Ascletis Publishes Interim Data of Phase II Study in Taiwan For Its Interferon-Free HCV Regimen

Company initiated clinical trials in Mainland China for the same regimen

Hangzhou & Shaoxing, China (June 21, 2016)—Ascletis announced today it published on June 12 an interim report of EVEREST study at the oral session of the 5th Asian Pacific Association for the Study of the Liver Single Topic Conference on HCV held in Taiwan (2016 APASL STC on HCV in Kaohsiung). EVEREST study is a phase II clinical trial designed to evaluate the safety and efficacy of the interferon (IFN)-free regimen in treatment-naive Chinese HCV Genotype 1 non-cirrhotic patients conducted in Taiwan. The interim report showed that after 12-week IFN-free treatment, virological response rate (EOT) was 100%.

The company also announced today it has initiated clinical trials for the same IFN-free regimen in Mainland China.

The IFN-free regimen contains Ascletis' two direct-acting antiviral agents (DAAs), ASC08 (danoprevir), an NS3/4A protease inhibitor and ASC16 (ravidasvir), an NS5A inhibitor. Ascletis' IFN-free regimen received the priority review from China Food and Drug Administration (CFDA) in April, 2016.

"Many HCV patients are intolerated or ineligible to IFN-based therapies," said Professor Wei Lai, MD, former Chairman of the Chinese Society of Hepatology and Director of Institute of Hepatology at Peking University. "I'm very excited that Ascletis brings an all-oral IFN-free regimen for our patients in China. From the EVEREST study data published at 2016 APASL STC on HCV in Kaohsiung, we have now evidence that Ascletis' all-oral-IFN-free regimen is safe and effective for the Chinese HCV GT1 patients. I believe that we will continue getting good news in our upcoming clinical studies conducted in Mainland China."

"I'm very glad that we received the priority review from CFDA and positive phase 2 data for our IFN-free regimen," said Jinzi Wu, Ph.D., Ascletis' founder, President and CEO. "Ascletis is taking both triple and IFN-free regimens to marketplace and providing quality and affordable treatment for Chinese HCV patients."

About Ascletis

Ascletis is an innovative biotechnology company, dedicated to discovering, creating and commercializing important new treatments for infectious diseases and cancer. Ascletis is focused on clinical development of innovative medicines and commercialization for the growing Chinese pharmaceutical marketplace. Ascletis has assembled an entrepreneurial management and senior scientific team with a track record of successful pharmaceutical discovery and development at major global pharmaceutical and emerging biotechnology companies in the United States and Europe. To date the company has added four late-stage candidates to its product portfolio: ASC08, a clinical stage HCV protease inhibitor licensed from Roche; ASC16, a clinical stage HCV NS5A inhibitor licensed from Presidio Pharmaceuticals; ASC06, a clinical stage, first-in-class, systemically delivered RNAi therapeutic for the treatment of liver cancers licensed from Alnylam Pharmaceuticals; and ASC09, a next-generation HIV protease inhibitor licensed from Janssen, a Johnson & Johnson company. For more information, please visit www.ascletis.com.

About EVEREST:

EVEREST study conducted in Taiwan is a phase II study designed to evaluate the safety and efficacy of the IFN-free regimen containing ASC08 and ASC16 in treatment-naive Chinese HCV Genotype 1 non-cirrhotic Chinese patients. A total of 38 patients in Taiwan were enrolled. The primary endpoint is SVR12. The interim data showed that after 12-week IFN-free treatment, virological response rate (EOT) was 100% (38/38). SVR12 data are expected in September this year.

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