by & 52 \\
TREATME & committee & weeks \(\mid\) An \\
NT & review of ti-tumor \\
& dose & activity as \\
& limiting & measured \\
& toxicities & best \\
& (DLTs), & overall \\
& ancidence & response \\
& severity of & (BOR), 52 \\
& adverse \(\mid\) An \\
& events & ti-tumor \\
& (AEs) andivity as & measured \\
& clinically & by
\end{tabular}
\begin{tabular}{|c|c|}
\hline significant abnormalit & duration of response \\
\hline ies of & (DOR), 52 \\
\hline laboratory & weeks \(\mid\) An \\
\hline values, 42 & ti-tumo \\
\hline days|Dete & activity as \\
\hline rmination & measured \\
\hline of & by \\
\hline recommen & progressio \\
\hline ded phase & n -free \\
\hline dose & survival \\
\hline (RP2D) & (PFS), 52 \\
\hline regimen, & weeks \(\mid\) An \\
\hline Review of & ti-tumor \\
\hline DLTs, & activity as \\
\hline maximum & measured \\
\hline tolerated & by overall \\
\hline
\end{tabular}
\begin{tabular}{|c|c|}
\hline dose & survival \\
\hline (MTD), & (OS), 52 \\
\hline incidence & weeks \(\mid\) Ass \\
\hline and & essment of \\
\hline severity of & persistence \\
\hline AEs and & of ACTR as \\
\hline clinically & measured \\
\hline significant & by flow \\
\hline abnormalit & cytometry, \\
\hline ies of & 52 \\
\hline laboratory & weeks \(\mid\) Ass \\
\hline values, 42 & essment of \\
\hline days & persistence \\
\hline & of ACTR as \\
\hline & measured \\
\hline & by \\
\hline & quantitativ \\
\hline
\end{tabular}
polymeras
e chain
reaction
(qPCR), 52
weeks|Ass
essment of
ACTR
phenotype
and
function as
measured
by flow
cytometry,
52
weeks |Ass
essment of
induction
of
inflammat
ory
markers
and
cytokines/
chemokine
s after
ACTR T
cell
product
administra
tion,
Levels of
inflammat
ory
\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|}
\hline & & & & & & & & trough & \\
\hline & & & & & & & & levels, 52 weeks & \\
\hline WITHDRAW & Locally & DRUG: & PHAS & INTER & Allocation: & 0 & Dose & Best & 2020/4/6 \\
\hline N & Advanced & Liposomal & E1|PH & VENTI & NA | Interve & & limiting & overall & \\
\hline & Unresectabl & Irinotecan \({ }^{\text {O }}\) & ASE2 & ONAL & ntion & & toxicity & response & \\
\hline & e Gastric & THER: & & & Model: & & (DLT) & (BOR) as & \\
\hline & Adenocarci & Quality-of- & & & SINGLE_G & & (Phase I), & measured & \\
\hline & noma|Meta & Life & & & ROUP \| Mas & & DLT is & by & \\
\hline & static & Assessment & & & king: & & defined as & Response & \\
\hline & Gastroesoph & OTHER: & & & NONE | Pri & & follows: & Evaluation & \\
\hline & ageal & Questionnair & & & mary & & For & Criteria in & \\
\hline & Junction & e & & & Purpose: & & hematologi & Solid & \\
\hline & Adenocarci & Administrati & & & TREATME & & cal toxicity: & Tumors & \\
\hline & noma|Meta & on | BIOLOGI & & & NT & & Drug- & (RECIST) & \\
\hline & static & CAL: & & & & & related & version 1.1 & \\
\hline & Unresectabl & & & & & & grade 4 & criteria, & \\
\hline
\end{tabular}
\begin{tabular}{|c|c|c|c|}
\hline e Gastric & Ramuciruma & neutropeni & BOR will \\
\hline Adenocarci & b & a for more & be \\
\hline noma| Unre & & than 5 days & evaluated \\
\hline sectable & & without & from start \\
\hline Gastroesoph & & fever or & of \\
\hline ageal & & infection; & treatment \\
\hline Junction & & Grade 4 & until \\
\hline Adenocarci & & neutropeni & progressio \\
\hline noma | Gastr & & a of any & \(\mathrm{n} /\) recurren \\
\hline ic & & duration & ce., Up to 6 \\
\hline Adenocarci & & accompani & month | In \\
\hline noma | Gastr & & ed by fever & cidence of \\
\hline oesophageal & & or & adverse \\
\hline Junction & & infection, & events \\
\hline Adenocarci & & Grade 4 & graded \\
\hline noma & & thrombocy & according \\
\hline & & topenia. & to CTCAE \\
\hline
\end{tabular}
\begin{tabular}{ll} 
For non- & version 4.0, \\
hematologi & Analyses \\
cal toxicity: & of \\
All grade & safety/toxi \\
\(3-4\) that & city will be \\
represents & performed \\
a 2 grade & for all \\
increase & patients \\
over & having \\
baseline, & received at \\
excluding: & least one \\
Untreated & dose of \\
or & study \\
inadequate & drug., Up \\
ly treated & to \\
nausea, & months
\end{tabular}
diarrhea
lasting
shorter
than 24
hours;
Alopecia;
Grade
fatigue
that
returns to
grade 2 or
less within
7 days;
Grade 3
laboratory
abnormalit
ies that are
not
considered
clinically
significant
and that
return to
grade 2 or
less within
72 hours.,
Up to 28
days|Prog
ression-
free
survival
(PFS)
(Phase II),
PFS will be
calculated
from
treatment
start date
to date of
disease
progressio
n or date of
death due
to any
cause, or to
the time of
last follow-
up,
whichever
occurs
\begin{tabular}{|c|c|c|c|c|c|c|c|c|}
\hline & & & & & & & \begin{tabular}{l}
first., Up to \\
6 months
\end{tabular} & \\
\hline TERMINATE & Solid & DRUG: & PHAS & INTER & Allocation: & 16 & Define the & 2021/10/15 \\
\hline D & Tumor, & FT538|DRU & E1 & VENTI & NON_RAN & & Recommended Phase 2 & \\
\hline & Adult & G: & & ONAL & DOMIZED | & & Dose (RP2D), To define & \\
\hline & & Cyclophosph & & & Intervention & & the RP2D of FT538 in & \\
\hline & & amide \({ }^{\text {DRU }}\) & & & Model: & & combination with the & \\
\hline & & G: & & & SEQUENTI & & following mAbs in & \\
\hline & & Fludarabine | & & & AL|Maskin & & subjects with advanced & \\
\hline & & COMBINATI & & & g: & & solid tumors: avelumab, & \\
\hline & & ON_PRODU & & & NONE | Pri & & trastuzumab, cetuximab, & \\
\hline & & CT: & & & mary & & atezolizumab, & \\
\hline & & Monoclonal & & & Purpose: & & nivolumab, and & \\
\hline & & antibody - & & & TREATME & & pembrolizumab, Up to & \\
\hline & & Dose & & & NT & & \(\sim 1.5\) years | Incidence & \\
\hline & & Escalation \({ }^{\text {C }}\) & & & & & and Severity of Adverse & \\
\hline & & OMBINATIO & & & & & Events (AEs)0, To & \\
\hline
\end{tabular}

\begin{tabular}{|c|c|c|c|}
\hline Lung & AL|Maskin & events & Maximum \\
\hline Cancer \| Col & g : & (AEs) and & plasma \\
\hline orectal & NONE |Pri & serious & concentrati \\
\hline Cancer \({ }^{\text {Pan }}\) & mary & adverse & on (Cmax), \\
\hline creatic & Purpose: & events & 12 \\
\hline Cancer \| Can & TREATME & (SAEs) & Months | N \\
\hline cer | \(\mathrm{CRC} \mid \mathrm{C}\) & NT & graded & oncompart \\
\hline olon & & according & mental PK \\
\hline Cancer \| Bre & & to National & Parameters \\
\hline ast & & Cancer & of E-602 \\
\hline Cancer \| Gas & & Institute & (Phase 1), \\
\hline tric & & ( NCI ) & Area \\
\hline Cancer \| EGJ & & Common & under the \\
\hline |Esophagog & & Terminolo & plasma \\
\hline astric & & gy Criteria & concentrati \\
\hline Junction & & for & on-time \\
\hline Cancer \| Hea & & Adverse & curve \\
\hline
\end{tabular}
\begin{tabular}{llll} 
d and Neck & Events & (AUC), 12 \\
Cancer \(\mid\) Uro & (CTCAE) & Months \(\mid S\)
\end{tabular}
\begin{tabular}{ll} 
days|Obje & Months |O \\
ctive & bjective \\
Response & Response \\
Rate & Rate \\
(Phase 2), & \((\) Phase 1), \\
Objective & Objective \\
response & response \\
rate of & rate of \\
confirmed & confirmed \\
complete & complete \\
response & response \\
and partial & and partial \\
response, & response \\
12 & using \\
Months \(|\)\begin{tabular}{ll} 
D & Response
\end{tabular} \\
uration of & Evaluation \\
Response & Criteria in
\end{tabular}
\begin{tabular}{ll} 
(Phase 2), & Solid \\
Duration & Tumors \\
of & (RECIST) \\
Response & v1.1 and \\
of & Immunoth \\
confirmed & erapy \\
complete & Response \\
response & Evaluation \\
or partial & Criteria in \\
response., & Solid \\
16 & Tumors \\
Months \(\mid\) P & (iRECIST)., \\
rogression & 12 \\
Free & Months |D \\
Survival & uration of \\
(Phase 2), & Response \\
Time from & (Phase 1),
\end{tabular}
\begin{tabular}{|c|c|}
\hline first study treatment & Duration
of \\
\hline dose until & Response \\
\hline the first & of \\
\hline date when & confirmed \\
\hline progressiv & complete \\
\hline e disease & response \\
\hline (PD) is & or partial \\
\hline objectively & response, \\
\hline documente & 16 \\
\hline d or death & Months |P \\
\hline from any & rogression \\
\hline cause, 15 & Free \\
\hline Months \({ }^{\text {O }}\) & Survival \\
\hline verall & (Phase 1), \\
\hline Survival & Time from \\
\hline (Phase 2), & first dose \\
\hline
\end{tabular}
\begin{tabular}{ll} 
Time from & to first \\
first study & evidence of \\
treatment & radiograph \\
dose until & ically \\
death, 15 & detectable \\
Months & disease or \\
& death from \\
& any cause, \\
& 15 \\
& Months |O \\
& verall \\
& Survival \\
& (Phase 1 ), \\
& Time from \\
& first study \\
treatment
\end{tabular}\(\quad\)\begin{tabular}{l} 
dose until
\end{tabular}
death, 15
Months | In
cidence of
AEs and
SAEs
(Phase 2),
Incidence
of adverse
events
(AEs) and
serious
adverse
events
(SAEs)
graded
according
to National

\section*{Cancer}

Institute
(NCI)
Common
Terminolo
gy Criteria
for
Adverse
Events
(CTCAE)
v5.0, 15
Months \(\mid \mathrm{N}\)
oncompart
mental PK
Parameters
of E-602
(Phase 2),
Maximum
plasma
concentrati on (Cmax),
12
Months \(\mid \mathrm{N}\)
oncompart
mental PK
Parameters
of E-602
(Phase 2),
Area
under the
plasma
concentrati
on-time
curve

Months|S
ubjects
with
Antidrug
Antibodies
(Phase 2),
Number
and
percentage
of subjects
who
develop
detectable
antidrug
antibodies,
13 Months
\begin{tabular}{llllllll} 
RECRUITIN & Non-small DRUG: CDX- PHAS & INTER & Allocation: 130 & Dose & Safety and 2023/5/11 \\
G & Cell Lung 585 & E1 & VENTI & NA|Interve & escalation: Tolerabilit
\end{tabular}
\begin{tabular}{|c|c|c|}
\hline Carcinoma & cohorts, & dose \\
\hline Colorectal & The rates & through 90 \\
\hline Cancer \| Eso & of drug- & days after \\
\hline phageal & related & last \\
\hline Cancer \({ }^{\text {He }}\) & adverse & dose | Obje \\
\hline patic & events will & ctive \\
\hline Cancer \| Ren & be & Response \\
\hline al Cell & summarize & Rate, The \\
\hline Carcinoma & d, and & percentage \\
\hline Cholangioca & maximum & of patients \\
\hline rcinoma \({ }^{\text {Pa }}\) & tolerated & who \\
\hline ncreatic & dose will & achieve a \\
\hline Cancer | Oth & be & confirmed \\
\hline er Solid & determine & immune \\
\hline Tumors & d., & complete \\
\hline & Approxim ately 12 & \begin{tabular}{l}
response \\
(iCR) or
\end{tabular} \\
\hline
\end{tabular}
\begin{tabular}{ll} 
months \(\mid \mathrm{T}\) & immune \\
umor- & partial \\
specific & response \\
expansion & (iPR), \\
cohorts: To & Assessed \\
further & up to \\
evaluate & approxima \\
the safety & tely 1-3 \\
of CDX- & years.|Cli \\
\(585 \quad\) by & nical \\
tumor & Benefit \\
type., The & Rate, The \\
rates of & percentage \\
drug- & of patients \\
related & who \\
adverse & achieve \\
events will & best
\end{tabular}
\begin{tabular}{|c|c|}
\hline be & response of \\
\hline summarize & confirmed \\
\hline d, and & iCR or iPR, \\
\hline further & or immune \\
\hline evaluated & stable \\
\hline in specific & disease \\
\hline tumor & (iSD) for at \\
\hline types., & least four \\
\hline Approxim & months, \\
\hline ately 6 & Assessed \\
\hline months & up to \\
\hline & approxima \\
\hline & tely 1-3 \\
\hline & years.|Dur \\
\hline & ation of \\
\hline & Response, \\
\hline
\end{tabular}

The
from
which
measurem
ent criteria
are first
met for iCR
or iPR until
the first
date that
progressiv
e disease is
objectively
documente
d, First
occurrence
of
a
documente
d objective
response to
disease
progressio
n or death
(up to
approxima
tely 1-3
years)|Pro
gression-
free
Survival,
The time
from start
of study
drug to
n or death,
whichever
occurs
first, Cycle
1 , day 1 to
the first
occurrence
of disease
progressio
\(n\) or death
due to any
cause (up
to
approxima
tely 1-3
years) \(\mid \mathrm{Ov}\)
erall
Survival,
The time
from start
of study
drug to
death, The
time from
start of
study drug
to death
from any
cause (up
to
approxima
tely
years)|Pha
rmacokinet
ic
Evaluation
, CDX-585
serum
concentrati
ons will be
measured
at specified
visits, Prior
to, during,
and at
multiple
time points
after doses
1-4. Prior
other dose
from fifth
dose, and
at 30 and
90 days
post last
dose of
study
treatment
Immunoge
nicity
Evaluation
, Samples
will be
obtained
for
three doses
and every
other dose
from the
fifth dose
of study
treatment,
then 30
and 90
days after
the last
dose
\begin{tabular}{llllll} 
UNKNOWN & Gastric & DRUG: & PHAS & INTER & Allocation: 20 \\
& Cancer & Toripalimab & E2 & VENTI & NA|Interve \\
& & combined & & ONAL & ntion \\
& with & & Model: \\
& oxaliplatin & & SINGLE_G \\
& and & & ROUP|Mas \\
& Tegafur,Gime & king: \\
& racil and & & NONE|Pri \\
& Oteracil & mary \\
& Porassium & & Purpose: \\
& Capsules & & TREATME \\
& & & NT
\end{tabular}

Objective Response 2020/2/1
Rate, The percentage of patients whose tumors shrink to a certain extent and remain there for a certain period of time, including \(\mathrm{CR}+\mathrm{PR}\) cases, All subjects receive tumor assessment every 6 weeks until desease progress, up to 24 mons. Objective response rate is defined as the date from ICF signation to the date of first documented progression or date of
\begin{tabular}{llllll} 
UNKNOWN & Stomach & DRUG: & PHAS & INTER & Allocation: 20 \\
& Cancer|Gas & Atezolizuma & E2 & VENTI & NA|Interve
\end{tabular}
\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|}
\hline & & & & & & & days after last patient last study drug treatment & \begin{tabular}{l}
patient \\
inclusion
\end{tabular} & \\
\hline RECRUITIN & Gastric & DRUG: & PHAS & INTER & Allocation: & 357 & Part 1: & Part 1: & : 2020/6/3 \\
\hline G & Cancer & Fluorouracil & E2 & VENTI & RANDOMI & & Occurrenc & Objective & \\
\hline & & (5- & & ONAL & ZED|Interv & & e of & Response & \\
\hline & & FU) |DRUG: & & & ention & & adverse & Rate & \\
\hline & & Capecitabine & & & Model: & & events & (ORR), & \\
\hline & & | BIOLOGIC & & & PARALLEL & & (AEs) and & Confirmed & \\
\hline & & AL: & & & | Masking: & & serious & ORR per & \\
\hline & & Durvalumab & & & NONE | Pri & & adverse & RECIST 1.1 & \\
\hline & & | DRUG: & & & mary & & events & is the & \\
\hline & & Oxaliplatin | & & & Purpose: & & (SAEs), & percentage & \\
\hline & & BIOLOGICA & & & TREATME & & graded & of patients & \\
\hline & & L: & & & NT & & according & with & \\
\hline
\end{tabular}
\begin{tabular}{|c|c|c|}
\hline Trastuzumab & to NCI & Complete \\
\hline | DRUG: & CTCAE & Response \\
\hline Trastuzumab & v5.0, & or Partial \\
\hline deruxtecan| & Occurrenc & Response \\
\hline DRUG: & e of AEs & that is \\
\hline Cisplatin | BI & and SAEs & subsequen \\
\hline OLOGICAL: & graded & tly \\
\hline Pembrolizum & according & confirmed. \\
\hline ab|BIOLOGI & to NCI & , Efficacy \\
\hline CAL: & CTCAE & will be \\
\hline \multirow[t]{7}{*}{MEDI5752} & v5.0, Safety & assessed at \\
\hline & will be & an average \\
\hline & assessed & \\
\hline & up to the & approxima \\
\hline & follow-up & tely 12 \\
\hline & period, & months | P \\
\hline & approxima & art 2 and \\
\hline
\end{tabular}
\begin{tabular}{lll} 
tely & 24 & Part \\
months. \(\mid \mathrm{P}\) & Occurrenc \\
art & \(1:\) & e \\
Ocurrence & adverse \\
of dose- & events \\
limiting & (AEs) and \\
toxicities & serious \\
(DLTs), & adverse \\
Occurrenc & events \\
e of dose & (SAEs), \\
limiting & Occurrenc \\
toxicities, & e of & AEs \\
Safety will & and \(\quad\) SAEs \\
be assessed & graded \\
up to the & according \\
follow-up & to \(\quad\) NCI \\
period, & CTCAE
\end{tabular}
\begin{tabular}{lll} 
approxima & v5.0, Safety \\
tely & 24 & will be \\
months. \(\mid\) P & assessed \\
art & \(1:\) & up \\
Changes & follow-up \\
from & period, \\
baseline in & approxima \\
laboratory & tely 24 \\
parameters & months \(\mid P\) \\
Changes & art 2 and \\
in & Part \(\quad 3:\) \\
laboratory & Changes \\
parameters & from \\
(every in & baseline in \\
appropriat & laboratory \\
e units) & parameters \\
compared & Changes
\end{tabular}
\begin{tabular}{ll} 
to baseline & in \\
results., & laboratory \\
Safety will & parameters \\
be assessed & (every in \\
up to the & appropriat \\
follow-up & e units) \\
period, & compared \\
approxima & to baseline \\
tely \(\quad 24\) & results., \\
months. \(\mid \mathrm{P}\) & Safety will \\
art \(\quad 1:\) & be assessed \\
Changes & up \\
to \\
from & follow-up \\
baseline in & period, \\
vital signs, & approxima \\
Changes in & tely 24 \\
vital signs & months \(\mid\) P
\end{tabular}
\begin{tabular}{ll} 
results & art 2 and \\
compared & Part \(3:\) \\
to baseline & Changes \\
results., & from \\
Safety will baseline in \\
be assessed & vital signs, \\
up to the & Changes in \\
follow-up & vital signs \\
period, & results \\
approxima & compared \\
tely 24 & to baseline \\
months. \(\mid \mathrm{P}\) & results., \\
art \(\quad 1:\) & Safety will \\
Changes & beassessed \\
from & up \(\quad\) to \\
baseline in & follow-up \\
electrocard & period,
\end{tabular}
\begin{tabular}{ll} 
iogram & approxima \\
(ECG) & tely \(\quad 24\) \\
results, & months |P \\
Changes in & art 2 and \\
ECG & Part \(\quad 3:\) \\
results & Changes \\
compared & from \\
to baseline & baseline in \\
results., & body \\
Safety will & weight, \\
be assessed & Changes in \\
up to the & body \\
follow-up & weight in \\
period, & kilograms \\
approxima & compared \\
tely & 24
\end{tabular}
\begin{tabular}{|c|c|}
\hline \begin{tabular}{l}
art 2 and \\
Part 3:
\end{tabular} & Safety will
be assessed \\
\hline Endpoint & up to \\
\hline assessed & follow-up \\
\hline by & period, \\
\hline Investigato & approxima \\
\hline \(r\) per & tely 24 \\
\hline RECIST & months |P \\
\hline v1.1: & art 2 and \\
\hline Confirmed & Part 3: \\
\hline Objective & Changes \\
\hline Response & from \\
\hline Rate & baseline in \\
\hline (ORR), & electrocard \\
\hline Confirmed & iogram \\
\hline ORR per & (ECG) \\
\hline RECIST 1.1 & lts, \\
\hline
\end{tabular}
\begin{tabular}{ll} 
is the Changes in \\
percentage & ECG \\
of patients & results \\
with & compared \\
Complete & to baseline \\
Response results., \\
or Partial & Safety will \\
Response beassessed \\
that is up to \\
subsequen & follow-up \\
tly & period, \\
confirmed. & approxima \\
, & tely 24 \\
(Endpoint: & months \(\mid\) D \\
ORR) & uration of \\
Efficacy & Response \\
will be & (DoR),
\end{tabular}

be assessed
up to
approxima
tely \(\quad 24\)
months |D
isease
Control
Rate
(DCR),
DCR is the
percentage
of subjects
who have a
best
overall
response of
complete
response
(CR) or
partial
response
(PR) or
stable
disease
(SD),
Efficacy
will be
assessed at
an average
of
approxima
tely 12
months \(\mid \operatorname{Pr}\)
the date of
objective
disease
progressio
n or death,
Until
progressio
n or death,
efficacy
be assessed
up to
approxima
tely \(\quad 24\)
months \(\mid \mathrm{O}\)
verall
survival
(OS), OS is
the time
from date
of first
dose until
death due
to any
cause,
Until
```

death,
efficacy
(OS) will
be assessed
up to
approxima
tely 24
months|Se
rum
concentrati
on of T-
DXd, total
anti-HER2
antibody,
and
MAAA-
1181a in all

```

Individual
participant
data and
descriptive
statistics
will be
provided
for serum
concentrati
on data at
each time
point for
each dose
level for T-
DXd, total anti-HER2
antibody,
MAAA-
1181a,
While on
study drug
up to study
completion
approxima
tely 24
months \(\mid\) Se
rum
concentrati
on of
durvaluma
b in study
arms
including
T-DXd in
combinatio
n with
durvaluma
b,
Individual
participant
data and
descriptive
statistics
will be
provided
for serum
concentrati
on data at
each time
point for
durvaluma
b., While
on study
drug up to
study
completion
,
approxima
tely 24
months | Pr
esence of
ADAs for
T-DXd and
durvaluma
b and
MEDI5752
including
T-DXd and
durvaluma
b , and T -
DXd and
MEDI5752,
respectivel
y),

Individual
participant
data and
descriptive
statistics
will be
provided
for data at
each time
point for
each dose
level for T-
DXd and
durvaluma
b., While
on study
drug up to
study
completion
approxima
tely 24
months \(\mid\) Se
rum
including
T-DXd in
combinatio
n with
MEDI5752,
,
Individual
participant
data and
descriptive
statistics
will be
, While on
study drug
up to study
completion
approxima
tely 24
months |C
omparison
of ORR,
Compariso
objective
response
rate
between
participant
s using
local HER2
test results
and central
HER2 test
results
from
tumor
samples
with
evaluable
results,

While on
study drug
up to study
completion
,
approxima
tely 24
months |C
omparison
of DCR
Compariso
n
of
disease
control
rate
between
participant
s using
local HER2
test results
and central
HER2 test
results
from
tumor
samples
with
evaluable
results,
While on
study drug
up to study
completion
months \(\mid \mathrm{C}\)
omparison
of DoR,
Compariso
n
of
duration of
response
between
participant
s using
local HER2
test results
and central
HER2 test
results
from
tumor
samples
with
evaluable
results,
While on
study drug
up to study
completion
,
approxima
tely 24
months |C
omparison
of PFS,
Compariso
between
participant
s using
local HER2
test results
and central
HER2 test
results
from
tumor
samples
with
evaluable
results,
While on
study drug
up to study
completion
approxima
tely 24
months |C
omparison
of OS,
Compariso
n of overall
survival
between
participant
s using
local HER2
test results
and central
HER2 test
results
from
tumor
samples
with
evaluable
results,
While on
study drug
up to study
completion
approxima
tely \(\quad 24\)
months
\begin{tabular}{lllllllll} 
ACTIVE_NO & Advanced & BIOLOGICA & PHAS & INTER & Allocation: 198 & Number of Objective 2018/3/14 \\
T_RECRUITI & Malignancie & L: & E1 & VENTI & NON_RAN & participant Response
\end{tabular}
\begin{tabular}{|c|c|}
\hline adverse & rate., Every \\
\hline events as & 8 weeks \\
\hline assessed & (Part A) or \\
\hline by CTCAE & every 9 \\
\hline v4.0, & weeks \\
\hline Through & (Part B) \\
\hline Day 90 of & through \\
\hline last dose & study \\
\hline & completion \\
\hline & an \\
\hline & average of \\
\hline & 1 \\
\hline & year \(\mid\) Disea \\
\hline & se Control \\
\hline & Rate \\
\hline & (DCR), The \\
\hline & treatment \\
\hline
\end{tabular}

Toripalima
b will be
assessed
using
RECIST 1.1
to
determine
disease
control
rate., Every
8 weeks
(Part A) or
every 9
weeks
(Part B)
through
study
completion
, an
average of
1
year|Prog
ression-
Free
survival
(PFS), The
treatment
effect of
Toripalima
b will be
assessed
using
RECIST 1.1
determine
progressio
n-free
survival
time.,
Every 8
weeks
(Part A) or
every 9
weeks
(Part B)
through
study
completion
, an
average of

1
year|Over
all survival
(OS),
Through
study
completion
, an
average of
1 year
\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|}
\hline COMPLETE & Advanced & DRUG: & PHAS & INTER & Allocation: & 85 & Dose & Safety & 2020/3/16 \\
\hline \multirow[t]{6}{*}{D} & \multirow[t]{6}{*}{Solid Tumor} & SRF617|DRU & E1 & VENTI & NON_RAN & & Limiting & Analysis: & \\
\hline & & G: & & ONAL & DOMIZED | & & Toxicity of & Summary & \\
\hline & & Gemcitabine & & & Intervention & & SRF617, & of adverse & \\
\hline & & | DRUG: & & & Model: & & Evaluation & events & \\
\hline & & Albumin- & & & PARALLEL & & of dose- & (AEs) and & \\
\hline & & Bound & & & | Masking: & & limiting & based on & \\
\hline
\end{tabular}
\begin{tabular}{|c|c|c|c|}
\hline Paclitaxel|D & NONE | Pri & toxicity & treatment- \\
\hline RUG: & mary & (DLT)., & emergent \\
\hline Pembrolizum & Purpose: & Assessed & AEs \\
\hline ab & TREATME & during first & (TEAEs), \\
\hline & NT & 28 days of treatment & Safety and tolerability \\
\hline & & & of SRF617 \\
\hline & & & monothera \\
\hline & & & py and \\
\hline & & & combinatio \\
\hline & & & n therapy \\
\hline & & & will be \\
\hline & & & assessed \\
\hline & & & by \\
\hline & & & summarizi \\
\hline & & & ng adverse \\
\hline & & & events \\
\hline
\end{tabular}
will be
based on
treatment-
emergent
AEs
(TEAEs). A
TEAE is an
AE that
emerges or
worsens in
the period
from the
first dose
of study
drug to 30
days after
study drug
assessed
by per
CTCAE
version 5.0
or higher.,
Up to 24
month | P
harmacoki
netics (PK)
of SRF617,
Serum
concentrati
ons
of
SRF617
will be
collected
and
analyzed
to evaluate
the PK of
SRF617.,
Up to 24
months |P
harmacod
ynamics of
SRF617,
Pharmaco
dynamics
of SRF617
will be
evaluated
occupancy.
, Up to 24
months \(\mid \mathrm{O}\)
bjective
response
rate (ORR),
ORR will
be
estimated
by the
percentage
of patients
achieving a
best
overall
response of
CR or PR
per
iRECIST.,
Up to 24
months |D
uration of
response
(DoR),
DoR is
defined as
the time
from the
first
documente
d response
(CR or PR)
documente
d disease
progressio
n as
determine
d by
applicable
disease
criteria, or
documente
d death
due to any
cause,
whichever
occurs
first., Up to
months |D
isease
control
rate (DCR),
DCR is
defined as
the
percentage
of patients
with CR,
partial PR,
or stable
disease
lasting a
minimum
of
weeks., Up
to \(\quad 24\)
months \(\mid \operatorname{Pr}\)
ogression-
free
survival
(PFS), PFS
is defined
as the time
from the
first
treatment
on study
with study
drug to
documente
d disease
determine
d by
applicable
disease
criteria or
death., Up
to 24
months |L
andmark
PFS rate,
Landmark
PFS is
defined as
the
percentage
of patients
who have
not
developed
PFS events
(ie, death
or
documente
d disease
progressio
n as
determine
d by
applicable
disease
criteria) at
6 months, 1
enzymatic
activity,
Levels of
intratumor
al CD39
enzymatic
activity
will be
evaluated
in patients
receiving
pretreatme
nt and on-
treatment
tumor
biopsies
via an in
situ
ATPase
histochemi
stry assay.,
Up to 24
months
\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|}
\hline RECRUITIN & Hepatocellu & DIAGNOSTI & NA & INTER & Allocation: & 400 & Distributio & Heterogen & 2020/10/28 \\
\hline \multirow[t]{16}{*}{G} & lar & C_TEST: & & VENTI & NON_RAN & & n of & eity of & \\
\hline & Cancer \| Cho & FoundationO & & ONAL & DOMIZED| & & mutations & targetable & \\
\hline & langiocarcin & ne 庐 CDx & & & Intervention & & in patients & alterations & \\
\hline & oma |Gallbl & and & & & Model: & & with HCC, & in paraffin & \\
\hline & adder & FoundationO & & & SINGLE_G & & intra- and & embedded & \\
\hline & Cancer | Pan & ne 庐 Liquid & & & ROUP | Mas & & extrahepati & specimen & \\
\hline & creatic & & & & king: & & c CCA, & vs. cfDNA, & \\
\hline & Cancer 1 Oes & & & & NONE | Pri & & GBCA, & Number of & \\
\hline & ophageal & & & & mary & & PDAC and & differences & \\
\hline & Cancer 1 Sto & & & & Purpose: & & gastric & (heterogen & \\
\hline & mach & & & & OTHER & & cancer, & eity) in & \\
\hline & Cancer & & & & & & Relative & targetable & \\
\hline & & & & & & & frequency & alterations & \\
\hline & & & & & & & of & in paraffin & \\
\hline & & & & & & & targetable & specimen & \\
\hline & & & & & & & mutations & vs. cfDNA, & \\
\hline
\end{tabular}
\begin{tabular}{ll} 
(incl. TMB & up to 4 \\
and MSI & weeks after \\
status) & biospecime \\
computed & n \\
as the & provision \\
number of & Relative \\
patients & frequency \\
who & of \\
harbors at & targetable \\
least one & mutations \\
mutation & (incl. TMB \\
divided by & and MSI \\
the & status) per \\
number of & disease \\
total & group, \\
patients in & Relative \\
the pooled & frequency
\end{tabular}
\begin{tabular}{ll} 
patient & of \\
population & targetable \\
, up to 4 & mutations \\
weeks after & (incl. TMB \\
biospecime & and MSI \\
n & status) per \\
provision & disease \\
& \begin{tabular}{l} 
group, up \\
\\
\\
\\
\\
to 4 weeks
\end{tabular} \\
& biospecime \\
& n \\
& \begin{tabular}{l} 
provision
\end{tabular} \\
& patients
\end{tabular}
accordance
to their
genomic
profiles,
Number of
patients
receiving
therapies
in
accordance
to their
genomic
profiles, up
to 4 weeks
after
biospecime
\begin{tabular}{|c|c|c|c|c|c|c|c|c|}
\hline & & & & & & & n provision & \\
\hline RECRUITIN & Pancreatic & DRUG: & PHAS & INTER & Allocation: & 110 & Response rate, & 2017/9/21 \\
\hline G & Cancer \| Gas & Cyclophosph & E1|PH & VENTI & NON_RAN & & Percentage of patients & \\
\hline & tric & amide|DRU & ASE2 & ONAL & DOMIZED | & & who have a clinical & \\
\hline & Cancer \| Gas & G: & & & Intervention & & response ( \(\mathrm{PR}+\mathrm{CR}\) ) to & \\
\hline & trointestinal & Fludarabine & & & Model: & & treatment (objective & \\
\hline & Cancer \({ }^{\text {Col }}\) & BIOLOGICA & & & SEQUENTI & & tumor regression), 6 & \\
\hline & on & L: Anti-KRAS & & & AL|Maskin & & weeks and 12 weeks & \\
\hline & Cancer \(\|\) Rec & G12V mTCR & & & g : & & following & \\
\hline & tal Cancer & PBL|DRUG: & & & NONE | Pri & & administration of the cell & \\
\hline & & Aldesleukin & & & mary & & product, then every 3 & \\
\hline & & & & & Purpose: & & months \(x 3\), then every 6 & \\
\hline & & & & & TREATME & & months x 2 years, then & \\
\hline & & & & & NT & & per PI & \\
\hline & & & & & & & discretion \(\mid\) Frequency & \\
\hline & & & & & & & and severity of & \\
\hline
\end{tabular}
\begin{tabular}{llllll} 
UNKNOWN & Advanced & OTHER: Cell NA & INTER & Allocation: 18 \\
& Gastric & infusion for & VENTI & RANDOMI & \\
& Cancer|Gas & Dose-finding & ONAL & ZED|Interv \\
& troesophage & (Group & & ention \\
& al Cancer & A) \(\mid\) OTHER: & & Model: \\
& & Cell infusion & & SEQUENTI
\end{tabular}
treatment-related
adverse events, Grade
and type of toxicity per dose level; fraction of patients who experience a DLT at a given dose level, and number and grade of each type of DLT, From time of cell infusion to two weeks after cell infusion

Safety Tumor 2019/10/8
assessment assessment
, , Imaging
Evaluation of the
of adverse chest,
events and abdomen
\begin{tabular}{llll} 
for Extended & AL |Maskin & severity & and pelvis \\
research & g: & according & (either
\end{tabular}
\begin{tabular}{|c|c|}
\hline \begin{tabular}{l}
reduction) \\
related to
\end{tabular} & evaluation
is the \\
\hline UCB-NK & baseline \\
\hline treatment & examinatio \\
\hline could not & \(n\) of this \\
\hline recover to & \\
\hline 鈮 ? 3 & After the \\
\hline degree, 7 & infusion, \\
\hline days|Non & patients \\
\hline hematologi & need \\
\hline c toxicity, & return to \\
\hline Any non & the \\
\hline hematologi & hospital at \\
\hline toxic & the 1st, \\
\hline reaction & 2nd, \\
\hline 鈮? degree & 4th, 6th \\
\hline & and 12th \\
\hline related to & \\
\hline
\end{tabular}
\begin{tabular}{ll} 
UCB－NK & month（卤 \\
treatment & 7 days）and \\
cannot be & every \\
reduced to & months（卤 \\
鈮？degree & 1 \\
within 3 & month） \\
days and & 12th the \\
no further & month to \\
improvem & check the \\
ent is & imaging of \\
found； & chest， \\
Gastric & abdomen \\
mucosal & and pelvis \\
injury & and tumor \\
including & markers． \\
gastric & Follow up \\
hemorrhag & to the
\end{tabular}
\begin{tabular}{ll} 
e 鈮 ? & disease \\
degree & progress,
\end{tabular}


\begin{tabular}{|c|c|}
\hline days) \(\mid \mathrm{Nu}\) & state \\
\hline mber of & plasma \\
\hline participant & concentrati \\
\hline with & on (Cmax, \\
\hline adverse & ss), Days 1, \\
\hline events & 8, 15, 16 \\
\hline (AEs), AEs & and 22 of \\
\hline characteriz & Cycle \\
\hline ed by type, & (each cycle \\
\hline frequency, & is \\
\hline severity (as & days)|The \\
\hline graded by & pharmacok \\
\hline National & inetic \\
\hline Cancer & profile \\
\hline Institute & single and \\
\hline Common & multiple \\
\hline Terminolo & ses \\
\hline
\end{tabular}
\begin{tabular}{ll} 
gy Criteria & 07265028 \\
for & alone and \\
Adverse & in \\
Events & combinatio \\
\(\backslash[\mathrm{NCI}\) & \(\mathrm{n} \quad\) with \\
CTCAE \(\backslash]\) & sasanlimab \\
version & through \\
5.0), & Tmax., \\
timing, & Time to \\
seriousnes & maximal \\
s, and & observed \\
relationshi & plasma \\
p to study & concentrati \\
therapy., & on of PF- \\
Baseline & 07265028 \\
through up & (Tmax) \\
to \(\quad 2\) & and Time
\end{tabular}

\begin{tabular}{ll} 
NCI & profile of \\
CTCAE & single and \\
version & multiple \\
5.0 ), and & doses PF- \\
timing., & 07265028 \\
Baseline & alone and \\
through up & in \\
to \(\quad 2\) & combinatio \\
years |Obj & n with \\
ective & sasanlimab \\
response & through \\
rate (ORR) & AUC, Area \\
in Dose & under the \\
Expansion & concentrati \\
(Part 2), on versus
\end{tabular}
\begin{tabular}{ll} 
based on zero to the \\
Response & last \\
Evaluation & quantifiabl \\
Criteria in & e time \\
Solid & point prior \\
Tumors & to the next \\
(RECIST) & dose \\
v1.1, & (AUClast) \\
Baseline & of PF- \\
through up & 07265028 \\
to 2 years & and area \\
or until & under the \\
disease & \begin{tabular}{l} 
curve
\end{tabular} \\
progressio & within one \\
n & dose \\
& interval at
\end{tabular}

\section*{state}
(AUCtau,s
s), Days 1,
\(8,15,16\)
and 22 of
Cycle 1
(each cycle
is \(\quad 28\)
days)|The
effect of
food on the
pharmacok
inetic
profile of
PF-
07265028
through
Cmax.,
Maximum
observed
plasma
concentrati
on of PF-
07265028
(Cmax)
under
fasted and
fed
conditions
in the
subset of
participant
s, Days 1, 8,
15,16 and
cycle is 28
days)|The
effect of
food on the
pharmacok
inetic
profile of
PF-
07265028
through
Tmax,
Time to
maximal
observed
plasma
fed
conditions
in the
subset of
participant
s, Days 1, 8,
15,16 and
22 of Cycle
1 (each
cycle is 28
days)|The
food on the
pharmacok inetic
profile of
PF-
07265028
through
AUC, Area
under the
concentrati
on versus
time curve
from time
zero to the
last
quantifiabl
e time
point prior
to the next
dose
(AUClast)
of PF-
07265028
under
fasted and
fed
conditions
in the
subset of
participant
s, Days 1,8,
15,16 and
22 of Cycle

1 (each
cycle is 28
days)|The
pharmacok
inetic
profile of
sasanlimab
when
given in
combinatio
n with PF-
07265028
through
Cmin,
Minimum
plasma
concentrati
measured
pre-dose
plasma
concentrati
on, Day 1
of cycle 1
(each cycle
is 28 days),
Day 1 of
cycle 2,
Day 1 of
cycle 3,

Day 1 of
cycle 5 and
thereafter
every 6
cycles
(each cycle
is \(\quad 28\)
days)|The
immunoge
nicity of
sasanlimab
when
given in
combinatio
n with PF-
07265028
through

NAb,
Incidence
and titers
of anti-
drug
antibodies
(ADA) and
neutralizin
g
antibodies
(NAb)
against
sasanlimab
, Day 1 of
cycle 1
(each cycle
is 28 days),
Day 1 of
cycle 2,
Day 1 of
cycle 3,
Day 1 of
cycle 5 and
thereafter
every 6
cycles
(each cycle
is \(\quad 28\)
days)|The
effect of
PF-
07265028
alone and
combinatio
n with
sasanlimab
on tumor
immune
biomarker
S
modulatio
\(n\), Levels of
intratumor
T cells and
PD-L1
expression
in pre- and
post-
treatment
tumor
biopsies,
Baseline
through up
to 2
years |OR
R in Dose
Escalation
(Part 1),
Tumor
response
assessment
based on
RECIST
1.1, From
baseline
throughdisease
progressio
n or study
completion
(approxim
ately 2
years) \(\mid \mathrm{Ti}\)
me to
event
endpoints
(DOR) in
Dose
Expansion
(Part 2),
Duration
of response
(DOR) as
assessed
using
RECIST
1.1., From
baseline
through
disease
progressio
n or study
completion
(approxim
ately 2
years) \(\mid \mathrm{Ti}\)
me to
event
endpoints
(PFS) in
Dose
Expansion
(Part 2),
Progressio
n free
survival
(PFS) as
assessed
using
RECIST
1.1., From
baseline
through
disease
progressio
n or study
completion
years) \(\mid \mathrm{Ti}\)
me to
event
endpoints
(OS) in
Dose
Expansion
(Part 2),
Overall
survival
(OS)
assessed
proportion
of patients
alive, From

\begin{tabular}{|c|c|c|c|c|}
\hline ant & DUCT: & mary & adjacent & (PR), 6 \\
\hline Immunothe & radical & Purpose: & tissue & months | D \\
\hline \multirow[t]{15}{*}{rapy} & surgery after & TREATME & before and & isease-free \\
\hline & neoadjuvant & NT & after & survival \\
\hline & chemotherap & & treatment, & (DFS), \\
\hline & y & & Changes in & Time from \\
\hline & & & the & study \\
\hline & & & number of & entry to \\
\hline & & & CD8+ & disease \\
\hline & & & tumor- & recurrence \\
\hline & & & infiltrating & or patient \\
\hline & & & lymphocyt & death due \\
\hline & & & es in the & to disease \\
\hline & & & tumor and & progressio \\
\hline & & & adjacent & \(\mathrm{n}, \quad 2\) \\
\hline & & & tissues of & years |Ove \\
\hline & & & the & rall \\
\hline
\end{tabular}
\begin{tabular}{|c|c|}
\hline \begin{tabular}{l}
experimen \\
tal group
\end{tabular} & survival (OS), Time \\
\hline before and & from study \\
\hline after the & entry to \\
\hline surgery & death from \\
\hline compared & any cause., \\
\hline with the & 2 \\
\hline control & years |The \\
\hline group., 6 & rapeutic \\
\hline months & drug \\
\hline & safety, \\
\hline & Adverse \\
\hline & events \\
\hline & (AEs), \\
\hline & serious \\
\hline & adverse \\
\hline & events \\
\hline
\end{tabular}
drug-
related
AEs, SAEs,
and class-
specific
AEs (eg,
hypertensi
on,
proteinuri
a, and
hand-foot
syndrome)
, 6
months |S
urgical
safety, R0
resection
rate,
operative
mortality,
surgical
complicati
ons
(bleeding,
anastomoti
c leakage,
incision
infection),
reoperatio
n rate,
hospital
stay, etc., 6
months
\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|}
\hline UNKNOWN & Gastric & DRUG: MBP- & PHAS & INTER & Allocation: & 62 & To & To & May-09 \\
\hline & Adenocarci & 426/Leucovo & E1|PH & VENTI & NA | Interve & & determine & characteriz & \\
\hline & noma|Gastr & rin/5-FU & ASE2 & ONAL & ntion & & the dose of & e the safety & \\
\hline & oesophageal & & & & Model: & & MBP-426 & profile of & \\
\hline & Junction & & & & SINGLE_G & & for use in & the & \\
\hline & Adenocarci & & & & ROUP|Mas & & the Phase & combinatio & \\
\hline & noma|Esop & & & & king: & & II portion & n therapy, & \\
\hline & hageal & & & & NONE | Pri & & of this & 4 & \\
\hline & Adenocarci & & & & mary & & study of & months |T & \\
\hline & noma & & & & Purpose: & & MBP-426 & o & \\
\hline & & & & & TREATME & & administer & determine & \\
\hline & & & & & NT & & ed every 21 & the plasma & \\
\hline & & & & & & & days in & and urine & \\
\hline & & & & & & & combinatio & pharmacok & \\
\hline & & & & & & & \(n\) with & inetics of & \\
\hline & & & & & & & leucovorin & MBP-426 & \\
\hline & & & & & & & (folinic & when & \\
\hline
\end{tabular}
acid or FA) given in
and combinatio
fluorouraci n with
1 (5-FU), 4 leucovorin months and 5-FU, 4 months |T
o
undertake
a
preliminar
y
exploratio
n of anti-
tumor
activity of
the
combinatio
\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|}
\hline & & & & & & & & \begin{tabular}{l}
n therapy, \\
4
\end{tabular} & \\
\hline & & & & & & & & months |T & \\
\hline & & & & & & & & o & \\
\hline & & & & & & & & characteriz & \\
\hline & & & & & & & & e the safety & \\
\hline & & & & & & & & profile of & \\
\hline & & & & & & & & the & \\
\hline & & & & & & & & & \\
\hline & & & & & & & & n therapy, & \\
\hline & & & & & & & & 16 months & \\
\hline TERMINATE & Colorectal & PROCEDUR & PHAS & INTER & Allocation: & 18 & Anti- & Disease & 2020/6/17 \\
\hline D & Cancer \| Gas & E: Hepatic & E2 & VENTI & NA | Interve & & tumour & control & \\
\hline & tric & Biopsy | DRU & & ONAL & ntion & & efficacy:ov & rate, Best & \\
\hline & Cancer \({ }^{\text {O }}\) Oes & G: BO-112 & & & Model: & & erall & response & \\
\hline & ophageal & & & & SINGLE_G & & response & for CR, PR & \\
\hline & Cancer & & & & ROUP | Mas & & rate, ORR & as well as & \\
\hline
\end{tabular}
\begin{tabular}{|c|c|c|c|}
\hline Pembrolizum & king: & based on & stable \\
\hline \multirow[t]{16}{*}{ab} & NONE | Pri & the BOR & disease \\
\hline & mary & using & (SD) using \\
\hline & Purpose: & RECIST 1.1 & RECIST \\
\hline & TREATME & of repeated & 1.1, \\
\hline & NT & IT & Througho \\
\hline & & administra & ut study \\
\hline & & tions of & completion \\
\hline & & BO-112 in & \\
\hline & & metastatic & average of \\
\hline & & liver & 3 \\
\hline & & lesions in & years \({ }^{\text {Obj }}\) \\
\hline & & combinatio & ective \\
\hline & & n with IV & response \\
\hline & & pembroliz & rate, Based \\
\hline & & umab, & on best \\
\hline & & Througho & overall \\
\hline
\end{tabular}
\begin{tabular}{ll} 
ut study & response \\
completion & using \\
an & RECIST \\
average of & modified \\
3 & for \\
years.|Saf & immune- \\
ety: & \begin{tabular}{l} 
based
\end{tabular} \\
Adverse & therapies \\
Events, & (iRECIST), \\
Number & Througho \\
and & ut study \\
proportion & completion \\
of subjects &, \\
with study & average of \\
treatment- & 3 \\
related & years |Dise \\
TEAEs & ase Control
\end{tabular}
\begin{tabular}{|c|c|}
\hline with & Rate, \\
\hline severity & Comprisin \\
\hline Grade & g best \\
\hline (NCI- & response \\
\hline CTCAE v & for CR, PR \\
\hline 5.0), & as well as \\
\hline Througho & SD using \\
\hline ut study & iRECIST, \\
\hline completion & Througho \\
\hline an & ut study \\
\hline average of & completion \\
\hline 3 years & an \\
\hline & average of \\
\hline & 3 \\
\hline & years |Dur \\
\hline & ation of \\
\hline & response, \\
\hline
\end{tabular}

\section*{Duration}
of
response,
Up to 36
months |P
FS,
Progressio
n-free
survival,
Up to 36
months |S
urvival
Rate,
Overall
Survival
Rate, Up to
36 months
\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|}
\hline COMPLETE & Liver & BIOLOGICA & PHAS & INTER & Allocation: & 5 & Safety of & Radiograp & 2017/2/1 \\
\hline \multirow[t]{16}{*}{D} & \multirow[t]{16}{*}{Metastases} & L: anti-CEA & E1 & VENTI & NA | Interve & & CAR-T cell & hic & \\
\hline & & CAR-T cells & & ONAL & ntion & & hepatic & treatment & \\
\hline & & & & & Model: & & artery & response & \\
\hline & & & & & SINGLE_G & & infusions & by MRI, & \\
\hline & & & & & ROUP | Mas & & delivered & Changes in & \\
\hline & & & & & king: & & using the & tumor size, & \\
\hline & & & & & NONE |Pri & & Surefire & 10 & \\
\hline & & & & & mary & & Infusion & weeks \(\mathrm{Ra}^{\text {R }}\) & \\
\hline & & & & & Purpose: & & System & diographic & \\
\hline & & & & & TREATME & & (SIS) as & treatment & \\
\hline & & & & & NT & & Measured & response & \\
\hline & & & & & & & by & by PET, & \\
\hline & & & & & & & Number of & Changes in & \\
\hline & & & & & & & Participant & tumor & \\
\hline & & & & & & & s with & metabolic & \\
\hline & & & & & & & Adverse & activity, 10 & \\
\hline
\end{tabular}
\begin{tabular}{ll} 
Events, To weeks|CA \\
determine & R-T \\
the safety & detection \\
and & in liver \\
regimen & tumors, \\
limiting & Quantificat \\
toxicity & ion of \\
(RLT) of & CAR-T \\
anti-CEA cells in \\
CAR-T & liver tumor \\
hepatic & core \\
artery & biopsies, \\
infusions & 10 \\
(HAI) via & weeks \(\mid C A\) \\
the & R-T \\
Surefire & detection \\
Infusion & in normal
\end{tabular}
\begin{tabular}{|c|c|}
\hline System & liver tissue, \\
\hline (SIS) for & Quantificat \\
\hline CEA- & ion of \\
\hline expressing & CAR-T \\
\hline liver & cells in \\
\hline metastases & normal \\
\hline , 10 weeks & liver core \\
\hline & biopsies, \\
\hline & 10 \\
\hline & weeks |CA \\
\hline & R-T \\
\hline & detection \\
\hline & in \\
\hline & extrahepati \\
\hline & c sites, \\
\hline & Quantificat \\
\hline & ion of \\
\hline
\end{tabular}

CAR-T in
blood
samples,
10
weeks|Ser
um
Cytokine
Levels,
Measurem
ent of
cytokines
as
indicators
of immune
response,
10
weeks|CE

A level,
Measurem
ent
serum
tumor
marker
( \(\mathrm{ng} / \mathrm{ml}\) ),
10
weeks \(\mid \mathrm{Tu}\)
mor
biopsy,
Assessmen
t of tumor
necrosis
and
fibrosis, 10
weeks |Saf

Direct
Intrapancr
eatic CAR-
T
Retrograde
Venous
Infusions
(RVI)
Delivered
Using the
Surefire
Infusion
System
(SIS), RVI
via the
Surefire
\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|}
\hline & & & & & & & & Infusion & \\
\hline & & & & & & & & System & \\
\hline & & & & & & & & (SIS) for & \\
\hline & & & & & & & & CEA+ & \\
\hline & & & & & & & & Primary & \\
\hline & & & & & & & & Pancreatic & \\
\hline & & & & & & & & Tumors & \\
\hline & & & & & & & & Following & \\
\hline & & & & & & & & In-liver & \\
\hline & & & & & & & & Disease & \\
\hline & & & & & & & & Control, 10 weeks & \\
\hline UNKNOWN & Malignant & BIOLOGICA & PHAS & INTER & Allocation: & 20 & Adverse & Objective & Nov-15 \\
\hline & Glioma of & L: anti-MUC1 & E1|PH & VENTI & NA | Interve & & events & Response & \\
\hline & Brain | Color & CAR-T cells & ASE2 & ONAL & ntion & & attributed & Rate, The & \\
\hline & ectal & & & & Model: & & to the & objective & \\
\hline & Carcinoma & & & & SINGLE_G & & administra & response & \\
\hline
\end{tabular}
\begin{tabular}{|c|c|c|c|}
\hline Gastric & ROUP \({ }^{\text {Mas }}\) & tion of the & rate (ORR) \\
\hline \multirow[t]{16}{*}{Carcinoma} & king: & anti-MUC1 & is defined \\
\hline & NONE | Pri & CAR-T & as the \\
\hline & mary & cells, & proportion \\
\hline & Purpose: & Determine & of patients \\
\hline & TREATME & the toxicity & who \\
\hline & NT & profile of & achieve \\
\hline & & the MUC1 & radiograph \\
\hline & & targeted & ic partial or \\
\hline & & CAR-T & complete \\
\hline & & cells with & response \\
\hline & & Common & (PR or CR) \\
\hline & & Toxicity & according \\
\hline & & Criteria for & to the \\
\hline & & Adverse & Response \\
\hline & & Effects & Evaluation \\
\hline & & (CTCAE) & Criteria in \\
\hline
\end{tabular}
\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|}
\hline & & & & & & & version & Solid & \\
\hline & & & & & & & 4.0., 2 years & Tumors & \\
\hline & & & & & & & & (RECIST) & \\
\hline & & & & & & & & v1.1 & \\
\hline & & & & & & & & guideline., & \\
\hline & & & & & & & & Safety & \\
\hline & & & & & & & & follow-up & \\
\hline & & & & & & & & is 100 days & \\
\hline & & & & & & & & from last & \\
\hline & & & & & & & & CAR-T & \\
\hline & & & & & & & & infusion. & \\
\hline RECRUITIN & Locally & DRUG: & PHAS & INTER & Allocation: & 190 & Major & R0 & May-23 \\
\hline G & Advanced & Oxaliplatin & E3 & VENTI & RANDOMI & & Pathologic & resection & \\
\hline & Gastric & by arterial & & ONAL & ZED|Interv & & al & rate, The & \\
\hline & Carcinoma & infusion plus & & & ention & & Response & proportion & \\
\hline & & S-1|DRUG: & & & Model: & & rate, The & of patients & \\
\hline & & SOX & & & PARALLEL & & percentage & with & \\
\hline
\end{tabular}
\begin{tabular}{llll} 
neoadjuvant \(\mid\) & |Masking: & of people margin- \\
DRUG: & NONE|Pri & who has free
\end{tabular}
of gastric
cancer at 2
years after
treatment,
2 years|2-
year
Overall
Survival
Rate, The
percentage
of
individual
\(s\) in this
study who
are alive
two years
after their
diagnosis
or the start
of
treatment.,
2
years | path
ological
Complete
Response
rate, The
percentage
of people
with
complete
disappeara
nce of all
invasive
\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|c|}
\hline & & & & & & & & & carcinoma & \\
\hline & & & & & & & & & \begin{tabular}{l}
cells., 6 \\
months
\end{tabular} & \\
\hline UNKNOWN & Solid & DRUG: & Ad- & PHAS & INTER & Allocation: & 40 & The & Preliminar & 2018/10/1 \\
\hline & Tumor \| Ly & p53 & & E2 & VENTI & NA | Interve & & primary & y & \\
\hline & mphoma & & & & ONAL & ntion & & efficacy & assessment & \\
\hline & & & & & & Model: & & endpoint is & of & \\
\hline & & & & & & SINGLE_G & & objective & Duration & \\
\hline & & & & & & ROUP \| Mas & & response & of & \\
\hline & & & & & & king: & & rate (ORR), & Response & \\
\hline & & & & & & NONE | \(\operatorname{Pri}\) & & Objective & (DoR) by & \\
\hline & & & & & & mary & & response & RECIST & \\
\hline & & & & & & Purpose: & & rate will be & 1.1, & \\
\hline & & & & & & TREATME & & evaluated & RECIST 1.1 & \\
\hline & & & & & & NT & & by RECIST & will be & \\
\hline & & & & & & & & 1.1, & used to & \\
\hline & & & & & & & & Change in & determine & \\
\hline
\end{tabular}
\begin{tabular}{lll} 
tumor size & Duration \\
at the end & of \\
of Cycle 2 & Response \\
(each cycle & (DoR), Day \\
is & 28 & 1 \\
through \\
days) \(\mid\) Safe & end of \\
ty & study, \\
assessment & approxima \\
s of & tely \\
adverse & years \(\mid\) Prel \\
events per & iminary \\
CTCAE, & assessment \\
Safety & of \\
evaluation & progressio \\
s will & \(n\) \\
tabulate free & survival \\
adverse & (PFS) by
\end{tabular}
\begin{tabular}{|c|c|}
\hline events per & RECIST \\
\hline CTCAE, & 1.1, \\
\hline Signed & RECIST 1.1 \\
\hline Informed & will be \\
\hline Consent & used to \\
\hline through 30 & determine \\
\hline Days & progressio \\
\hline following & n free \\
\hline the final & survival, \\
\hline treatment & Day 1 \\
\hline & through \\
\hline & end of \\
\hline & study, \\
\hline & approxima \\
\hline & tely 2 years \\
\hline
\end{tabular}
\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|}
\hline ACTIVE_NO & HER2- & DRUG: ZW25 & PHAS & INTER & Allocation: & 279 & The & Serum & Sep-16 \\
\hline T_RECRUITI & expressing & (Zanidatama & E1 & VENTI & NA | Interve & & proportion & concentrati & \\
\hline \multirow[t]{15}{*}{NG} & \multirow[t]{15}{*}{Cancers} & b) | DRUG: & & ONAL & ntion & & of patients & ons of & \\
\hline & & Paclitaxel|D & & & Model: & & who & ZW25, & \\
\hline & & RUG: & & & SINGLE_G & & experience & Througho & \\
\hline & & Capecitabine & & & ROUP \| Mas & & dose- & ut the & \\
\hline & & | DRUG: & & & king: & & limiting & duration of & \\
\hline & & Vinorelbine & & & NONE | Pri & & toxicities & the study; & \\
\hline & & DRUG: & & & mary & & (DLTs) & up to 2 & \\
\hline & & Tucatinib|D & & & Purpose: & & (Part 1), Up & years |The & \\
\hline & & RUG: & & & TREATME & & to 8 & proportion & \\
\hline & & Tucatinib & & & NT & & months |T & of patients & \\
\hline & & & & & & & he & who & \\
\hline & & & & & & & proportion & develop & \\
\hline & & & & & & & patients & detectable & \\
\hline & & & & & & & who & anti-drug & \\
\hline & & & & & & & experience & antibodies, & \\
\hline
\end{tabular}
\begin{tabular}{|c|c|}
\hline laboratory & Througho \\
\hline abnormalit & ut the \\
\hline ies and/or & duration of \\
\hline adverse & the study; \\
\hline events as & up \\
\hline defined by & years |The \\
\hline CTCAE & proportion \\
\hline v4.03 that & of patients \\
\hline are related & with \\
\hline to & objective \\
\hline treatment & response \\
\hline (Parts 2 & (partial \\
\hline and 3), & response \\
\hline Througho & or \\
\hline ut the & complete \\
\hline duration of & response) \\
\hline the study; & as defined \\
\hline
\end{tabular}
\begin{tabular}{ll} 
up to 2 & by RECIST \\
years & 1.1 criteria, \\
& Througho \\
& ut the \\
& duration of \\
& the study; \\
& up to 2 \\
& years \(\mid\) Pro \\
& gression \\
& free \\
& survival as \\
& defined by \\
& RECIST 1.1 \\
& criteria, \\
& Througho \\
& ut the \\
& duration of
\end{tabular}
the study;
up to 2
years |The
proportion
patients
who
experience
laboratory
abnormalit
ies and/or
adverse
events as
defined by
CTCAE
v4.03 that
are related
to
\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|}
\hline & & & & & & & & treatment & \\
\hline & & & & & & & & (Part 1), & \\
\hline & & & & & & & & Througho & \\
\hline & & & & & & & & ut the & \\
\hline & & & & & & & & duration of & \\
\hline & & & & & & & & the study; & \\
\hline & & & & & & & & \[
\text { up to } 2
\] & \\
\hline & & & & & & & & years & \\
\hline ACTIVE_NO & Stomach & DRUG: & PHAS & INTER & Allocation: & 30 & Pathologic & R0 & 2020/9/16 \\
\hline T_RECRUITI & Neoplasms | & Camrelizuma & E2 & VENTI & NA | Interve & & complete & resection & \\
\hline NG & Digestive & b|DRUG: & & ONAL & ntion & & response & rate, 2-4 & \\
\hline & System & SOX|PROCE & & & Model: & & (pCR) rate, & months \({ }^{\text {O }}\) & \\
\hline & Neoplasms | & DURE: & & & SINGLE_G & & The AJCC & verall & \\
\hline & Neoplasms | & Surgery & & & ROUP \| Mas & & TRG & response & \\
\hline & Digestive & & & & king: & & system & rate(ORR), & \\
\hline & System & & & & NONE | Pri & & was used & 2-4 & \\
\hline & Diseases |St \(^{\text {S }}\) & & & & mary & & in this & months | D & \\
\hline
\end{tabular}
\begin{tabular}{|c|c|c|c|}
\hline omach & Purpose: & study to & isease \\
\hline Diseases \(\mathrm{N}^{\text {N }}\) & TREATME & determine & control \\
\hline eoplasms by & NT & the effects & rate(DCR), \\
\hline Site & & of & 2-4 \\
\hline & & treatment. & months | M \\
\hline & & TRG 0 & ajor \\
\hline & & indicating & pathologic \\
\hline & & athologic & al response \\
\hline & & complete & (MPR), The \\
\hline & & response & AJCC TRG \\
\hline & & (pCR), 2-4 & system \\
\hline & & months & was used \\
\hline & & & in this \\
\hline & & & study to \\
\hline & & & determine \\
\hline & & & the effects \\
\hline & & & \\
\hline
\end{tabular}

\begin{tabular}{lc} 
v8|Clinical & TREATME \\
Stage III & NT \\
Gastroesoph & \\
ageal & \\
Junction & \\
Adenocarci & \\
noma AJCC & \\
v8|Clinical \\
Stage IV \\
Cutaneous \\
Melanoma \\
AJCC \\
v8|Clinical \\
Stage IV \\
Gastric \\
Cancer \\
AJCC
\end{tabular}
\begin{tabular}{|c|c|}
\hline v8|Clinical & treated at a grade 3+ \\
\hline Stage IV & given dose adverse \\
\hline Gastroesoph & level events will \\
\hline ageal & combinatio also be \\
\hline Junction & n and described \\
\hline Adenocarci & observed and \\
\hline noma AJCC & for at least summarize \\
\hline v8 | Locally & 21 days \(d\) in a \\
\hline Advanced & from start similar \\
\hline Gastric & of fashion. \\
\hline Adenocarci & treatment Overall \\
\hline noma | Local & to assess toxicity \\
\hline ly & toxicity., incidence \\
\hline Advanced & Up to 21 as well as \\
\hline Gastroesoph & days|Resp toxicity \\
\hline ageal & onse rate of profiles by \\
\hline Junction & sonidegib dose level \\
\hline
\end{tabular}
\begin{tabular}{|c|c|c|}
\hline Adenocarci & in & and patient \\
\hline noma|Local & combinatio & will be \\
\hline ly & \(n\) with & explored \\
\hline Advanced & pembroliz & and \\
\hline Urothelial & umab (Part & summarize \\
\hline Carcinoma & B), & d. \\
\hline Metastatic & Assessed & Frequency \\
\hline Gastric & by & distributio \\
\hline Adenocarci & Response & ns, \\
\hline noma | Meta & Evaluation & graphical \\
\hline static & Criteria in & techniques \\
\hline Gastroesoph & Solid & and other \\
\hline ageal & Tumors & descriptive \\
\hline Junction & (RECIST) & measures \\
\hline Adenocarci & & \\
\hline noma | Meta & criteria., & the basis of \\
\hline static Head & Up to 30 & these \\
\hline
\end{tabular}
\begin{tabular}{|c|c|c|}
\hline and Neck & days post & analyses., \\
\hline Squamous & treatment & Up to 30 \\
\hline Cell & & days post \\
\hline Carcinoma & & treatment | \\
\hline Metastatic & & Response \\
\hline Lung Non- & & profile, \\
\hline Small Cell & & Responses \\
\hline Carcinoma & & will be \\
\hline Metastatic & & calculated \\
\hline Malignant & & based on \\
\hline Solid & & RECIST 1.1 \\
\hline Neoplasm| & & for this \\
\hline Metastatic & & study. Best \\
\hline Melanoma & & response is \\
\hline Metastatic & & defined to \\
\hline Urothelial & & be the best \\
\hline Carcinoma & & objective \\
\hline
\end{tabular}
\begin{tabular}{ll} 
Recurrent & status \\
Head and & recorded \\
Neck & from the \\
Squamous & start of the \\
Cell & treatment \\
Carcinoma | & until \\
Refractory & disease \\
Lung Non- & progressio \\
Small Cell & n/recurren \\
Carcinoma| & ce (taking \\
Stage & as \\
Cutaneous & reference \\
Squamous & for \\
Cell & progressiv \\
Carcinoma & e disease \\
of the Head & the \\
and Neck & smallest
\end{tabular}
\begin{tabular}{ll} 
AJCC & measurem \\
v8|Stage IV & ents \\
Lung & recorded \\
Cancer & since the \\
AJCC & treatment \\
v8|Unresect & started). \\
able & Responses \\
Malignant & will be \\
Solid & summarize \\
Neoplasm | & d \\
Unresectabl & simple \\
e Melanoma & descriptive \\
& summary \\
& statistics \\
& delineating \\
& complete \\
& and partial
\end{tabular}
responses
as well as
stable and
progressiv
e disease in
this patient
population
., Up to 30
days post
treatment
Duration
of response
(DOR),
Determine
d only for
patients
with
objective
response
who have
not
experience
d
radiograph
ic or
clinical
progressio
n will be
the date of
the last
available
post-
baseline
evaluable
tumor
assessment
., From the
date on
which an
objective
response is
first
determine
d until the
first date
on which
radiograph
ic disease
progressio
\(n \quad\) is
determine
d, assessed
up to 30
days|Dise
ase control
rate (DCR),
Assessed
by RECIST
v1.1. DCR
defined as
proportion
complete
response
(CR),
partial
response
(PR), or
stable
disease
and do not
experience
subsequen
t
radiograph
for \(\backslash>=6\)
months
from the
time of
treatment
initiation.,
At 6
months |O
verall
survival
(OS), Will
be
estimated
using

Kaplan-
Meier
method.,
From
study
entry to
death from
any cause,
assessed
up to 30
days post
treatment
Progressio
n-free
survival
(PFS),
Disease
n will be
determine
d based on
RECIST 1.1
criteria.
PFS will be
estimated
using the
Kaplan-
Meier
method.,
From
study
entry to the
first of
either
\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|}
\hline & & & & & & & & disease progressio n or death from any cause, assessed up to 30 days post treatment & \\
\hline RECRUITIN & Sarcoma|C & DRUG: & EARL & INTER & Allocation: & 20 & Subject & Disease & 2023/3/2 \\
\hline G & arcinoma|B & Recombinant & Y_PH & VENTI & NA | Interve & & incidence & Assessmen & \\
\hline & reast & oncolytic & ASE1 & ONAL & ntion & & of adverse & \(t\) for & \\
\hline & Cancer 1 Pan & herpes & & & Model: & & events, To & Disease & \\
\hline & creatic & simplex virus & & & SINGLE_G & & characteriz & Control & \\
\hline & Cancer \(/ \mathrm{Col}\) & type 1 (R130) & & & ROUP | Mas & & e the safety & Rate, & \\
\hline & orectal & & & & & & profile of & Evaluate & \\
\hline & Cancer \| Gas & & & & NONE | \(\operatorname{Pri}\) & & R130 & the efficacy & \\
\hline
\end{tabular}
\begin{tabular}{|c|c|c|c|}
\hline tric & mary & injection in & endpoints \\
\hline Cancer \({ }_{\text {Liv }}\) & Purpose: & patients & of DCR by \\
\hline er & TREATME & with & the \\
\hline Cancer \({ }^{\text {Lun }}\) & NT & advanced & investigato \\
\hline g & & solid & \(r \quad\) with \\
\hline Cancer | Gy & & tumors as & RECIST \\
\hline necologic & & measured & v1.1 and \\
\hline Cancer & & by the & iRECIST, \\
\hline & & incidence & Every 10 \\
\hline & & of Grade & weeks for \\
\hline & & 鈮 ? 3 & 12 months \\
\hline & & Common & \\
\hline & & Terminolo & \\
\hline & & gy Criteria & \\
\hline & & for & \\
\hline & & Adverse & \\
\hline & & Events, & \\
\hline
\end{tabular}
version 5.0

\section*{(CTCAE}
v5.0), Up
to 6
months|S
ubject
incidence
of
laboratory
abnormalit
ies,
Detection
of liver and
renal
function,
electrocard
iogram,
routine
blood
examinatio
n etc., Up
to \(\quad 1\)
month|Sy
stemic
Immune
Response,
Detection
of
increased
systemic
immune
Response
markers in
sera
（IL2，IL4，IL
6，IL8，IL10，
TNFa 镇孖
FN 纬，etc．）
and
peripheral
blood
mononucle
ar cells by
multi－
Color
fluorescen
ce－
activated
cell sorting
（FACS），
\begin{tabular}{|c|c|c|c|c|c|c|c|c|}
\hline & & & & & & Up to 6 months & & \\
\hline RECRUITIN & Cancer, & OTHER: Clinical Trial & OBSER & Observation & 50000 & Proportion & Impact of & 2018/1/1 \\
\hline G & Metastatic & Matching & VATI & al Model: & & of patients & CTE on & \\
\hline & Cancer \| Can & & ONAL & | Time & & Eligible for & Overall & \\
\hline & cer of & & & Perspective: & & CTE & Survival & \\
\hline & Pancreas \({ }^{\text {C }}\) & & & p & & versus & (OS), & \\
\hline & ancer of & & & & & Actual & estimated & \\
\hline & Liver | Canc & & & & & CTE, CTE & by Kaplan- & \\
\hline & er of & & & & & Accrual, & Meier and & \\
\hline & Stomach \(\mid \mathrm{C}\) & & & & & Through & Cox & \\
\hline & ancer & & & & & study & multivaria & \\
\hline & Liver | Canc & & & & & completion & ble & \\
\hline & er of & & & & & an & survival & \\
\hline & Rectum \({ }^{\text {Ca }}\) & & & & & average of & analysis, & \\
\hline & ncer of & & & & & 1 year & OS, 4 & \\
\hline & Kidney \({ }^{\text {Ca }}\) & & & & & & years | Imp & \\
\hline
\end{tabular}
\begin{tabular}{|c|c|}
\hline ncer of & act of CTE \\
\hline Esophagus | & on \\
\hline Cancer of & Progressio \\
\hline Cervix \({ }^{\text {Can }}\) & n-Free \\
\hline cer of & Survival \\
\hline Colon | Canc & (PFS), \\
\hline er of & estimated \\
\hline Larynx | Can & by Kaplan- \\
\hline cer, & Meier and \\
\hline Lung | Canc & Cox \\
\hline er, & multivaria \\
\hline Breast \| Canc & ble \\
\hline er, & survival \\
\hline Advanced & analysis, \\
\hline Cancer & PFS, 4 \\
\hline Prostate | Ca & years | Iden \\
\hline ncer of & tification of \\
\hline
\end{tabular}
\begin{tabular}{ll} 
Neck |Canc & Barriers to \\
er of & \begin{tabular}{l} 
CTE,
\end{tabular} \\
Skin |Neuro & identify \\
endocrine & barriers to \\
Tumors |Ca & accruals to \\
rcinoma |Mi & clinical \\
smatch & trials, as \\
Repair & measured \\
Deficiency | & and \\
BRCA Gene & reported \\
Rearrangem & by \\
ent \(\mid\) Non & questionna \\
Hodgkin & ire, \\
Lymphoma & Through \\
\(\mid\) Leukemia & study \\
\(\mid\) Non Small & completion \\
Cell Lung &,
\end{tabular}
\begin{tabular}{ll} 
Cancer|Cho & average of \\
langiocarcin & 1 \\
oma |Gliobl & year|Real \\
astoma|Cen & World \\
tral Nervous & Data \\
System & Analytics, \\
Tumor |Mel & To \\
anoma |Uro & Analyze \\
thelial & Individual \\
Carcinoma | & Standard \\
Bladder & of \\
Cancer |Ova & Chemother \\
rian & apy \\
Cancer |End & Utilization \\
ometrial & (nominal), \\
Cancer |Test & across \\
icular & treatment
\end{tabular}
\begin{tabular}{|c|c|}
\hline Cancer \| Bre & lines \\
\hline ast & (numeric); \\
\hline Cancer \| CO & data will \\
\hline VID|Myelof & be \\
\hline ibrosis | Mye & combined \\
\hline loproliferati & and \\
\hline ve & aggregated \\
\hline Neoplasm| & to report \\
\hline Myeloprolif & chemother \\
\hline erative & apy \\
\hline Disorders \({ }^{\text {F }}\) & utilization \\
\hline ollicular & rate (\%)., \\
\hline Lymphoma & Through \\
\hline | Mantle & study \\
\hline Cell & completion \\
\hline Lymphoma & an \\
\hline | Marginal & average of \\
\hline
\end{tabular}
Zone 1
Lymphoma
|Myelodys
plastic
Syndromes
year | Virtu
al Tumor
Board
Utilization,
VTB Use
Rate,
Through
study
completion
, an
average of 1
year|Time
from
Interventio
n to Actual

\begin{tabular}{ll} 
R2-positive & NONE |Pri \\
Colorectal & mary \\
Cancer|HE & Purpose: \\
R2-positive & TREATME \\
Gastroesoph & NT \\
ageal & \\
Cancer|HE & \\
R2-positive & \\
Endometrial & \\
Cancer &
\end{tabular}
\begin{tabular}{|c|c|}
\hline (SAEs), & years |PK \\
\hline Escalation & (Cmin) of \\
\hline period, 2 & BDC-1001, \\
\hline years|Inci & Escalation \\
\hline dence and & and \\
\hline nature of & expansion \\
\hline dose- & periods, 2 \\
\hline limiting & years |PK \\
\hline toxicities & (AUC0-t) \\
\hline (DLTs), & of BDC- \\
\hline Escalation & 1001, \\
\hline period, up & Escalation \\
\hline & period, 2 \\
\hline days| Incid & years|PK \\
\hline ence of & (AUC0-inf) \\
\hline potential- & of BDC- \\
\hline immune & 1001, \\
\hline
\end{tabular}
\begin{tabular}{ll} 
related & Escalation \\
toxicities, & period, 2 \\
Escalation & years|PK \\
period, 2 & \((\mathrm{CL}) \quad\) of \\
years \(\mid\) Max & BDC-1001, \\
imum & Escalation \\
tolerable & period, 2 \\
dose & years |PK \\
(MTD) or a & \((\) Vz) of \\
tolerated & BDC-1001, \\
dose below & Escalation \\
MTD, & period, 2 \\
Escalation & years|PK \\
period, 2 & (t1/2) of \\
years|Obj & BDC-1001, \\
ective & Escalation \\
response & period, 2
\end{tabular}
\begin{tabular}{|c|c|}
\hline rate (ORR) of & \begin{tabular}{l}
years |Obj \\
ective
\end{tabular} \\
\hline confirmed & response \\
\hline complete & rate (ORR) \\
\hline or partial & using \\
\hline responses & RECIST \\
\hline (CR, PR), & 1.1, \\
\hline Expansion & Escalation \\
\hline period, 2 & period, 2 \\
\hline years & years |Dur \\
\hline & ation of \\
\hline & response \\
\hline & (DOR), \\
\hline & Escalation \\
\hline & and \\
\hline & expansion \\
\hline & periods, 2 \\
\hline
\end{tabular}
rate (DCR)
of
confirmed
CR, PR, or
stable
disease
(SD)
lasting 4 or
more
weeks,

Escalation
and
expansion
periods, 2
years | Pro

Free
Survival
(PFS),
Escalation
and
expansion
periods, 2
years | Inci
dence of
anti-BDC-
1001
antibodies,
Escalation
and
expansion
periods, 2
years | Inci
dence of
adverse
events
(AEs) and
serious
adverse
events
(SAEs),
Expansion
period, 2
years | Inci
dence of
potential-
immune
related
toxicities,
\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|}
\hline & & & & & & & & \begin{tabular}{l}
Expansion \\
period, 2 \\
years
\end{tabular} & \\
\hline RECRUITIN & Solid & DRUG: & PHAS & INTER & Allocation: & 490 & Assessmen & Evaluation & 2019/11/11 \\
\hline G & Tumor, & DF1001|DRU & E1|PH & VENTI & NON_RAN & & \(t \quad\) of & of DF1001 & \\
\hline & Adult & G: & ASE2 & ONAL & DOMIZED & & number of & Pharmaco & \\
\hline & & Nivolumab & & & Intervention & & dose & kinetics, & \\
\hline & & DRUG: Nab & & & Model: & & limiting & Concentrat & \\
\hline & & paclitaxel & & & SEQUENTI & & toxicities & ion vs time & \\
\hline & & & & & AL|Maskin & & experience & of DF1001 & \\
\hline & & & & & g : & & d on study & will be & \\
\hline & & & & & NONE | Pri & & as defined & measured & \\
\hline & & & & & mary & & per criteria & using & \\
\hline & & & & & Purpose: & & in the & blood & \\
\hline & & & & & TREATME & & study & samples & \\
\hline & & & & & NT & & protocol, & taken a & \\
\hline & & & & & & & & various & \\
\hline
\end{tabular}
\begin{tabular}{ll} 
the & time points \\
number of & on study, \\
adverse & From start \\
events & of \\
experience & treatment \\
d during & up through \\
the study & \(28 \quad\) days \\
that meet & after last \\
dose & treatment. \\
limiting & |Evaluatio \\
toxicity & n \\
criteria per & DF1001 \\
the study & Immunoge \\
protocol., & nicity, \\
First 3 & Evaluate \\
weeks of & the \\
treatment & immunoge
\end{tabular}
\begin{tabular}{ll} 
for each & nicity of \\
subject. \(\mid A\) & DF1001 by \\
ssess & measuring \\
Overall & the \\
Response & number of \\
Rate, To & patients \\
assess the & developing \\
Overall & anti- \\
Response & DF1001 \\
Rate (ORR) & antibodies, \\
per & Every 3 \\
RECIST & weeks up \\
version 1.1 & to 28 days \\
criteria per & after last \\
an & treatment. \\
Independe & |Assess \\
nt & Best
\end{tabular}
\begin{tabular}{ll} 
Endpoint & Overall \\
Review & Response, \\
Committee & To assess \\
(IERC), & Best \\
Through & Overall \\
\(90 \quad\) days & Response \\
after & (BOR) by \\
completion & IERC \\
of the & (efficacy \\
study, an & expansion \\
average of & cohorts)., \\
1 & Through \\
year.|Asse & 90 days \\
ss number & after \\
of adverse & completion \\
events & of the \\
observed & study, an
\end{tabular}
\begin{tabular}{ll} 
during & average of \\
treatment & 1 \\
with & year. \(\mid\) Asse \\
DF1001 in & ss \\
combinatio & Duration \\
n with & of \\
Nivoluma & Response, \\
b, \(\quad\) To & To assess \\
assess the & Duration \\
safety of & of \\
DF1001 in & Response \\
Combinati & (DOR) for \\
on therapy & confirmed \\
with & responses \\
nivolumab & of DF1001 \\
by & per an \\
measuring & IERC
\end{tabular}
\begin{tabular}{ll} 
Number of & (efficacy \\
subjects & expansion \\
with & cohorts)., \\
Treatment- & From time \\
Emergent & of \\
Adverse & initiation \\
Events & of therapy \\
according & until the \\
to the & date of first \\
National & documente \\
Cancer & d tumor \\
Institute & progressio \\
Common & n , assessed \\
Terminolo & up to 24 \\
gy Criteria & months \(\mid \mathrm{A}\) \\
for & ssess \\
Adverse & Progressio
\end{tabular}
\begin{tabular}{ll} 
Events & n Free \\
(NCI- & Survival \\
CTCAE) & (PFS), To \\
Version & assess \\
5.0, & Progressio \\
Screening & \(\mathrm{n} \quad\) Free \\
visit up to & Survival \\
\(28 \quad\) days & (PFS) for \\
after last & DF1001 per \\
treatment & an IERC \\
on & (efficacy \\
study. & Ass \\
expansion \\
ess & cohorts)., \\
number of & From time \\
adverse & of \\
events & initiation \\
observed & of therapy
\end{tabular}
\begin{tabular}{ll} 
during & until the \\
treatment & date of first \\
with & documente \\
DF1001 in & d tumor \\
combinatio & progressio \\
n with Nab & n, assessed \\
paclitaxel, & up to 24 \\
To assess & months |A \\
the safety & ssess \\
of DF1001 & Overall \\
in & Survival \\
Combinati & (OS) Time., \\
on therapy & To assess \\
with Nab & Overall \\
paclitaxel & Survival \\
by & (OS), Time \\
measuring & from
\end{tabular}
\begin{tabular}{ll} 
Number of enrollment \\
subjects & in the \\
with & study until \\
Treatment- & death, \\
Emergent & measured \\
Adverse & up to 2 \\
Events & years after \\
according & last \\
to the & treatment \\
National & on \\
Cancer & study. \(\mid\) Ass \\
Institute & ess ORR by \\
Common & Investigato \\
Terminolo & \(r\) \\
gy Criteria & Assessmen \\
for & t., \\
Adverse & assess
\end{tabular}
\begin{tabular}{|c|c|}
\hline Events & confirmed \\
\hline (NCI- & ORR by \\
\hline CTCAE) & Investigato \\
\hline Version & r \\
\hline 5.0, & Assessmen \\
\hline Screening & \\
\hline visit up to & patients \\
\hline 28 days & enrolled in \\
\hline after last & the dose \\
\hline treatment & escalation \\
\hline on study. & phase and \\
\hline & in the \\
\hline & efficacy \\
\hline & expansion \\
\hline & phase., \\
\hline & From time \\
\hline & of \\
\hline
\end{tabular}
initiation
of therapy
until the
date of first
documente
d tumor
progressio
n , assessed
up to 24
months \(\mid \mathrm{A}\)
ssess DOR
by
Investigato
r
Assessmen
t., To
assess
DOR for
confirmed
responses
by
Investigato
r
Assessmen
\(t\) for
patients
enrolled in
the dose
escalation
phase and
in the
efficacy
expansion
phase.,From time
of
initiation
of therapy
until the
date of first
documente
d tumor
progressio
n, assessed
up to 24
months |A
ssess BOR
by
Investigato
r
Assessmen
t., To
assess
confirmed
BOR by
Investigato
r
Assessmen
\(t\) for
patients
enrolled in
the dose
escalation
phase and
in the
efficacy
expansion
phase.,

Through
90 days
after
completion
of the
study, an
average of
1
year. |Asse
ss PFS by
Investigato
r
Assessmen
t., To
assess PFS
by
Investigato

Assessmen
\(t\) for
patients
enrolled in
the dose
escalation
phase and
in the
efficacy
expansion
phase.,
From time
of
initiation
of therapy
until the
\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|}
\hline & & & & & & & & date of first documente d tumor progressio n , assessed up to 24 months & \\
\hline RECRUITIN & Anatomic & DRUG: & PHAS & INTER & Allocation: & 36 & Incidence & The & 2022/3/31 \\
\hline G & Stage III & Cyclophosph & E1 & VENTI & NA | Interve & & of adverse & number & \\
\hline & Breast & amide | BIOL & & ONAL & ntion & & events, The & and & \\
\hline & Cancer & OGICAL: & & & Model: & & maximum & percentage & \\
\hline & AJCC & Neoantigen & & & SINGLE_G & & grade for & of & \\
\hline & v8|Anatomi & Peptide & & & ROUP | Mas & & each type & participant & \\
\hline & c Stage IIIA & Vaccine| \({ }^{\text {BIO }}\) & & & king: & & of adverse & s who & \\
\hline & Breast & LOGICAL: & & & NONE | Pri & & event will & completed & \\
\hline & Cancer & Pembrolizum & & & mary & & be & the & \\
\hline & AJCC & ab | BIOLOGI & & & Purpose: & & recorded & sequencing & \\
\hline
\end{tabular}
\begin{tabular}{|c|c|c|c|c|}
\hline v8 | Anatomi & CAL: & TREATME & for each & with \\
\hline c Stage IIIB & Sargramosti & NT & patient. & satisfactor \\
\hline Breast & m & & The & \(y\) data \\
\hline Cancer & & & attribution, & quality \\
\hline AJCC & & & grade, and & registratio \\
\hline v8 | Anatomi & & & type of & \(n \quad\) and \\
\hline c Stage IIIC & & & adverse & identified \\
\hline Breast & & & event (AE), & at least 10 \\
\hline Cancer & & & the dose & actionable \\
\hline AJCC & & & level, the & peptides, \\
\hline v8|Anatomi & & & tumor & meet the \\
\hline c Stage IV & & & type, and & eligibility \\
\hline Breast & & & the prior & criteria for \\
\hline Cancer & & & treatment & registratio \\
\hline AJCC & & & will be & n , and able \\
\hline v8|Clinical & & & tabulated & to initiate \\
\hline Stage III & & & for each & vaccine \\
\hline
\end{tabular}
\begin{tabular}{|c|c|c|}
\hline Cutaneous & patient, Up & production \\
\hline Melanoma & to 2 years & , Feasibility \\
\hline AJCC & from first & will be \\
\hline v8|Clinical & vaccine & defined as \\
\hline Stage III & administra & the \\
\hline Gastric & tion & number \\
\hline Cancer & & and \\
\hline AJCC & & percentage \\
\hline v8|Clinical & & of \\
\hline Stage III & & participant \\
\hline Gastroesoph & & s who \\
\hline ageal & & completed \\
\hline Junction & & the \\
\hline Adenocarci & & sequencing \\
\hline noma AJCC & & with \\
\hline v8|Clinical & & satisfactor \\
\hline Stage III & & \(y\) data \\
\hline
\end{tabular}
\begin{tabular}{ll} 
Merkel Cell & quality \\
Carcinoma & registratio \\
AJCC & \(\mathrm{n} \quad\) and \\
v8|Clinical & identified \\
Stage IV & at least 10 \\
Cutaneous & actionable \\
Melanoma & peptides, \\
AJCC & meet the \\
v8|Clinical & eligibility \\
Stage & criteria for \\
Gastric & registratio \\
Cancer & n, and able \\
AJCC & to initiate \\
v8|Clinical & vaccine \\
Stage IV & production \\
Gastroesoph & within 16 \\
ageal & weeks., Up
\end{tabular}
\begin{tabular}{|c|c|}
\hline Junction & to 16 \\
\hline Adenocarci & weeks \(\mid\) Im \\
\hline noma AJCC & munogenic \\
\hline v8|Clinical & ity \\
\hline Stage IV & responders \\
\hline Merkel Cell & The \\
\hline Carcinoma & number \\
\hline AJCC & and \\
\hline v8|Clinical & percentage \\
\hline Stage IVA & of patients \\
\hline Gastric & who are \\
\hline Cancer & vaccine \\
\hline AJCC & immunity \\
\hline v8|Clinical & responders \\
\hline Stage IVA & will be \\
\hline Gastroesoph & calculated. \\
\hline ageal & The \\
\hline
\end{tabular}
\begin{tabular}{ll} 
Junction & immunity \\
Adenocarci & responder \\
noma AJCC & for each \\
v8|Clinical & patient is \\
Stage IVB & defined as \\
Gastric & \(\backslash>=20 \%\) of \\
Cancer & neoantigen \\
AJCC & s \\
v8|Clinical & formulated \\
Stage IVB & into \\
Gastroesoph & vaccine \\
ageal & with \\
Junction & least 3 -fold \\
Adenocarci & of \\
noma AJCC & increase at \\
v8|Locally & any \\
Advanced & timepoint,,
\end{tabular}CervicalWithin 24
Carcinoma weeks
Locally
Advanced
Endometrial
Carcinoma
Locally
Advanced
Gastric
Adenocarci
noma|Local
lyAdvanced
Gastroesoph
ageal
Junction
Adenocarci
noma | Local
ly
Advanced
Head and
Neck
Squamous
Cell
Carcinoma
Locally
Advanced
Hepatocellu
lar
Carcinoma|
Locally
Advanced
Lung Non-
Small Cell

\section*{Carcinoma |}

Locally
Advanced
Malignant
Solid
Neoplasm |
Locally
Advanced
Melanoma|
Locally
Advanced
Merkel Cell
Carcinoma
Locally
Advanced
Renal Cell
Carcinoma

Locally
Advanced
Skin
Squamous
Cell
Carcinoma
Locally
Advanced
Triple-
Negative
Breast
Carcinoma |
Locally
Advanced
Unresectabl
e Breast
Carcinoma

Locally
Advanced
Unresectabl
e Cervical
Carcinoma |
Locally
Advanced
Unresectabl
e Gastric
Adenocarci
noma|Local
ly
Advanced
Unresectabl
e
Gastroesoph
ageal

\section*{Junction}

Adenocarci
noma|Local
ly
Advanced
Unresectabl
e Renal Cell
Carcinoma|
Locally
Advanced
Urothelial
Carcinoma
Metastatic
Cervical
Carcinoma |
Metastatic
Endometrial

\section*{Carcinoma |}

Metastatic
Gastric
Adenocarci
noma|Meta
static
Gastroesoph
ageal
Junction
Adenocarci
noma|Meta
static Head
and Neck
Squamous
Cell
Carcinoma |
Metastatic

Hepatocellu
lar
Carcinoma
Metastatic
Lung Non-
Small Cell
Carcinoma
Metastatic
Malignant
Solid
Neoplasm |
Metastatic
Melanoma |
Metastatic
Merkel Cell
Carcinoma|
Metastatic

\section*{Renal Cell}

Carcinoma|
Metastatic
Skin
Squamous
Cell
Carcinoma
Metastatic
Triple-
Negative
Breast
Carcinoma |
Metastatic
Urothelial
Carcinoma|
Pathologic
Stage III

\section*{Cutaneous}

Melanoma
AJCC
v8 | Patholo
gic Stage III
Gastric
Cancer
AJCC
v8 |Patholo
gic Stage III
Gastroesoph
ageal
Junction
Adenocarci
noma AJCC
v8|Patholo
gic Stage III
Merkel Cell
Carcinoma
AJCC
v8|Patholo
gic Stage
IIIA
Cutaneous
Melanoma
AJCC
v8 | Patholo
gic Stage
IIIA Gastric
Cancer
AJCC
v8|Patholo
gic Stage
IIIA

\section*{Gastroesoph}
ageal
Junction
Adenocarci
noma AJCC
v8|Patholo
gic Stage
IIIB
Cutaneous
Melanoma
AJCC
v8 | Patholo
gic Stage
IIIB Gastric

\section*{Cancer}

AJCC
v8 | Patholo

gic

Stage

IIIB
Gastroesoph
ageal
Junction
Adenocarci
noma AJCC
v8|Patholo
gic Stage
IIIC
Cutaneous
Melanoma
AJCC
v8 | Patholo
gic Stage
IIIC Gastric
Cancer

AJCC
v8 | Patholo
gic Stage
IIID
Cutaneous
Melanoma
AJCC
v8 | Patholo
gic Stage IV
Cutaneous
Melanoma
AJCC
v8 | Patholo
gic Stage IV

\section*{Gastric}

Cancer
AJCC
v8|Patholo
gic Stage IV
Gastroesoph
ageal
Junction
Adenocarci
noma AJCC
v8 |Patholo
gic Stage IV
Merkel Cell
Carcinoma
AJCC
v8|Patholo
gic Stage
IVA
Gastroesoph
ageal

\section*{Junction}

Adenocarci
noma AJCC
v8 | Patholo
gic Stage
IVB
Gastroesoph
ageal
Junction
Adenocarci
noma AJCC
v8|Postneo
adjuvant
Therapy
Stage III
Gastric

\section*{Cancer}

AJCC
v8|Postneo
adjuvant
Therapy
Stage III
Gastroesoph
ageal
Junction
Adenocarci
noma AJCC
v8|Postneo
adjuvant
Therapy
Stage IIIA
Gastroesoph
ageal
Junction

Adenocarci
noma AJCC
v8|Postneo
adjuvant
Therapy
Stage IIIB
Gastroesoph
ageal
Junction
Adenocarci
noma AJCC
v8|Postneo
adjuvant
Therapy
Stage IV
Gastric

\section*{Cancer}

AJCC
v8|Postneo
adjuvant
Therapy
Stage IV
Gastroesoph
ageal
Junction
Adenocarci
noma AJCC
v8| Postneo
adjuvant
Therapy
Stage IVA
Gastroesoph
ageal
Junction

Adenocarci
noma AJCC
v8|Postneo
adjuvant
Therapy
Stage IVB
Gastroesoph
ageal
Junction
Adenocarci
noma AJCC
v8|Prognos
tic Stage III
Breast
Cancer
AJCC
v8|Prognos

\section*{tic Stage \\ IIIA Breast}

Cancer
AJCC
v8|Prognos
tic Stage IIIB
Breast
Cancer
AJCC
v8|Prognos
tic Stage IIIC
Breast
Cancer
AJCC
v8|Prognos
tic Stage IV
Breast

\section*{Cancer}

AJCC
v8|Skin
Squamous
Cell
Carcinoma
Stage III
Cervical
Cancer
AJCC
v8|Stage III

\section*{Cutaneous}

Squamous
Cell
Carcinoma
of the Head
and Neck

AJCC
v8|Stage III
Hepatocellu
lar
Carcinoma
AJCC
v8|Stage III
Lung
Cancer
AJCC
v8|Stage III
Renal Cell
Cancer
AJCC
v8|Stage III
Uterine
Corpus

\section*{Cancer}

AJCC
v8|Stage
IIIA
Cervical
Cancer
AJCC
v8|Stage
IIIA
Hepatocellu
lar
Carcinoma
AJCC
v8|Stage
IIIA Lung
Cancer
AJCC
v8|Stage
IIIA Uterine
Corpus
Cancer
AJCC
v8|Stage
IIIB Cervical
Cancer
AJCC
v8|Stage
IIIB
Hepatocellu
lar
Carcinoma
AJCC
v8|Stage
IIIB Lung

\section*{Cancer}

AJCC
v8 |Stage
IIIB Uterine
Corpus

\section*{Cancer}

AJCC
v8|Stage
IIIC Lung
Cancer
AJCC
v8|Stage
IIIC Uterine
Corpus
Cancer
AJCC
v8|Stage

\section*{IIIC1}

Uterine
Corpus
Cancer
AJCC
v8|Stage
IIIC2
Uterine
Corpus
Cancer
AJCC
v8|Stage IV
Cervical
Cancer
AJCC
v8|Stage IV
Cutaneous

\section*{Squamous}

Cell

\section*{Carcinoma}
of the Head
and Neck
AJCC
v8|Stage IV
Hepatocellu
lar

\section*{Carcinoma}

AJCC
v8|Stage IV
Lung
Cancer
AJCC
v8|Stage IV
Renal Cell

\section*{Cancer}

AJCC
v8|Stage IV
Uterine
Corpus

\section*{Cancer}

AJCC
v8|Stage
IVA
Cervical
Cancer
AJCC
v8|Stage
IVA
Hepatocellu
lar
Carcinoma

\section*{AJCC}
v8|Stage
IVA Lung
Cancer
AJCC
v8|Stage
IVA Uterine
Corpus
Cancer
AJCC
v8|Stage
IVB Cervical
Cancer
AJCC
v8|Stage
IVB
Hepatocellu

\section*{lar}

Carcinoma
AJCC
v8|Stage
IVB Lung
Cancer
AJCC
v8|Stage
IVB Uterine
Corpus
Cancer
AJCC
v8|Triple-
Negative
Breast
Carcinoma|
Unresectabl
e Cervical
Carcinoma
Unresectabl
e
Endometrial
Carcinoma
Unresectabl
e Gastric
Adenocarci
noma|Unre
sectable
Gastroesoph
ageal
Junction
Adenocarci
noma|Unre
sectable

Head and
Neck
Squamous
Cell
Carcinoma
Unresectabl
e
Hepatocellu
lar
Carcinoma
Unresectabl
e Lung Non-
Small Cell
Carcinoma|
Unresectabl
e Malignant
Solid

\section*{Neoplasm |}

Unresectabl
e
Melanoma |
Unresectabl
e Merkel
Cell
Carcinoma
Unresectabl
e Renal Cell
Carcinoma
Unresectabl
e Skin
Squamous
Cell
Carcinoma |
Unresectabl
\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|}
\hline & e Triple- & & & & & & & & \\
\hline & Negative & & & & & & & & \\
\hline & Breast & & & & & & & & \\
\hline & Carcinoma & & & & & & & & \\
\hline & Unresectabl & & & & & & & & \\
\hline & e Urothelial & & & & & & & & \\
\hline & Carcinoma & & & & & & & & \\
\hline ACTIVE_NO & Adenocarci & DRUG: & PHAS & INTER & Allocation: & 262 & Progressio & Progressio & 2018/11/7 \\
\hline T_RECRUITI & noma of the & Nivolumab| & E2 & VENTI & RANDOMI & & n -free & \(n\)-free & \\
\hline NG & Stomach |G & DRUG: & & ONAL & ZED|Interv & & survival & survival & \\
\hline & astroEsopha & Ipilimumab | & & & ention & & (PFS) Arm & (PFS) Arm & \\
\hline & geal Cancer & DRUG: & & & Model: & & \(A\) and B, & A1, A2, C, & \\
\hline & & mFOLFOX| & & & PARALLEL & & PFS, & PFS, & \\
\hline & & DRUG: FLOT & & & | Masking: & & defined as & defined as & \\
\hline & & & & & NONE | Pri & & time from & time from & \\
\hline & & & & & mary & & randomiza & randomiza & \\
\hline & & & & & Purpose: & & tion to the & tion/enrol & \\
\hline
\end{tabular}
\begin{tabular}{|c|c|}
\hline TREATME & date of first ment to the \\
\hline \multirow[t]{16}{*}{NT} & observed date of first \\
\hline & disease observed \\
\hline & progressio disease \\
\hline & n as progressio \\
\hline & assessed n as \\
\hline & by the assessed \\
\hline & investigato by the \\
\hline & r using CT investigato \\
\hline & criteria or r using CT \\
\hline & death from criteria or \\
\hline & any cause death from \\
\hline & assessed any cause \\
\hline & every 8 assessed \\
\hline & weeks for every 8 \\
\hline & up to 3 weeks for \\
\hline & years Arm up to 3 \\
\hline
\end{tabular}
\begin{tabular}{|c|c|}
\hline A versus & years for \\
\hline Arm B, Up & Arm A1, \\
\hline to 3 & Arm A2 \\
\hline years | Pro & and Arm \\
\hline gression- & C, Up to 3 \\
\hline free & years | Pro \\
\hline Survival & gression- \\
\hline rate at 6 & free \\
\hline months & Survival \\
\hline Arm A2 & rate at \\
\hline and C, PFS & months \\
\hline rate at 6 & Arms \\
\hline months is & and B, PFS \\
\hline defined as & rate at \\
\hline proportion & months \\
\hline of patients & defined as \\
\hline being & proportion \\
\hline
\end{tabular}
\begin{tabular}{|c|c|}
\hline known to be alive & of patients being \\
\hline and free of & known to \\
\hline disease & be alive \\
\hline progressio & and free of \\
\hline n as & disease \\
\hline assessed & progressio \\
\hline by the & n as \\
\hline investigato & assessed \\
\hline r using CT & by the \\
\hline criteria at 6 & investigato \\
\hline months & r using CT \\
\hline after & criteria at 6 \\
\hline randomiza & months \\
\hline tion/enrol & after \\
\hline ment, 6 & randomiza \\
\hline months & tion, \\
\hline
\end{tabular}
\begin{tabular}{ll} 
after & months \\
randomiza & after \\
tion/enrol & randomiza \\
ment & tion|Over \\
& all \\
& Response \\
& Rate \\
& \((\) ORR), \\
& ORR \\
& defined as \\
& proportion \\
& of patients \\
& with \\
& complete \\
& or partial \\
& response \\
& \((C R+\) PR)
\end{tabular}
as assessed
according
to RECIST
criteria
every 8
weeks for
up to 2
years, Up
to 2
years|Dur
ation of
response
and
disease
stabilizatio
n,
Duration
of response
and
disease
stabilizatio
n defined
as time
from
documenta
tion of
tumor
response
(CR, PR) or
disease
stabilizatio
\(\mathrm{n} \quad(\mathrm{SD})\)
according
to RECIST
disease
progressio
n or death
for up to 3
years, Up
to 3
years |Ove
rall
survival
(OS),
Overall
survival
according
to Kaplan-
Meier
assessed
from
randomiza
tion/enrol
ment to the
date of
death from
any cause,
Up to 3
years | Inci
dence and
severity of
adverse
events,
incidence
and
severity of
adverse
events
according
to CTCAE
(Common
Terminolo
gy Criteria
for
Adverse
Events)
Version
4.03
criteria as
assessed
every 2
weeks
during
treatment
and until
100 days
after the
last dose of
study
drug, Up
to 27
months |P
atient
reported
outcomes:
Quality of
life,
Quality of
life as
measured
by
months
until first
observed
disease
progressio
n or death
for up to 3
years, Up
to 3
years | Pro
gression-
free
survival
(PFS) by
PD-L1
expression
status,
Subgroup
analysis of
PFS,
defined as
time from
randomiza
tion/enrol
ment to the
date of first
observed
disease
progressio
n as
assessed
by the
investigato
r using CT
criteria or
death from
any cause
assessed
every 8
years,
according
to PD-L1
expression
status, Up
to 3
years |Ove
rall
survival
(OS) by
PD-L1
expression
status,
Subgroup
analysis of
overall
survival
according
to Kaplan-
Meier
assessed
from
randomiza
tion/enrol
ment to the
date of
death from
any cause
according
to PD-L1
expression
\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|}
\hline \multirow[b]{2}{*}{RECRUITIN} & \multirow[b]{2}{*}{Gastrointest} & \multirow[b]{2}{*}{DRUG:} & \multirow[b]{2}{*}{PHAS} & \multirow[b]{2}{*}{INTER} & \multirow[b]{2}{*}{Allocation:} & \multirow[b]{2}{*}{20} & \multirow[b]{2}{*}{Maximum} & \multicolumn{2}{|l|}{\begin{tabular}{l}
status, Up \\
to 3 years
\end{tabular}} \\
\hline & & & & & & & & Progressio & 2020/5/15 \\
\hline \multirow[t]{14}{*}{G} & inal & Cyclophosph & E1|PH & VENTI & NON_RAN & & tolerated & n-Free & \\
\hline & Epithelial & amide|DRU & ASE2 & ONAL & DOMIZED | & & dose & Survival & \\
\hline & Cancer \| Gas & G: & & & Intervention & & (MTD), & (PFS), & \\
\hline & trointestinal & Fludarabine & & & Model: & & Highest & Progressio & \\
\hline & Neoplasms | & BIOLOGICA & & & SEQUENTI & & dose at & n -Free & \\
\hline & Cancer of & L: Tumor- & & & AL|Maskin & & which less & Survival & \\
\hline & Gastrointest & Infiltrating & & & g: & & than or & (PFS) of & \\
\hline & inal & Lymphocytes & & & NONE |Pri & & equal to 1 & patients & \\
\hline & Tract \(/\) Cance & (TIL)|DRUG: & & & mary & & of 6 & with & \\
\hline & r, & Aldesleukin & & & Purpose: & & patients & metastatic & \\
\hline & Gastrointest & & & & TREATME & & experience & gastrointes & \\
\hline & inal | Gastroi & & & & NT & & d a DLT or & tinal & \\
\hline & ntestinal & & & & & & the highest & cancers & \\
\hline & Cancer \({ }^{\text {Col }}\) & & & & & & dose level & treated & \\
\hline
\end{tabular}
o-rectal
Cancer | Pan
creatic
Cancer |Gall
Bladder
Cancer \({ }^{\text {Col }}\)
on
Cancer \({ }^{\text {Eso }}\)
phageal
Cancer \| Sto
mach
Cancer

\begin{tabular}{ll} 
knockout & cancers \\
of CISH & treated \\
gene in & using the \\
patients & autologous \\
with & lymphocyt \\
refractory & es, 2 Years \\
metastatic & or Disease \\
gastrointes & Progressio \\
tinal & n|Toxicity \\
epithelial & profiles \\
cancers: & resulting \\
changes in & from \\
diameter, & treatment \\
Changes in & using these \\
the largest & engineered \\
diameter & tumor- \\
(unidimen & infiltrating
\end{tabular}
```

sional lymphocyt
measurem es,
ent) of the Incidence
tumor of targeted
lesions and toxicities
the events, 2
shortest Years or
diameter Disease
in the case Progressio
of
malignant
lymph
nodes are
used in the
RECIST
v1.1
criteria,

```

Every
Weeks for
the first
three
months,
then every
8 weeks
thereafter,
up to 2
years|Safe
ty of tumor
reactive
autologous
lymphocyt
es with
knockout
of the

\begin{tabular}{ll} 
the & changes of \\
biomarker & immune \\
s related to & microenvir \\
the efficacy & onment \\
of & before and \\
neoadjuva & after \\
nt therapy & neoadjuva \\
with PD-1 & nt \\
mab & treatment \\
combined & with PD-1 \\
with & mab \\
chemother & combined \\
apy in & with \\
locally & chemother \\
advanced & apy for \\
gastric & locally \\
cancer., & advanced
\end{tabular}
\begin{tabular}{ll} 
From the gastric \\
initiation & cancer., \\
date of & From the \\
patients & initiation \\
recruited & date of \\
into & patients \\
groups to & recruited \\
the date of & into \\
first & groups to \\
documente & the date of \\
d & first \\
progressio & documente \\
nor date of & d \\
death from & progressio \\
any cause, & n or date of \\
whichever & death from \\
came first, & any cause,
\end{tabular}
\begin{tabular}{|c|c|}
\hline assessed & whichever \\
\hline up to 2 & came first, \\
\hline years \({ }^{\text {Rela }}\) & assessed \\
\hline tive RNA & up to \\
\hline biomarker & years|Dru \\
\hline s, At the & g \\
\hline RNA level, & resistance \\
\hline to identify & mechanis \\
\hline the & m, \\
\hline biomarker & explore the \\
\hline s related to & drug \\
\hline the efficacy & resistance \\
\hline of & mechanis \\
\hline neoadjuva & \(\mathrm{m} \quad\) of \\
\hline nt therapy & locally \\
\hline with PD-1 & advanced \\
\hline mab & gastric \\
\hline
\end{tabular}
\begin{tabular}{|c|c|}
\hline combined
with & \begin{tabular}{l}
cancer \\
after
\end{tabular} \\
\hline chemother & neoadjuva \\
\hline apy in & nt therapy \\
\hline locally & with PD-1 \\
\hline advanced & mab \\
\hline gastric & combined \\
\hline cancer., & with \\
\hline From the & chemother \\
\hline initiation & apy., From \\
\hline date of & the \\
\hline patients & initiation \\
\hline recruited & date of \\
\hline into & patients \\
\hline groups to & recruited \\
\hline the date of & into \\
\hline first & groups to \\
\hline
\end{tabular}
documente the date of
d
progressio documente
n or date of d
death from
any cagressio
whichever death from
came first, any cause,
assessed whichever
up to 2 came first,
years \(\mid\) Pre assessed
diction \(\quad\) up to 2
model for years
efficacy, A
prediction
model for
the efficacy
combined
with
chemother
apy,
constructe
d on the
basis of
clinical
pathology,
gene
variation,
gene
expression
and other
factors.,

From the
date of
completing
collecting
data, to the
date of
death from
any cause
or the end
date of the
whole trail,
whichever
came first,
assessed
up to 2
years
\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|}
\hline COMPLETE & Clinical & DRUG: & PHAS & INTER & Allocation: & 9 & Progressio & Overall & 2019/4/19 \\
\hline D & Stage IV & Cyclophosph & E1|PH & VENTI & NA | Interve & & n -free & Survival, & \\
\hline & Gastric & amide \({ }^{\text {| BIOL }}\) & ASE2 & ONAL & ntion & & Survival, & Estimated & \\
\hline & Cancer & OGICAL: & & & Model: & & Estimated & using the & \\
\hline & AJCC & Cytokine- & & & SINGLE_G & & using the & product- & \\
\hline & v8 | Clinical & based & & & ROUP \| Mas & & product- & limit & \\
\hline & Stage IV & Biologic & & & king: & & limit & method of & \\
\hline & Gastroesoph & Agent IRX- & & & NONE | Pri & & method of & Kaplan & \\
\hline & ageal & 2 | BIOLOGIC & & & mary & & Kaplan & and Meier. & \\
\hline & Junction & AL: & & & Purpose: & & and Meier. & From the & \\
\hline & Adenocarci & Pembrolizum & & & TREATME & & From & time of & \\
\hline & noma AJCC & ab & & & NT & & initial & initial & \\
\hline & v8 | Clinical & & & & & & treatment & treatment & \\
\hline & Stage IVA & & & & & & until & until death & \\
\hline & Gastric & & & & & & progressio & from any & \\
\hline & Cancer & & & & & & n or death. & cause., Up & \\
\hline & AJCC & & & & & & Progressio & to 2 & \\
\hline
\end{tabular}
\begin{tabular}{|c|c|c|}
\hline v8 | Clinical & n is & years |Ove \\
\hline Stage IVA & defined & rall \\
\hline Gastroesoph & using & Response, \\
\hline ageal & Response & Per \\
\hline Junction & Evaluation & Response \\
\hline Adenocarci & Criteria In & Evaluation \\
\hline noma AJCC & Solid & Criteria In \\
\hline v8|Clinical & Tumors & Solid \\
\hline Stage IVB & Criteria & Tumors \\
\hline Gastric & (RECIST & Criteria \\
\hline Cancer & v1.1), as a & (RECIST \\
\hline AJCC & 20\% & v1.1) for \\
\hline v8|Clinical & increase in & target \\
\hline Stage IVB & the sum of & lesions and \\
\hline Gastroesoph & the longest & assessed \\
\hline ageal & diameter & by MRI: \\
\hline Junction & of target & Complete \\
\hline
\end{tabular}

Adenocarci
noma AJCC
v8|Metastat
ic Gastric
Adenocarci
noma | Meta
static
Gastroesoph
ageal
Junction
Adenocarci
noma|Path
ologic Stage
IV Gastric
Cancer
AJCC
v8 | Patholo
lesions, or Response
a (CR),
measurabl Disappear
e increase ance of all
in a non- target
target lesions;
lesion, or Partial
the Response
appearanc (PR),
e of new \(\backslash>=30 \%\)
lesions., decrease in
From first the sum of
day of the longest
study drug diameter
administra of target
tion to lesions;
disease Overall
\begin{tabular}{|c|c|c|}
\hline gic Stage IV & progressio & Response \\
\hline Gastroesoph & n or death, & \((\mathrm{OR})=\mathrm{CR}\) \\
\hline ageal & assessed & + PR, Up to \\
\hline Junction & up to 2 & 2 years \\
\hline Adenocarci & years & \\
\hline noma AJCC & & \\
\hline v8|Patholo & & \\
\hline gic Stage & & \\
\hline IVA & & \\
\hline Gastroesoph & & \\
\hline ageal & & \\
\hline Junction & & \\
\hline Adenocarci & & \\
\hline noma AJCC & & \\
\hline v8| Patholo & & \\
\hline gic Stage & & \\
\hline IVB & & \\
\hline
\end{tabular}

\section*{Gastroesoph}
ageal
Junction
Adenocarci
noma AJCC
v8|Postneo
adjuvant
Therapy
Stage IV
Gastric
Cancer
AJCC
v8|Postneo
adjuvant
Therapy
Stage IV
Gastroesoph
ageal
Junction
Adenocarci
noma AJCC
v8|Postneo
adjuvant
Therapy
Stage IVA
Gastroesoph
ageal
Junction
Adenocarci
noma AJCC
v8|Postneo
adjuvant
Therapy
Stage IVB

\section*{Gastroesoph}
ageal
Junction
Adenocarci
noma AJCC
v8|Recurre
nt Gastric
Adenocarci
noma \(\mid\) Recu
rrent
Gastroesoph
ageal
Junction
Adenocarci
noma
\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|}
\hline RECRUITIN & Liver & DRUG: & PHAS & INTER & Allocation: & 40 & Objective & progressio & 2022/4/10 \\
\hline \multirow[t]{16}{*}{G} & \multirow[t]{16}{*}{Metastases} & Tislelizumab & E2|PH & VENTI & NA | Interve & & Response & n -free & \\
\hline & & in & ASE3 & ONAL & ntion & & Rate & survival, & \\
\hline & & Combination & & & Model: & & (ORR), The & The length & \\
\hline & & with & & & SINGLE_G & & percentage & of time & \\
\hline & & Oxaliplatin & & & ROUP | Mas & & of people & during and & \\
\hline & & and Tegafur & & & king: & & in the & after the & \\
\hline & & & & & NONE | Pri & & study who & treatment, & \\
\hline & & & & & mary & & have a & that liver & \\
\hline & & & & & Purpose: & & partial or & metastasis & \\
\hline & & & & & TREATME & & complete & does not & \\
\hline & & & & & NT & & response to & get bigger & \\
\hline & & & & & & & the & or present & \\
\hline & & & & & & & treatment & new sites & \\
\hline & & & & & & & after 6 & of & \\
\hline & & & & & & & cycles of & metastasis, & \\
\hline & & & & & & & Tislelizum & according & \\
\hline
\end{tabular}
\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|}
\hline & & & & & & & ab & to & \\
\hline & & & & & & & +Tegafur + & RECIST1.1, & \\
\hline & & & & & & & Oxaliplatin & \[
\text { up to } 12
\] & \\
\hline & & & & & & & , according & months & \\
\hline & & & & & & & & after the & \\
\hline & & & & & & & RECIST1.1, & end of last & \\
\hline & & & & & & & about 6 & cycle of & \\
\hline & & & & & & & months & treatment & \\
\hline & & & & & & & after the & & \\
\hline & & & & & & & enrollment & & \\
\hline RECRUITIN & Advanced & DRUG: & PHAS & INTER & Allocation: & 131 & Number of & Objective & 2022/10/6 \\
\hline G & or & NC410|DRU & E1|PH & VENTI & NA | Interve & & participant & Response & \\
\hline & Metastatic & G: & ASE2 & ONAL & ntion & & s with & Rate per & \\
\hline & Solid & Pembrolizum & & & Model: & & treatment- & RECIST, & \\
\hline & Tumors | Mi & ab & & & SINGLE_G & & emergent & Objective & \\
\hline & crosatellite & & & & ROUP \| Mas & & adverse & response & \\
\hline & Instability & & & & king: & & events as & rate (ORR) & \\
\hline
\end{tabular}
\begin{tabular}{|c|c|c|c|}
\hline Low | Micro & NONE | Pri & assessed & per \\
\hline satellite & mary & by CTCAE & Response \\
\hline Instability & Purpose: & v5.0, & Evaluation \\
\hline High | Micro & TREATME & Frequency, & Criteria in \\
\hline satellite & NT & duration, & Solid \\
\hline Stable | Ovar & & and & Tumors \\
\hline ian & & severity of & (RECIST) \\
\hline Cancer \| Gas & & treatment- & v1.1, until \\
\hline tric & & emergent & disease \\
\hline Cancer \({ }^{\text {Col }}\) & & adverse & progressio \\
\hline o-rectal & & events & n, up to 24 \\
\hline Cancer | Eso & & (AEs), 24 & months |D \\
\hline phageal & & Months \(\mathrm{D}^{\text {D }}\) & uration of \\
\hline Cancer \({ }^{\text {E }}\) End & & efine a & Response \\
\hline ometrial & & recommen & per \\
\hline Cancer | Hea & & ded Phase & RECIST, \\
\hline d Neck & & 2 dose & Duration \\
\hline
\end{tabular}
\begin{tabular}{|c|c|c|}
\hline Cancer \(/\) Cer & (RP2D) of & of \\
\hline vical & NC410 & Response \\
\hline Cancer \| Lun & when & (DoR) per \\
\hline g Cancer & combined & Response \\
\hline & with & Evaluation \\
\hline & standard & Criteria in \\
\hline & dose & Solid \\
\hline & Pembroliz & Tumors \\
\hline & umab, A & (RECIST) \\
\hline & mTPI & v1.1, until \\
\hline & design will & disease \\
\hline & be utilized & progressio \\
\hline & to & n, up to 24 \\
\hline & determine & months | D \\
\hline & the RP2D & isease \\
\hline & of NC410, & Control \\
\hline & 42 days & Rate per \\
\hline
\end{tabular}

Disease

\section*{Control}

Rate (DCR)
per
Response
Evaluation
Criteria in
Solid
Tumors
(RECIST)
v1.1, until
disease
progressio
n, up to 24
months \(\mid \operatorname{Pr}\)
ogression-

Survival
(PFS) per
RECIST,
Progressio
n-free
Survival
(PFS) per
Response
Evaluation
Criteria in
Solid
Tumors
(RECIST)
v1.1, until
disease
progressio
\begin{tabular}{llllllll} 
& & & & & n, up to 24 \\
months
\end{tabular}
\begin{tabular}{llll} 
Serous & medication of \\
Ovarian & or & LY3435151 \\
Carcinoma & combinatio & ., & Cycle \\
Hepatocellu & n, & and & Day
\end{tabular} 1
\begin{tabular}{|c|c|}
\hline gy Criteria & in \\
\hline for & Combinati \\
\hline Adverse & on With \\
\hline Events & Pembroliz \\
\hline (NCI- & umab, PK: \\
\hline CTCAE) & Cmax of \\
\hline Version & LY3435151 \\
\hline 5.0: & in \\
\hline & Combinati \\
\hline 1. Any & on with \\
\hline death not & Pembroliz \\
\hline clearly due & umab., \\
\hline to the & Predose \\
\hline underlying & Cycle 1 \\
\hline disease or & Day 1 \\
\hline extraneous & through \\
\hline causes & Predose \\
\hline
\end{tabular}
\begin{tabular}{|c|c|}
\hline 2. & Cycle \\
\hline Neutropen & Day 1 （21 \\
\hline ic fever 2. & Da \\
\hline Any Grade & Cycles）｜O \\
\hline 鈮 ？non－ & verall \\
\hline hematologi & Response \\
\hline c toxicity & Rate \\
\hline 3．Grade & （ORR）： \\
\hline 鈮 & Percentage
of \\
\hline neutropeni & Participant \\
\hline or & s With \\
\hline thrombocy & Complete \\
\hline topenia & Response \\
\hline \(\>7\) days & （CR）or \\
\hline 4．Grade & Partial \\
\hline 鈮 & Response \\
\hline
\end{tabular}
\begin{tabular}{|c|c|}
\hline thrombocy & (PR), \\
\hline topenia & Overall \\
\hline with & response \\
\hline bleeding & rate is the \\
\hline 5. Grade & best \\
\hline 鈮 ? & response of \\
\hline nausea/vo & complete \\
\hline miting or & response \\
\hline diarrhea\> & (CR) or \\
\hline 72 hours & partial \\
\hline with & response \\
\hline adequate & (PR) as \\
\hline antiemetic & classified \\
\hline and other & by the \\
\hline supportive & independe \\
\hline care & nt central \\
\hline & review \\
\hline
\end{tabular}
\begin{tabular}{|c|c|}
\hline 鈮？fatigue & according \\
\hline & to the \\
\hline 鈮？week & \\
\hline & Response \\
\hline 7．Grade & Evaluation \\
\hline 鈮 & Criteria In \\
\hline electrolyte & Solid \\
\hline abnormalit & Tumors \\
\hline \(y\) that & （RECIST \\
\hline lasts \(\backslash>72\) & v1．1）．CR is \\
\hline hours， & a \\
\hline unless the & disappeara \\
\hline Participant & nce of all \\
\hline has clinical & target and \\
\hline symptoms， & non－target \\
\hline in which & lesions and \\
\hline case all & normalizat \\
\hline Grade & ion of \\
\hline
\end{tabular}
\begin{tabular}{ll} 
3+electroly & tumor \\
te & marker \\
abnormalit & level. PR is \\
y & an at least \\
regardless & \(30 \%\) \\
of duration & decrease in \\
should & the sum of \\
count as a & the \\
DLT & diameters \\
\(8 . \quad\) Grade & of target \\
鈮 & lesions \\
prolongati & (taking as \\
on of QT & reference \\
interval & the \\
corrected & baseline \\
using the & sum \\
Fridericia & diameter)
\end{tabular}
\begin{tabular}{ll} 
formula on & without \\
2 separate & progressio \\
electrocard & n of non- \\
iogram & target \\
readings & lesions or \\
approxima & appearanc \\
tely 5 min & e of new \\
apart., & lesions. \\
Baseline & Overall \\
through & response \\
Cycle 2 (21 rate is \\
Day & calculated \\
Cycles) & as a total \\
& \begin{tabular}{l} 
number of \\
\\
\end{tabular} \begin{tabular}{l} 
participant
\end{tabular} \\
& or with CR
\end{tabular}
the total
number of participant
s per
cohort
with at
least 1
measurabl
e lesion,
multiplied
by 100.,
Baseline
through
Disease
Progressio
n or Death
(Up to 4
Months)|
Disease
Control
Rate
(DCR):
Percentage
of
Participant
s With a
Best
Overall
Response
of \(C R, P R\),
and Stable
Disease,
Disease

\section*{Control}

Rate (DCR)
is the
percentage
of
participant
\(s\) with a
best
overall
response of
CR, PR, or
Stable
Disease
(SD) as per
Response
using
RECIST
criteria. CR
defined as the
disappeara
nce of all
target and
non-target
lesions and
no
appearanc
e of new
lesions. PR
defined as
at least a
30\%
decrease in
the sum of
the LD of
target
lesions
(taking as
reference
the
baseline
sum LD),
no
progressio
n of non-
target
lesions,
and no
appearanc
e of new
lesions. SD
is neither
sufficient
shrinkage
to qualify
for PR nor
sufficient
increase to
qualify for
PD for
target
lesions, no
progressio
n of non-
target
lesions,
and no
lesions. PD
is at least a
20\%
increase in
the sum of
the
diameters
of target
lesions,
with
reference
being the
smallest
sum on
study and
an absolute
increase of
at least 5
mm , or
unequivoc
al
progressio
n of non-
target
lesions, or
1 or more
new
lesions.,
Baseline
through
Measured
Progressiv
e Disease
(Up to 4
Months) |
Duration
of
Response
(DoR),
DOR is the
time from
the date of first
evidence of
complete
response
or partial
response to
the date of
n or the
date of
death due
to any
cause,
whichever
is earlier.
\(C R\) and \(P R\)
defined
using the
RECIST
v1.1. \(\quad C R\)
defined as
the
disappeara
nce of all
target and
non-target
lesions and
no
appearanc
e of new
lesions. PR
defined as
at least a
\(30 \%\)
decrease in
the sum of
the LD of
target
lesions
(taking as
reference
the
baseline
sum LD),
no
progressio
n of non-
target
lesions,
and no
appearanc
e of new
lesions. If a
responder
was not
known to
have died
have
objective
progressio
\(n\) as of the
data
inclusion
cutoff date,
duration of
response
was
censored at
the last
adequate
tumor
assessment
date. PD
was at least
increase in
the sum of
the
diameters
of target
lesions,
with
reference
being the
smallest
sum on
study and
an absolute
increase of
at least 5
mm , or
unequivoc
al
progressio
n of non-
target
lesions, or
1 or more
new
lesions.,
Date of CR
or PR to
Date of
Objective
Disease
Progressio
n or Death
Due to

Any Cause
(Up to 4
Months) |T
ime to
Response
(TTR),
Time to
response
(TTR) is
defined as
the time
from the
date of
start of
treatment
to the date
measurem
```

ent criteria
for
confirmed
CR or PR
(whichever
is first
recorded)
are first
met. For
participant
s who are
not known
to have
achieved
CR or PR
as of the
data

```
```

inclusion
cut-off
date, TTR
will be
censored at
the date of
the last
objective
disease
assessment
prior the
date of any
subsequen
t
systematic
anticancer
therapy.,

```
Baseline to
Date of CR
or PR (Up
to \(\quad 4\)
Months)| P
rogression
Free
Survival
(PFS), PFS
time was
measured
from the
date of
randomiza
tion until
the first
radiograph
documenta
tion of
progressio
n as
defined by
Response
Evaluation
Criteria in
Solid
Tumors
(RECIST)
version 1.1,
or death
from any
cause.
Progressiv
e Disease
(PD) was at
least a \(20 \%\)
increase in
the sum of
the
diameters
of target
lesions,
with
reference
being the
smallest
sum on
study and
an absolute
increase of
unequivoc
al
progressio
n of non-
target
lesions, or
1 or more
new
lesions. If a
participant
does not
have a
complete
baseline
disease
censored at
the date of
first dose,
regardless
of whether
or not
objectively
determine
d disease
progressio
\(n\) or death
has been
observed
censored at
the last
adequate
tumor
assessment
date.,
Baseline to
Objective
Progressio
n or Death
Due to
Any Cause
(Up to 4
Months)
\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|}
\hline COMPLETE & Progressive & BIOLOGICA & PHAS & INTER & Allocation: & 26 & The Safety & Clinical & May-07 \\
\hline D & Metastatic & L: ALT-801 & E1 & VENTI & NA | Interve & & and & Antitumor & \\
\hline & Malignancie & & & ONAL & ntion & & Toxicity of & Response & \\
\hline & s & & & & Model: & & ALT-801 in & to ALT- & \\
\hline & & & & & SINGLE_G & & Patients & 801, & \\
\hline & & & & & ROUP \| Mas & & With & Number of & \\
\hline & & & & & king: & & Progressiv & subjects & \\
\hline & & & & & NONE | Pri & & e & with a & \\
\hline & & & & & mary & & Metastatic & complete & \\
\hline & & & & & Purpose: & & Malignanci & response & \\
\hline & & & & & TREATME & & es, & (CR), & \\
\hline & & & & & NT & & Number of & partial & \\
\hline & & & & & & & serious & response & \\
\hline & & & & & & & adverse & (PR) or & \\
\hline & & & & & & & events per & stable & \\
\hline & & & & & & & cohort, 18 & disease & \\
\hline & & & & & & & months |T & (SD). CR is & \\
\hline
\end{tabular}
\begin{tabular}{ll} 
he & defined as \\
Maximum- & disappeara \\
tolerated & nce of all \\
Dose & tumor \\
(MTD) of & lesions \\
ALT-801, & selected for
\end{tabular} \begin{tabular}{ll} 
Number of & measurem \\
dose & ent. PR is \\
limiting & defined as \\
toxicities & at least \\
(DLTs). A & \(30 \%\) \\
DLT is a & decrease in \\
toxicity & the sum of \\
that results & all tumor \\
in patient & lesions \\
withdrawa & selected for \\
l from the & measurem
\end{tabular}
\begin{tabular}{ll} 
study as ent. Stable \\
defined in & disease is \\
the & defined as \\
protocol., & neither \\
18 months & sufficient \\
& tumor \\
& shrinkage \\
& to qualify \\
& for PR nor \\
& sufficient \\
& tumor \\
& increase to \\
& qualify for \\
& progressiv \\
& \(e \quad\) disease \\
(PD) which \\
is defined
\end{tabular}
increase
the sum of
the all
tumor
lesions
selected for
measurem
ent., 24
months | A
LT-801
Induced
Cell-
mediated
Immune
Responses,

Number of
tumor-
responsive
(interferon
-gamma
positive
(IFNg+))
immune
cells in
blood post
dosing, 24
months |I
mmunoge
nicity of
ALT-801,
Titer of
anti-drug
\begin{tabular}{|c|c|c|c|c|c|c|c|c|}
\hline & & & & & & & Abs at week 4, 24 months & \\
\hline RECRUITIN & Acute & PROCEDURE: & OBSER & Observation & 1000 & Procure, & Pan-cancer & 2020/11/11 \\
\hline G & Myeloid & Biospecimen & VATI & al Model: & & store and & gene panel & \\
\hline & Leukemia | & Collection | OTHER: & ONAL & | Time & & distribute & tumor next & \\
\hline & Anatomic & Medical Chart Review & & Perspective: & & longitudin & generation & \\
\hline & Stage III & & & p & & al & sequencing & \\
\hline & Breast & & & & & biospecime & test, & \\
\hline & Cancer & & & & & ns and & Statistical & \\
\hline & AJCC & & & & & associated & analysis & \\
\hline & v8| Anatomi & & & & & clinical & will be & \\
\hline & c Stage IV & & & & & data, Will & descriptive & \\
\hline & Breast & & & & & procure, & and will be & \\
\hline & Cancer & & & & & store and & analyzed & \\
\hline & AJCC & & & & & distribute & for each & \\
\hline & v8 | Clinical & & & & & longitudin & BSS as well & \\
\hline
\end{tabular}

Stage III
Cutaneous
Melanoma
AJCC
v8 | Clinical
Stage IV
Cutaneous
Melanoma
AJCC
v8 | Clinical
Stage IV
Esophageal
Adenocarci
noma AJCC
v8|Clinical
Stage IV
Esophageal
\begin{tabular}{ll} 
al & as study \\
biospecime & aggregate., \\
ns and & Until \\
associated & completion \\
clinical & of \\
data for & biospecime \\
current & n \\
and future & collection, \\
cancer & up to 3 \\
research in & years \(\mid\) Can \\
order to & cer \\
elucidate & Research \\
molecular & Data \\
mechanis & Commons, \\
ms of & The Cancer \\
sensitivity & Imaging \\
and & Archive
\end{tabular}

Squamous
Cell
Carcinoma
AJCC
v8|Clinical
Stage IV
Gastric
Cancer
AJCC
v8|Clinical
Stage IV
Gastroesoph
ageal
Junction
Adenocarci
noma AJCC
v8|Lung
\begin{tabular}{ll} 
intrinsic or & and \\
acquired & database of \\
resistance & Genotypes \\
to & and \\
standard & Phenotype \\
of care & s data \\
systemic & contributio \\
therapies, & n, \\
including & Statistical \\
immunoth & analysis \\
erapy. & will be \\
Cases will & descriptive \\
be & and will be \\
grouped & analyzed \\
according & for each \\
to patient & BSS as well \\
demograp & as study
\end{tabular}
\begin{tabular}{|c|c|c|}
\hline Non-Small & hics, & aggregate., \\
\hline Cell & cancer type & Until \\
\hline Carcinoma & and & completion \\
\hline Lung Small & treatment & of \\
\hline Cell & regimen. & biospecime \\
\hline Carcinoma & Statistical & n \\
\hline Malignant & analysis & collection, \\
\hline Solid & will be & up to 3 \\
\hline Neoplasm| & descriptive & years |Perc \\
\hline Metastatic & and will be & entage of \\
\hline Prostate & analyzed & minority \\
\hline Carcinoma & for each & and \\
\hline Multiple & Biospecim & underserv \\
\hline Myeloma |S & en Source & \\
\hline tage III Lung & Site (BSS) & participant \\
\hline Cancer & as well as & s accrued, \\
\hline AJCC & study & Statistical \\
\hline
\end{tabular}
\begin{tabular}{|c|c|}
\hline v8|Stage III & aggregate., analysis \\
\hline Ovarian & Up to 10 will be \\
\hline Cancer & years|Perc descriptive \\
\hline AJCC & entage of and will be \\
\hline v8|Stage IV & enrolled analyzed \\
\hline Colorectal & patients by for each \\
\hline Cancer & cancer type BSS as well \\
\hline AJCC & and as study \\
\hline v8|Stage IV & treatment aggregate., \\
\hline Lung & regimen Until \\
\hline Cancer & overall, completion \\
\hline AJCC & Will assess of \\
\hline v8|Stage IV & the biospecime \\
\hline Ovarian & percentage n \\
\hline Cancer & of enrolled collection, \\
\hline AJCC & patients by up to 3 \\
\hline v8|Stage IV & cancer type years |Perc \\
\hline
\end{tabular}
\begin{tabular}{|c|c|c|}
\hline Prostate & and & entage of \\
\hline Cancer & treatment & enrolled \\
\hline AJCC & regimen & patients for \\
\hline v8|Stage & overall and & whom \\
\hline IVB Prostate & those who & molecular \\
\hline Cancer & contribute & profiling is \\
\hline AJCC v8 & & attempted, \\
\hline & the Drug & Statistical \\
\hline & Resistance & analysis \\
\hline & and & will be \\
\hline & Sensitivity & descriptive \\
\hline & Network & and will be \\
\hline & and other & analyzed \\
\hline & approved & for each \\
\hline & investigato & BSS as well \\
\hline & rs. & as study \\
\hline & Statistical & aggregate. \\
\hline
\end{tabular}
\begin{tabular}{ll} 
analysis & Will also \\
will be & be assessed \\
descriptive & by patient \\
and will be & demograp \\
analyzed & hics, \\
for each cancer type \\
BSS as well & and \\
as study & treatment \\
aggregate., regimen., \\
Until & Until \\
completion & completion \\
of & of \\
biospecime & biospecime \\
n & \(n\) \\
collection, & collection, \\
up to 3 & up to 3 \\
years Perc & years
\end{tabular}
\begin{tabular}{ll}
\begin{tabular}{l} 
entage of \\
minority
\end{tabular} & entage of \\
and & patients for \\
underserv & whom \\
ed study & molecular \\
participant & profiling \\
s accrued, & results are \\
Statistical & generated, \\
analysis & Statistical \\
will be & analysis \\
descriptive & will be \\
and will be & descriptive \\
analyzed & and will be \\
for each & analyzed \\
BSS as well & for each \\
as study & BSS as well \\
aggregate., & as study
\end{tabular}
\begin{tabular}{|c|c|}
\hline Until & aggregate. \\
\hline completion & Will also \\
\hline of & be assessed \\
\hline biospecime & by patient \\
\hline n & demograp \\
\hline collection, & hics, \\
\hline up to 3 & cancer type \\
\hline years & and \\
\hline & treatment \\
\hline & regimen., \\
\hline & Until \\
\hline & completion \\
\hline & of \\
\hline & biospecime \\
\hline & n \\
\hline & collection, \\
\hline & up to 3 \\
\hline
\end{tabular}
```

years|Perc
entage of
enrolled
patients for
whom
samples
are
obtained at
each
longitudin
al
timepoint,
Statistical
analysis
will be
descriptive
and will be

```
analyzed
for each
BSS as well
as study
aggregate.
Will also
be assessed
by patient
demograp
hics,
cancer type
and
treatment
regimen.,
Until
completion
biospecime
n
collection
up to 3
years \(\mid\) Perc
entage of
collected
biospecime
ns that are
delivered
to the
Patient
Derived
Models
Repository
, Statistical
analysis
will be
descriptive
and will be
analyzed
for each
BSS as well
as study
aggregate.
Will also
be assessed
by patient
demograp
hics,
cancer type
and
treatment
regimen.,
\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|}
\hline & & & & & & & & Until completion of biospecime n collection, up to 3 years & \\
\hline NOT_YET_R & Gastric & DRUG: & PHAS & INTER & Allocation: & 90 & Pathologic & Objective & Oct-22 \\
\hline ECRUITING & Cancer & Sintilimab & E2 & VENTI & NA | Interve & & al & Response & \\
\hline & & & & ONAL & ntion & & complete & Rate & \\
\hline & & & & & Model: & & response & (ORR), & \\
\hline & & & & & SINGLE_G & & rate ( pCR ), & ORR refers & \\
\hline & & & & & ROUP | Mas & & pCR rate is & to the & \\
\hline & & & & & king: & & the & & \\
\hline & & & & & NONE | \(\operatorname{Pri}\) & & proportion & of subjects & \\
\hline & & & & & & & of patients & & \\
\hline
\end{tabular}
\begin{tabular}{|c|c|}
\hline Purpose: & who have confirmed \\
\hline PREVENTI & no residual best \\
\hline \multirow[t]{15}{*}{ON} & viable overall \\
\hline & tumor in response of \\
\hline & the complete \\
\hline & resected response \\
\hline & specimens. (CR) or \\
\hline & partial \\
\hline & The response \\
\hline & primary (PR), based \\
\hline & aim of the on RECIST \\
\hline & study is to 1.1 DCR \\
\hline & test the refers to \\
\hline & hypothesis the \\
\hline & that after percentage \\
\hline & neoadjuva of \\
\hline & nt therapy confirmed \\
\hline
\end{tabular}
\begin{tabular}{|c|c|}
\hline 镇 宗 & complete \\
\hline atients & remission \\
\hline with & (CR), \\
\hline ctDNA & partial \\
\hline clearance & remission \\
\hline result in a & (PR), and \\
\hline higher rate & stable \\
\hline of pCR ., an & disease \\
\hline average of & (SD) cases \\
\hline 6 months. & among \\
\hline & patients \\
\hline & with \\
\hline & evaluable \\
\hline & response., \\
\hline & an average \\
\hline & of 4 \\
\hline & months. |D \\
\hline
\end{tabular}
isease
Control
Rate
(DCR),
DCR refers
to the
proportion
(\%) of
patients
with at
least one
visit
response of
complete
response
(CR) or
partial
stable
disease
(SD) based
on
RECIST1.1,
an average
of 4
months.
Major
pathologic
al response
rate
(MPR),
MPR refers
to as the

\section*{proportion}
of patients
with less
than 10\%
viable
tumour at
resection.,
after
surgery 镇
审 \(n\)
average of
6
months.|T
umor
Regression
Grade
(TRG),

\section*{TGR}
grading
using the
Becker
criteria as
follows:
TRG1a (no
residual
tumor),
equivalent
to pCR ;
TRG1b
( \(\backslash<10 \%\)
residual
tumor);
TRG2
(10\%-50\%
residual
tumor);
TRG3
( \(\backslash 550 \%\)
residual
tumor)., an
average of
6
months. |R
0 resection
rate, R0
resection
rate refers
to the
proportion
of all
patients
with
negative
margins
under the
microscop
e of tumor
specimens
after
surgery to
the total
number of
participant
s., an
average of
6
months.|T
(tumor)
and/or
N(node)
downstagi
ng rate,
T(tumor)
and/or
N (node)
downstagi
ng is
defined as
the
postoperat
ive
pathologic
al \(\quad \mathrm{T}\)
and/or N
stage
lower than
the
original
stage by
imaging
before
neoadjuva
nt
treatment.,
an average
of 6
months.|3
0 -day post-
operative
surgical
complicati
on rate,
the
Clavien-
Dindo
classificati
on, 30 days
postoperat
ion.|Disea
se-free
survival
(DFS),
Disease-
free
survival
was
defined as
from the
surgery to
disease
recurrence
or death
（for any
reason）．，
up to 2
years after
surgery．｜
Overall
Survival 锛

圤 S 锛？
Overall
survival
was
defined as
from
patient
enrollment
to death of
any cause．，
up to 2
years after
surgery．｜I
ncidence of
Treatment－
Emergent
Adverse
Events 锛
圫 afety 镇？
Safety as
measured
by number
and grade
of adverse
events.
Numbers
of
Participant
s With
Treatment-
emergent
Adverse
Events
(TEAEs)
and
Serious
Adverse
Events

\begin{tabular}{|c|c|c|c|c|}
\hline ach & Pembrolizum & NONE | Pri & [safety and & from first \\
\hline Cancer \| Sto & ab & mary & tolerability & dose of \\
\hline mach & & Purpose: & ] of HER- & study drug \\
\hline Adenocarci & & TREATME & Vaxx in & to death \\
\hline noma | Gastr & & NT & combinatio & due from \\
\hline oesophageal & & & n with & any cause., \\
\hline Junction & & & chemother & From date \\
\hline Adenocarci & & & apy or & of \\
\hline noma & & & pembroliz & enrollment \\
\hline & & & umab, & until the \\
\hline & & & Treatment- & date of \\
\hline & & & Emergent & death from \\
\hline & & & Adverse & any cause, \\
\hline & & & Events & an average \\
\hline & & & \(\backslash\) [safety & of 1 \\
\hline & & & and & year | Prog \\
\hline & & & tolerability & ression \\
\hline
\end{tabular}
\begin{tabular}{ll} 
\l will be & Free \\
graded & Survival, \\
according & Progressio \\
to CTCAE & n Free \\
v5.0, From & Survival \\
date of & (PFS) \\
enrollment & defined as \\
through & the time \\
study & from first \\
completion & dose of \\
an & study drug \\
average of & to first \\
6 & documenta \\
months \(\mid O\) & tion of \\
bjective & progressiv \\
Response & e disease \\
Rate of & (PD) based
\end{tabular}
\begin{tabular}{|c|c|}
\hline HER-Vaxx & on RECIST \\
\hline in & 1.1, or to \\
\hline combinatio & death from \\
\hline n with & any cause, \\
\hline chemother & From date \\
\hline apy or & of \\
\hline pembroliz & enrollment \\
\hline umab, & until the \\
\hline Objective & date of first \\
\hline Response & documente \\
\hline Rate (ORR) & d \\
\hline measured & progressio \\
\hline from & n or date of \\
\hline enrollment & death from \\
\hline & any cause, \\
\hline proportion & an average \\
\hline of patients & of \\
\hline
\end{tabular}
\begin{tabular}{ll} 
achieving a & months |D \\
confirmed & uration of \\
best & Response, \\
overall & Duration \\
response of & of \\
complete & Response \\
response & (DoR) \\
(CR) or & measured \\
partial & from \\
response & earliest CR \\
(PR) & or PR until \\
according & first \\
to RECIST & documenta \\
1.1, From & tion of PD \\
date of & based on \\
enrollment & RECIST 1.1 \\
until the & or death
\end{tabular}

\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|}
\hline RECRUITIN & MSI-H & DRUG: & PHAS & INTER & Allocation: & 184 & Overall & Clinical & 2021/4/12 \\
\hline \multirow[t]{16}{*}{G} & Colorectal & Spartalizuma & E2 & VENTI & NON_RAN & & Response & Benefit & \\
\hline & Cancer \| Mel & b|DRUG: & & ONAL & DOMIZED | & & rate (ORR) & Rate (CBR) & \\
\hline & anoma|Ana & Tislelizumab & & & Intervention & & (Cohort 3), & in patients & \\
\hline & 1 & & & & Model: & & Proportion & with high & \\
\hline & Carcinoma & & & & PARALLEL & & of patients & mRNA & \\
\hline & Mesothelio & & & & | Masking: & & with best & PD1 & \\
\hline & ma | Triple & & & & NONE | Pri & & overall & expressing & \\
\hline & Negative & & & & mary & & response of & tumors & \\
\hline & Breast & & & & Purpose: & & complete & (Cohort 3), & \\
\hline & Cancer 1 Lun & & & & TREATME & & response & Proportion & \\
\hline & g & & & & NT & & (CR) or & of patients & \\
\hline & Adenocarci & & & & & & partial & with a best & \\
\hline & noma | Chol & & & & & & response & overall & \\
\hline & angiocarcin & & & & & & (PR), as per & response of & \\
\hline & oma | Cervic & & & & & & local & CR, PR or & \\
\hline & al & & & & & & investigato & an overall & \\
\hline
\end{tabular}
\begin{tabular}{|c|c|c|}
\hline Carcinoma & r 麓 & lesion \\
\hline Kidney & assessment & response of \\
\hline Clear Cell & and & Stable \\
\hline Carcinoma｜ & according & Disease \\
\hline Stomach & to & （SD）or \\
\hline Adenocarci & Response & Non－ \\
\hline noma｜Esop & Evaluation & PR／Non－ \\
\hline hageal & Criteria in & progressio \\
\hline Adenocarci & Solid & n disease \\
\hline noma｜Uteri & Tumors & （PD） \\
\hline ne & （RECIST） & lasting \\
\hline Adenocarci & version 1.1 & 鈮 ？ 24 \\
\hline noma｜Head & criteria．， & weeks， \\
\hline and Neck & Until & based on \\
\hline Squamous & objective & local \\
\hline Cell & tumor & investigato \\
\hline Carcinoma & response， & r 麓 s \\
\hline
\end{tabular}
\begin{tabular}{|c|c|c|}
\hline Sarcoma \({ }^{\text {L }}\) & on average & assessment \\
\hline ung & 10 months & according \\
\hline Squamous & & to RECIST \\
\hline Cell & & v1.1., Until \\
\hline Carcinoma & & objective \\
\hline Urothelial & & tumor \\
\hline Carcinoma & & response, \\
\hline Thyroid & & on average \\
\hline Carcinoma & & 10 \\
\hline Hepatocellu & & months \(\mid \operatorname{Pr}\) \\
\hline lar & & ogression \\
\hline Carcinoma & & free \\
\hline Uveal & & survival \\
\hline Melanoma & & (PFS) in \\
\hline HER2- & & patients \\
\hline positive & & with high \\
\hline Breast & & mRNA \\
\hline
\end{tabular}
\begin{tabular}{|c|c|}
\hline Cancer \| Pan & PD1 \\
\hline creatic & expressing \\
\hline Adenocarci & tumors \\
\hline noma | Squa & (Cohort 3), \\
\hline mous & Time from \\
\hline Esophageal & allocation \\
\hline Carcinoma & to the first \\
\hline Epithelial & occurrence \\
\hline Ovarian & of disease \\
\hline Cancer \| Ute & progressio \\
\hline rine & \(n, \quad\) as \\
\hline Carcinosarc & determine \\
\hline oma |Small & d locally \\
\hline Cell Lung & by the \\
\hline Cancer \| Hor & investigato \\
\hline mone & r using \\
\hline Receptor & RECIST \\
\hline
\end{tabular}
\begin{tabular}{ll} 
Positive / & v.1.1, or \\
HER2- & death from \\
negative & any cause, \\
Breast & whichever \\
Cancer|Lun & occurs \\
g first., From \\
Adenocarci & date of \\
noma & allocation \\
EGFR- & to disease \\
mutated/ & progressio \\
ALK & n or death \\
Traslocation & from any \\
|Colorectal & cause,whic \\
Adenocarci & hever came \\
noma |Prost & first, \\
ate & assessed \\
Adenocarci & up
\end{tabular}
\begin{tabular}{|c|c|}
\hline noma | Carci & approxima \\
\hline noma of & tely 36 \\
\hline Unknown & months | D \\
\hline Primary \({ }^{\text {Ot }}\) & uration of \\
\hline her & response \\
\hline Histology & (DoR) in \\
\hline & patients \\
\hline & with high \\
\hline & mRNA \\
\hline & PD1 \\
\hline & expressing \\
\hline & tumors \\
\hline & (Cohort 3), \\
\hline & Time from \\
\hline & the first \\
\hline & occurrence \\
\hline & of a \\
\hline
\end{tabular}
documente
d objective
response to
disease
progressio
n, as
determine
d locally
by the
investigato
\(r\) through
use of
RECIST
v.1.1, or
death from
any cause,
whichever
n or death
from any
cause,whic
hever came
first,
assessed
up
to
approxima
tely 36
months \(\mid \mathrm{Ti}\)
me
to
patients
with high
mRNA
PD1
expressing
tumors
(Cohort 3),
Time from
allocation
to the first
objective
tumor
response
(tumor
shrinkage
of 鈮? \(0 \%\) )
observed
for patients
who
achieved a
CR or PR.,
Until
objective
tumor
response,
on average
10
months \(\mid \mathrm{O}\)
verall
survival
(OS) in
patients
with high
mRNA
PD1
expressing
tumors
(Cohort 3),
Time from
allocation
to death
from any
cause,
From date
of
allocation
to death
assessed
up
approxima
tely 36
months |P
FS
compared
to PFS on
prior line
of therapy
(pre-PFS)
in patients
with high
mRNA
PD1
expressing
tumors
(Cohort 3),
PFS on
study
treatment
compared to PFS on prior line of therapy (pre-PFS)., From date of
allocation
to disease
progressio
n or death
from any
cause,whic
hever came
first,
assessed
up
to
approxima
tely 36
months
RR in
patients
with low
mRNA
PD1-
expressing
tumors
(Cohorts 1
and 2),
Proportion
of patients
with best
overall
response of
complete
response
(CR) or
partial
response
(PR), as per
local
investigato
r 麓 s
assessment
and
according
to
Response
EvaluationCriteria in
Solid
Tumors
(RECIST)
version 1.1
criteria.,
Until
objective
tumor
response,
on average
10
months \(\mid \mathrm{C}\)
BR in
patients
with low
mRNA
expressing
tumors
(Cohorts 1
and 2),
Proportion
of patients
with a best
overall
response of
CR, PR or
an overall
lesion
response of
Stable
Disease
(SD)

\section*{Non-}

PR/Non-
progressio
n disease
(PD)
lasting
鈮 ? 24
weeks,
based on
local
investigato
r 麓 s
assessment
according
to RECIST
v1.1., Until
objective
tumor
response,
on average
10
months |P
FS in
patients
with low
mRNA
PD1
expressing
tumors
(Cohorts
1and 2),
Time from
allocation
to the first
occurrence
of disease
progressio
n , as
determine
d locally
by the
investigato
r using
RECIST
v.1.1, or
death from
any cause,
whichever
occurs
first., From
date of

\section*{first,}
assessed
up to
approxima
tely 36
months |D
oR in
patients
with low
mRNA
expressing
tumors
(Cohorts
1and 2),
Time from
the first
occurrence
of
a
documente
d objective
response to
disease
progressio
n , as
determine
d locally
investigato
\(r\) through
use of
RECIST
v.1.1, or
death from
any cause,
whichever
occurs
first, From
date of
allocation
to disease
progressio
n or death
from any
cause, whic
hever came
first,
assessed
up to
approxima
tely 36
months |Tt
R in
patients
with low
mRNA
PD1
expressing
tumors
(Cohorts 1
and 2),

Time from
allocation
to the first
objective
tumor
response
(tumor
shrinkage
of 鈮 ? \(0 \%\) )
observed
for patients
who
achieved a
CR or PR.,
Until
objective
tumor
response,
on average
10
months \(\mid \mathrm{O}\)
\(S\) in
patients
with low
mRNA
PD1
expressing
tumors
(Cohorts 1
and 2),
Time from
allocation
to death
from any
cause,
From date
of
allocation
to death
assessed
up to
approxima
tely 36
months | P
FS
compared
to PFS on
prior line
of therapy
(pre-PFS)
in patients
with low
mRNA
PD1
expressing
tumors
(Cohorts 1
and 2), PFS
on study
treatment
compared
to PFS on
prior line
of therapy
(pre-PFS).,
From date
of
allocation
to disease
progressio
n or death
from any
cause,whic
hever came
first,
assessed
up
to
approxima
tely 36
months | In
cidence,
seriousnes
s,
treatment-
related and
intensity of
Treatment
Emergent
Adverse
Events,
Incidence,
seriousnes
s,
treatment-
related and
intensity of
Treatment
Emergent
Adverse
Events
(TEAEs)
assessed
by the NCI
Common
Terminolo
gy for
Classificati
on
of
Adverse
Events
(CTCAE)
version 5,
including
dose
reductions,
delays and
treatment
discontinu
ations.,

During the
whole
treatment
period
(from
baseline
until
patients'
final
treatment
which is
defined as
the end of
the
Treatment
Phase of
the study,
\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|}
\hline & & & & & & & & an average & \\
\hline & & & & & & & & of 10 & \\
\hline & & & & & & & & months & \\
\hline RECRUITIN & Solid & BIOLOGICA & PHAS & INTER & Allocation: & 22 & Safety of & Overall & 2021/8/1 \\
\hline G & Tumor \| Bre & L: RAPA-201 & E1|PH & VENTI & NA | Interve & & RAPA-201 & Response & \\
\hline & ast & Rapamycin & ASE2 & ONAL & ntion & & Cell & Rate, To & \\
\hline & Cancer Sm \(^{\text {S }}\) & Resistant T & & & Model: & & Therapy, & determine & \\
\hline & all Cell and & Cells |DRUG: & & & SINGLE_G & & To & the overall & \\
\hline & Non-small & Chemotherap & & & ROUP | Mas & & determine & RECISTv1. & \\
\hline & Cell Lung & \(y\) Prior to & & & king: & & the safety & 1 criteria & \\
\hline & Cancer \| Tri & RAPA-201 & & & NONE | Pri & & of RAPA- & response & \\
\hline & ple Negative & Therapy & & & mary & & 201 cell & rate & \\
\hline & Breast & & & & Purpose: & & therapy & (partial & \\
\hline & Cancer \| Gas & & & & TREATME & & when used & response & \\
\hline & tric & & & & NT & & & or better) & \\
\hline & Cancer | Eso & & & & & & combinatio & of & \\
\hline & phageal & & & & & & n with a & autologous & \\
\hline
\end{tabular}
\begin{tabular}{|c|c|c|}
\hline Adenocarci & carboplati & RAPA-201 \\
\hline noma | Gastr & n plus & cells and \\
\hline ic Junction & paclitaxel & standard- \\
\hline Adenocarci & (CP) & of-care \\
\hline noma|Esop & standard- & chemother \\
\hline hageal & of-care & apy \\
\hline Squamous & chemother & (carboplati \\
\hline Cell & apy & n \\
\hline Carcinoma & regimen. & paclitaxel) \\
\hline Head and & Specificall & in patients \\
\hline Neck & y , the & with solid \\
\hline Cancer \({ }^{\text {Squ }}\) & treatment & tumors \\
\hline amous Cell & will be & resistant to \\
\hline Carcinoma & determine & PD-(L)1., \\
\hline of Oral & d to be safe & One (1) \\
\hline Cavity \| Squ & & year after \\
\hline amous Cell & following & the last \\
\hline
\end{tabular}

\section*{Carcinoma}
of
Larynx|Squ
amous Cell
Carcinoma
of
Nasopharyn
\(x \mid\) Squamou
s Cell
Carcinoma
of Other
Specified
Sites of
Skin | Carcin
oma of
Unknown
Primary | Bl
```

parameters dose of
are met: RAPA-201
(Metric \#1) cells.|Prog
using the ression
metric of Free
"unresolve Survival
d grade 3 (PFS) and
toxicity Overall
attributabl Survival
e to the (OS), To
RAPA-201 characteriz
cell e the effect
therapy": of therapy
for positive on solid
determinat tumor
ion of disease
safety, this control, as

```
adder
Cancer | Mal
ignant
Melanoma
\begin{tabular}{lll} 
metric & measured \\
must occur & by \\
in 3 or & progressio \\
fewer & n & free \\
patients & survival \\
out of the & (PFS) and \\
initial 10 & overall \\
patients; & survival \\
(Metric \#2) & (OS)., One \\
using the & (1) year \\
metric of & after the \\
"grade 4 & last dose of \\
non- & RAPA-201 \\
hematologi & cells. \(\mid\) Qual \\
c toxicity & ity of & Life
\end{tabular}
```

attributabl effect of
e to RAPA- therapy on
201 cell quality of
therapy": life (QOL)
for positive using the
determinat Short
ion of Form-36
safety, this Survey.,
metric One (1)
must occur year after
in 1 or the last
fewer dose of
patients RAPA-201
out of the cells.
initial 10
patients;
and

```
(Metric \#3)
using the
metric of
"grade 5
toxicity
that is
probably
attributabl
e to RAPA-
201 cell
therapy":
for positive
determinat
ion of
safety, this
metric
must occur
in 1 or few
patients
out of the
initial 10
patients.,
Completio
n of RAPA-
201
Therapy as
Defined by
the End-of-
Treatment
Visit,
which
occurs on
average at
6-months

\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|}
\hline \begin{tabular}{l}
TERMINATE \\
D
\end{tabular} & Advanced
or & \begin{tabular}{l}
DRUG: \\
NC410
\end{tabular} & \begin{tabular}{l}
PHAS \\
E1|PH
\end{tabular} & \begin{tabular}{l}
INTER \\
VENTI
\end{tabular} & \begin{tabular}{l}
Allocation: \\
NA | Interve
\end{tabular} & 46 & Number of participant & \begin{tabular}{l}
Objective \\
Response
\end{tabular} & 2020/6/10 \\
\hline & Metastatic & & ASE2 & ONAL & ntion & & s with & Rate per & \\
\hline & Solid & & & & Model: & & treatment- & RECIST, & \\
\hline & Tumors \({ }^{\text {Ov }}\) & & & & SINGLE_G & & emergent & Objective & \\
\hline & arian & & & & ROUP | Mas & & adverse & response & \\
\hline & Cancer \| Gas & & & & king: & & events as & rate (ORR) & \\
\hline & tric & & & & NONE | Pri & & assessed & per & \\
\hline & Cancer \(/ \mathrm{Col}\) & & & & mary & & by CTCAE & Response & \\
\hline & o-rectal & & & & Purpose: & & v5.0, & Evaluation & \\
\hline & Cancer & & & & TREATME & & Frequency, & Criteria in & \\
\hline & & & & & NT & & duration, & Solid & \\
\hline & & & & & & & and & Tumors & \\
\hline & & & & & & & severity of & (RECIST) & \\
\hline & & & & & & & treatment- & v1.1 and & \\
\hline & & & & & & & emergent & modified & \\
\hline & & & & & & & adverse & RECIST & \\
\hline
\end{tabular}
\begin{tabular}{lll} 
events & & (mRECIST \\
(AEs), & up & ) v1.1, 14 \\
to & 14 & months |D \\
months & D & uration of \\
efine & a & Response \\
maximum & per \\
tolerated & RECIST, \\
dose & Duration \\
(MTD) or & of \\
pharmacol & Response \\
ogically & (DoR) per \\
active dose & Response \\
(PAD), A 3 & Evaluation \\
+3 design & Criteria in \\
will & be & Solid \\
utilized & to & Tumors \\
determine & (RECIST)
\end{tabular}
\begin{tabular}{ll} 
the MTD of & v1.1 and \\
NC410, 28 & modified \\
days & RECIST \\
& (mRECIST \\
& months |D \\
& isease \\
& Control \\
& Rate per \\
& RECIST, \\
& Disease \\
& Control \\
& Rate (DCR) \\
& per \\
& Response \\
& Evaluation \\
& Criteria in
\end{tabular}
Solid
Tumors
(RECIST)
v1.1 and
modified
RECIST
(mRECIST
) v1.1, 14
months |M
aximum
Plasma
Concentrat
ion (Cmax)
of NC410,
To
evaluate
the

Plasma

\section*{Concentrat}
ion (Cmax)
of NC410,
14 weeks```

