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ASIA EDITION

# Taiwan FDA nods Ph II trial of Hep C drug

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**Taiwan FDA nods Ph II trial of Hep C drug**

**Singapore:** China based Ascletis has received Taiwan Food and Drug Administration (TFDA) approval to start phase II clinical trial for its all-oral interferon (IFN)-free regimen to treat chronic hepatitis C (CHC).

The regimen contains Ascletis' two direct-acting antiviral agents (DAA), the NS3/4A protease inhibitor ASC08 and the NS5A inhibitor ASC16 and the trial will be conducted at 6 major hospitals in Taiwan starting in September 2015, led by principal investigator Prof Jia-Hoang Kao, director, Clinical Research Institute, Taiwan University.

The phase II study, named EVEREST, is designed to evaluate the antiviral activity, safety and pharmacokinetics of the regimen.

"Due to the long treatment duration, significant adverse effects and various kinds of contraindications, many patients cannot tolerate treatment with interferon," said Professor Zhuang Hui, academician, Chinese Engineering Academy and the honorary Chairman of the Chinese Society of Hepatology, at Peking University Health Science Center, "Ascletis is the first domestic company in China to conduct clinical trials of an all-oral IFN-free HCV regimen. This is exciting news for all Chinese HCV patients. We hope the data to be generated in the EVEREST study can accelerate the approval process in mainland China and Taiwan, as new treatment options are urgently needed to reduce HCV prevalence in China."

"Therapies based on DAAs have predominated the CHC markets in the developed countries; however, there are no DAAs approved in China yet and the combination of PEG-interferon-alpha and ribavirin is still widely used as the Standard of Care (SoC)," said Dr Jinzi J. Wu, founder, president and CEO, Ascletis.

Ascletis also filed earlier this year the clinical trial application for the same IFN-free regimen with China Food and Drug Administration (CFDA). With the successful phase II study of its triple therapy at the beginning of 2015, Ascletis aims to bring both triple and IFN-free therapies to the marketplace to meet different clinical needs of Chinese patients.