ASC40 (TVB-2640) Phase 2 NASH Trial Completed Patient Enrollment in China

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Shanghai, China and San Francisco, California, United States, November 19，2020 – Gannex Pharma Co., Ltd., a wholly owned company of Ascletis Pharma Inc. (HKEX:1672) and Sagimet Biosciences Inc. jointly announced today that they have completed patient enrollment in the ASC40 (TVB-2640) Phase 2 NASH trial in China. The trial in China with 30 patients enrolled is part of the global Phase 2 clinical program.

On June 17, Sagimet Biosciences Inc., announced positive results on oral, once-daily dosing of NASH drug candidate ASC40 (TVB-2640) from its Phase 2 (FASCINATE-1) clinical trial in the United States. The preliminary data showed that ASC40 (TVB-2640) significantly reduced liver fat, the primary efficacy endpoint of this trial, with a 61% responder rate in the 50 mg group. Participants also showed improvement in markers of liver function and fibrosis. In this randomized, placebo-controlled trial of 99 patients in the United States, clinicians evaluated the safety and efficacy of ASC40 (TVB-2640) for 12 weeks. ASC40 (TVB-2640) was well-tolerated with a benign adverse event profile, predominantly grade 1 adverse events and no on-treatment serious adverse events.

“This is the first Phase 2 NASH trial that has completed patient enrollment in mainland China, which enables the completion of 12 week treatment of all patients in February 2021,” said Dr. Junping Shi, Deputy Dean of the Affiliated Hospital of Hangzhou Normal University, Deputy Leader of the Fatty Liver and Alcoholic Hepatology Group of the Chinese Medical Association Hepatology Branch, principal investigator of ASC40 (TVB-2640) Phase 2 trial in China.” We are excited by results from the Phase 2 NASH trial in the United States. Based upon the data from the bridging study in China, I believe the efficacy of ASC40 (TVB-2640) in Chinese patients will be similarly potent.”

“Additional data from U.S. patients were recently presented by Dr. Rohit Loomba at The Liver Meeting of American Association for the Study of Liver Diseases (AASLD) that confirm the potential benefit of TVB-2640 to NASH patients. We are excited to move forward with our planned Phase 2b biopsy trial, as well as work with our partner Gannex to understand better dosing of TVB-2640 in Chinese patients,” said George Kemble, CEO of Sagimet.

“We are pleased that we completed the patient enrollment ahead of the schedule and want to thank all patients and doctors. I look forward to the completion of this Phase 2 NASH trial in China,” said Dr. Jinzi J. Wu, Founder, Chairman and CEO of Ascletis.

About TVB-2640
TVB-2640 is an orally bioavailable, first-in-class FASN inhibitor. FASN is a key enzyme in the de novo lipogenesis (DNL) pathway that is responsible for the synthesis of excess fat and activation of fibrogenic and inflammatory mechanisms in the liver of patients with NASH. Sagimet’s approach targets these key drivers of NASH. The company announced in June 2020 initial results of a randomized, placebo-controlled Phase 2 trial, FASCINATE-1, which evaluated the impact of TVB-2640 in 99 NASH patients in the United States. Sagimet and its partner, Gannex Pharma Co., Ltd., have completed the enrollment of 30 NASH patients in China. Based upon the strength of this Phase 2 imaging and biomarker data, Sagimet expects to initiate a Phase 2b biopsy trial in 1H 2021. The company has demonstrated in preclinical models that blocking FASN not only reduces liver fat, but directly reduces fibrosis and inflammation– addressing three major drivers of NASH.

About Sagimet
Sagimet Biosciences is a clinical-stage biopharmaceutical company focused on developing novel therapeutics to treat important diseases such as the liver disease NASH and specific cancers, with focus on targeting dysfunctional metabolic pathways. The company has unique expertise in FASN biology and has created a pipeline of proprietary FASN inhibitors. For more information, please visit www.sagimet.com.

About Ascletis
Ascletis is an innovative R&D driven biotech and listed on Hong Kong Stock Exchange (Ascletis, 1672.HK). Ascletis is committed to developing and commercializing innovative drugs of viral hepatitis, NASH and HIV/AIDS, for unmet medical needs in China and globally. Led by a management team with deep expertise and a proven track record, Ascletis has developed into a fully integrated platform covering the entire value chain from discovery and development to manufacturing and commercialization. Ascletis has three marketed products and thirteen R&D pipeline drug candidates or combination therapies (nine of them developed in house). 1. Viral hepatitis: (i) marketed all oral HCV regimen of Asclevir® and Ganovo® combination (RDV/DNV regimen) and ASC18 fixed dose combination (FDC), with bridging study finished, is an upgraded version of RDV/DNV regimen. ASC18FDC will further enhance the competitiveness of Ascletis ‘ hepatitis C products. (ii) marketed Pegasys ® for HBV clinical cure; (iii) breakthrough therapies for HBV clinical cure. 2. NASH: global development of novel drug candidates against three different targets – FASN, THR-beta and FXR, and three combination therapies. NASH is a global disease, Ascletis conducts global clinical research in Europe, America and China. 3. HIV/AIDS: ASC09F is a FDC treatment of HIV targeting protease. The clinical trial application of ASC09F has been approved. For more information, please visit www.ascletis.com.

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