# Ascletis Pharma Inc.
# 歌禮製藥有限公司

*(incorporated in the Cayman Islands with limited liability)*

**(Stock Code: 1672)**

## VOLUNTARY ANNOUNCEMENT

## ASC40 (TVB2640) SIGNIFICANTLY REDUCED LIVER FAT WITH A 61% RESPONDER RATE IN PHASE 2 NASH TRIAL

The board of directors (the "**Board**") of Ascletis Pharma Inc. (the "**Company**") is pleased to announce that one of the business partners of the Company, Sagimet Biosciences Inc. ("**Sagimet**"), announced today positive results on oral, once-daily non-alcoholic steatohepatitis (NASH) drug candidate TVB-2640 (Company code: ASC40) from its Phase 2 (FASCINATE-1) clinical trial. The preliminary data shows that TVB-2640 significantly reduced liver fat, the primary efficacy endpoint of this trial, with a 61% responder rate in the 50mg group. Participants also showed improvement in markers of liver function and fibrosis. The Company, through one of its subsidiaries, has an exclusive license to develop, manufacture and commercialize ASC40 (TVB-2640) and related compounds in Greater China. In conjunction with the exclusive license agreement, Sagimet raised US$25 million in its Series E financing led by the Company (through one of its subsidiaries) and certain new and existing investors.

In the Phase 2 (FASCINATE-1) randomized, placebo-controlled trial of 99 NASH patients in the United States, clinicians evaluated the safety and efficacy of oral, once-daily dosing of TVB-2640 for 12 weeks. Study participants were required to 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 liver fibrosis. The study demonstrated a statistically significant dose-dependent, relative reduction in liver fat of 28.2% in the 50 mg group versus an increase of 4.5% in the placebo group. TVB-2640 also significantly decreased ALT by up to 20.4% and LDL-cholesterol by up to 7.6% at week 12. These decreases indicate improved liver function and metabolic health.

| | **TVB-2640 50 mg (n=28)** | **TVB-2640 25 mg (n=30)** | **Placebo (n=27)** |
|---|---|---|---|
| **Mean relative change in liver fat**<br>***P-value vs placebo*** | -28.2%<br>*p=0.0011* | -9.6%<br>*p=0.0535* | +4.5% |
| **Patients achieving ≥30% reduction in liver fat (responder rate)**<br>***P-value vs placebo*** | 60.7%<br><br>*p=0.0008* | 23.3%<br><br>*p=0.2281* | 11.1% |

TVB-2640 was well-tolerated with a benign adverse event profile, predominantly grade 1 events and no on-treatment serious adverse events.

An additional 50 mg cohort of 25-30 NASH patients in China has started screening.

The Company has two additional drug candidates, developed in house, in its NASH pipeline. ASC41 is a highly potent and selective agonist for thyroid hormone receptor beta (THR-beta) and received IND approval from China's NMPA. ASC42 is a pre-IND NASH candidate against a different target. These three NASH candidates can be used alone or in combination.

**Cautionary Statement required by Rule 18A.05 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited:** We cannot guarantee that we will be able to market, ASC40 successfully.

By order of the Board
**Ascletis Pharma Inc.**
**歌禮製藥有限公司**
**Jinzi Jason WU**
*Chairman*

Hangzhou, the People's Republic of China
June 17, 2020

*As at the date of this announcement, the Board of Directors of the Company comprises Dr. Jinzi Jason WU and Mrs. Judy Hejingdao WU, as executive Directors; Dr. Ru Rong JI, Dr. Yizhen WEI, Mr. Jiong GU and Ms. Lin HUA, as independent non-executive Directors.*