Korea University Medical Center Ansan Hospital
Institutional Review Board

Tel : 82-31-412-6514 / Fax : 82-31-412-4225

123, jeokgeum-ro, Danwon-gu, Ansan-si, Gyeonggi-do, 425-707, KOREA

Certificate Of Approval

BOARD ACTION DATED : 23 Aug, 2011

IRB File NO. : AS11102-001

INVESTIGATOR : Professor Hyung Joon Yim, M.D., Ph.D

SPONSOR : Not Applicable

PROTOCOL NO. : Not Applicable

TITLE : Management of entecavir-resistant chronic hepatitis B with adefovir-based combination therapies

APPROVAL INCLUDES : Study protocol, Case report form, Waiver of Informed consent, Curriculum vitae, etc.

ALL CONDITIONS OF APPROVAL PREVIOUSLY ESTABLISHED BY KUMCASH IRB FOR THIS RESEARCH PROJECT CONTINUE TO APPLY.

CONTINUING REVIEW RFPORT INTERVAL : 12month

IF YOU HAVE ANY QUSTIONS, CONTACT KUMCASH IRB (Tel : 82-31-412-6514)

This is to certify that the information contained herein is true and correct as reflected in the records of the Korea University Medical Center Ansan Hospital Institutional Review Board. **We certify that KUMCASH IRB is in full compliance with Good Clinical Practice as defined under the Korea Food and Drug Administration (KFDA) regulations and the International Conference on Harmonisation (ICH) guidelines.**

Nak Woo Lee

Chairperson

2015. Jan. 30.

Date

ALL KUMC ASH IRB APPROVED INVESTIGATORS MUST COMPLY WITH THE FOLLOWING

1. Conduct the research as required by the protocol.
2. Provide non-Korean speaking subjects with a certified translation of the approved Consent Form in the subject's first language. The translated version must be approved by the KUMCASH IRB.
3. Obtain pre-approval from the KUMCASH IRB of any changes in the research activity (except when necessary to protect human subjects; immediately report to the KUMCASH IRB any such emergency changes for the protection of human subjects).
4. Report to the KUMCASH IRB the death, hospitalization, or serious illness of any study subject.
5. Promptly report to the KUMCASH IRB any new information that may adversely affect the safety of the subjects or the conduct of the trial.
6. Provide reports to the KUMCASH IRB concerning the progress of the research, when requested.
7. Obtain pre-approval of study advertisements from the KUMC ASH IRB before use.
8. Conduct the informed consent process without coercion or undue influence, and provide the potential subject sufficient opportunity to consider whether or not to participate.

Korea FDA regulations require that the KUMC ASH IRB conduct review of approved research. You will receive Continuing Review Report forms from the KUMC IRB. These reports must be returned even though your study may not have started.

SPONSOR :
CRO :
OTHER :
INSTITUTION :

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