3-V Biosciences Commences Dosing in Phase 2 Clinical Study of the FASN Inhibitor TVB-2640 in Patients with NASH

04/30/2019 at 4:00 PM EDT

San Mateo, California, United States, and Hangzhou and Shaoxing, China, 30 April 2019 – 3-V Biosciences, Inc. (3-V Biosciences) and Ascletis Pharma Inc. (Ascletis, 1672.HK) announced today that 3-V Biosciences has recently dosed its first patient in a Phase 2 clinical trial of the FASN (fatty acid synthase) inhibitor TVB-2640 (Ascletis code: ASC40) in patients with non-alcoholic steatohepatitis (NASH).

According to Rohit Loomba, MD, University of California San Diego, Director, NAFLD Research Center, and Coordinating Investigator of the now enrolling Phase 2 study of TVB-2640, “Lipid synthesis is an important driver of NASH. The imaging techniques in this study will give us a very clear understanding of the impact this drug has on liver fat, a key driver of this disease.”

In this randomized, placebo-controlled study, investigators will evaluate the impact of TVB-2640 in about 90 NASH patients in the United States and about 25-30 NASH patients in China. Study participants will have at least 8% liver fat at baseline, as measured by magnetic resonance imaging-estimated proton density fat fraction (MRI-PDFF), and evidence of stage F1 to F3 fibrosis. The primary endpoint is the impact of TVB-2640 on liver fat reduction, compared to baseline, following 12 weeks of daily, continuous dosing. Investigators will also evaluate TVB-2640’s impact on levels of plasma triglycerides, liver enzymes, inflammatory and fibrotic biomarkers.

In February 2019, 3-V Biosciences and Ascletis entered into an exclusive license agreement, under which 3-V Biosciences granted Ascletis an exclusive license to develop, manufacture and commercialize TVB-2640 (Ascletis code: ASC40) and related compounds in Greater China. In connection with this Phase 2 trial, Ascletis is working with 3-V Biosciences in China on regulatory submissions, clinical site selection, and trial monitoring.

“The initiation of our Phase 2 clinical trial is a very important advance for TVB-2640 and for 3-V Biosciences. We are very encouraged by the data from the Phase 1 studies and this next step is critical in determining the impact TVB-2640 may have in the treatment of NASH patients,” said William McCulloch, MB, ChB, FRCP, FFPM, Chief Medical Officer of 3-V Biosciences.

“We are excited about the first patient dosed in this Phase 2 trial and working with 3-V Biosciences in China to move this first-in-class drug candidate forward,” said Jinzi J. Wu, PhD, Founder, Chairman and CEO of Ascletis.

About TVB-2640 (ASC40)

TVB-2640 is an orally bioavailable, first-in-class inhibitor of FASN. FASN is a key enzyme in the de novo lipogenesis (DNL) pathway that is responsible for the synthesis of excess fat in the liver of patients with NASH. 3-V’s approach targets this key driver of NASH. The company demonstrated in a Phase 1 trial that TVB-2640 inhibited liver fat synthesis in subjects with characteristics of metabolic syndrome. The 3-V team believes these data provide clinical proof-of-mechanism for TVB-2640. Dysregulation of FASN activity is also found in several other diseases, including certain cancers where cells become dependent upon DNL.

About 3-V Biosciences

3V-Biosciences is a clinical-stage biopharmaceutical company focused on developing novel therapeutics for the treatment of a range of diseases including the liver disease NASH and certain cancers, with focus on targeting dysfunctional metabolic pathways. 3-V Biosciences has unique expertise in FASN biology and believes that targeting FASN provides an intervention point for clinical benefit. For more information, please visit www.3vbio.com.

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’ mission is to address unmet medical needs in three therapeutic areas: viral, cancer and fatty liver diseases. Led by a management team with deep expertise and a proven track record, Ascletis has developed a fully integrated platform covering the entire value chain from discovery and development to manufacturing and commercialization. Ascletis is now commercializing two drugs, Ganovo® (danoprevir), the first direct-acting anti-viral agent for hepatitis C developed domestically for China, and Pegasys® (peginterferon alfa-2a), a well-established pegylated interferon for hepatitis B&C partnered with Roche. Ascletis’ R&D pipeline consists of antibody-based immunotherapy, first/best-in-class small molecules and siRNA at various clinical development stages. For more information, please visit www.ascletis.com.

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