FASN Inhibitor ASC40 Demonstrates Positive Phase 2 Topline Clinical Results from China Cohort of Patients with NASH

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- Oral FASN inhibitor ASC40 shown to meaningfully reduce liver fat with a 50% responder rate

- Consistent improvement in biomarkers of liver inflammation as observed in U.S. cohort

SHANGHAI, China and SAN MATEO, Calif., March 8, 2021 /PRNewswire/ -- Gannex Pharma Co., Ltd., a wholly-owned company of Ascletis Pharma Inc. (HKEX: 1672), and Sagimet Biosciences Inc. jointly announced today positive topline results from the China cohort of a Phase 2 randomized, placebo-controlled clinical trial of oral, once-daily fatty acid synthase (FASN) inhibitor ASC40 (known as TVB-2640 outside of China) that is being evaluated as a potential treatment for nonalcoholic steatohepatitis (NASH). The preliminary data showed that ASC40 meaningfully reduced liver fat, the primary efficacy endpoint of this trial, with a 50% responder rate (patients achieving ≥30% reduction). Participants also showed robust improvement in ALT, a liver enzyme associated with inflammation. These data from the China cohort are consistent with those of the US cohort, previously reported at the AASLD Liver Meeting in November 2020.

"I am pleased that the first Phase 2 NASH trial in mainland China has been completed on schedule and resulted in positive data," 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. "Based on the positive Phase 2 data, we have selected doses for the Phase 2b/3 NASH trial in China."

The China cohort of this Phase 2 trial evaluated the safety and efficacy of an oral, once-daily dosing of 50 mg of ASC40 or matching placebo for 12 weeks in 30 patients with NASH. Trial participants were required to have at least 8% liver fat at baseline, as measured by magnetic resonance imaging-proton density fat fraction (MRI-PDFF), and evidence of stage F1 to F3 liver fibrosis on liver biopsy or characteristics of metabolic syndrome. The study demonstrated a relative reduction in liver fat of 28.2% in the ASC40 group versus a reduction of 11.1% in the placebo group. ASC40 also showed a statistically significant decrease in ALT by 29.8% (p=0.0499) (mean decrease of 33 U/L at week 12), which indicates reduction of liver inflammation. In 63% of patients on ASC40 ALT decreased by17 U/L or greater, which has been shown to correlate with liver biopsy response in NASH patients.

ASC40 was well tolerated with no serious adverse events. All treatment emergent adverse events were grade 1 or 2 and there were no statistically significant changes in serum triglycerides.

"The completion of the ASC40 Phase 2 NASH trial in China demonstrates execution excellence by Gannex and its partner Sagimet," said Dr. Jinzi J. Wu, Founder, Chairman and CEO of Ascletis. "It has given us valuable experience and knowledge for Gannex to move forward with all of our NASH clinical programs."

About ASC40

ASC40 (known as TVB-2640 outside of China) is an orally bioavailable, potentially 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. ASC40 targets these key drivers of NASH. Sagimet 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 patients with NASH in the United States. Sagimet 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 Ascletis

Ascletis is an innovative R&D driven biotech with two commercial products and listed on Hong Kong Stock Exchange (Ascletis, 1672.HK). Ascletis is committed to developing and commercializing antiviral, steatohepatitis, and tumor-related innovative drugs 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' pipeline is focused primarily on three therapeutic areas: 1. HCV: one commercial stage product, one near commercial stage drug and two R&D stage drug candidates. Ganovo® (Danoprevir) is the first direct-acting anti-viral agent for hepatitis C, developed by a domestic firm in China. 2. HBV: one commercial stage product and three R&D stage drug candidates. Pegasys® (Peginterferon alfa-2a) is a leading marketed pegylated interferon for hepatitis B&C partnered with Roche. 3. NASH (Non-Alcoholic SteatoHepatitis): three R&D stage drug candidates against three different targets for combination treatments. For more information, please visit www.ascletis.com.

About Sagimet Biosciences

Sagimet is a clinical-stage biopharmaceutical company focused on developing a portfolio of internally-discovered, selective fatty acid synthase (FASN) inhibitors for the treatment of several diseases that result from the overproduction of the fatty acid palmitate. Based on its clinical and preclinical data, Sagimet believes that its wholly-owned pipeline of oral FASN inhibitors has the potential to offer effective treatments for indications in several therapeutic areas of high unmet medical need including liver diseases and cancers. TVB-2640, an oral, once-daily pill, is Sagimet's lead drug candidate that was selected from more than 1,200 compounds in its library of FASN inhibitors and has been studied in over 260 subjects, including healthy volunteers and patients with non-alcoholic steatohepatitis (NASH) or cancer. For more information, please visit www.sagimet.com.

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