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ASIA EDITION

Ascletis receives IND approval for its NASH drug

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ASC40 is an orally bioavailable, first-in-class inhibitor of fatty acid synthase (FASN)

Ascletis Pharma Inc., an innovative R&D driven, commercial-stage biotechnology company addressing unmet medical needs in therapeutic areas including anti-viral, cancer and fatty liver diseases, on 27 August 2019, announces that together with Sagimet Biosciences (formerly 3-V Biosciences, Inc), it received, through its subsidiary, IND approval from National Medical Products Administration (NMPA) for its non-alcoholic steatohepatitis (NASH) drug candidate ASC40 (Sagimet Biosciences code: TVB-2640).

ASC40 (TVB-2640), an orally bioavailable, first-in-class inhibitor of fatty acid synthase (FASN), is currently in a global Phase 2 trial in NASH of which the first patient was dosed in late April 2019 in the USA.

In this randomized, placebo-controlled global Phase 2 trial, investigators are evaluating the impact of ASC40 (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 ASC40 (TVB-2640) on liver fat reduction, compared to baseline, following 12 weeks of daily, continuous dosing. Investigators will also evaluate ASC40 (TVB-2640)'s impact on levels of plasma triglycerides, liver enzymes, inflammatory and fibrotic biomarkers.

"We are excited by IND approval of ASC40 (TVB-2640) from NMPA for the global multi-centre trial," said Jinzi J. Wu, PhD, Founder, Chairman and CEO of Ascletis, "Sagimet and Ascletis teams are working hand-in-hand to accelerate the advancement of ASC40 (TVB-2640) on a global scale."