Ascletis Pharma Inc.
歌禮製藥有限公司
(incorporated in the Cayman Islands with limited liability)
(Stock Code: 1672)

VOLUNTARY ANNOUNCEMENT

ASCLETIS' STRATEGIC PARTNER SAGIMET BIOSCIENCES ANNOUNCES POSITIVE INTERIM PHASE 2B CLINICAL TRIAL DATA WITH ASC40 (DENIFANSTAT), A FIRST-IN-CLASS FATTY ACID SYNTHASE INHIBITOR, IN MODERATE-TO-SEVERE NON-ALCOHOLIC STEATOHEPATITIS (NASH) PATIENTS

– *ASC40 (Denifanstat) showed statistically significant improvements across key disease markers in FASCINATE-2 study after 26 weeks of treatment*

– *Highlights to be included in oral presentation session at The Liver Meeting on Sunday, November 6, 2022 at 2 pm EST*

This announcement is made by Ascletis Pharma Inc. (the "**Company**" or "**Ascletis**", together with its subsidiaries, the "**Group**") on a voluntary basis for the purpose of keeping the shareholders of the Company and potential investors abreast of the latest business development of the Group.

The board of directors (the "**Board**") of the Company announces that Ascletis' strategic partner Sagimet Biosciences Inc. ("**Sagimet Biosciences**") announced positive interim data from its Phase 2b clinical trial (FASCINATE-2) with ASC40 (Denifanstat), a fatty acid synthase (FASN) inhibitor, in non-alcoholic steatohepatitis (NASH) patients. Data showed statistically significant improvements across key markers of NASH, reinforcing results observed in earlier studies, including statistically significant reductions in markers of liver fat, inflammation and fibrosis.

Dr. Stephen Harrison, visiting professor, University of Oxford, and medical director of Pinnacle Research Center, will include interim data highlights in an oral presentation at The Liver Meeting of the American Association for the Study of Liver Diseases (AASLD), being held from November 4, 2022 to November 8, 2022 in Washington, DC, the United States.

The Phase 2b **FASCINATE-2 study** is a randomized, double-blind, placebo-controlled trial of 168 NASH patients with moderate-to-severe fibrosis (Stage F2 or F3), as confirmed by liver biopsy. In the planned interim analysis, 52 patients were evaluated after 26 weeks of treatment with either 50 mg ASC40 (Denifanstat) or placebo.

Improvement across biomarkers after 26 weeks of treatment:

	ASC40 (Denifanstat) 50 mg (n=30)	**Placebo (n=22)**	**P-value vs placebo**
Relative reduction in liver fat	-34.1%	-1.5%	p<0.002
≥30% reduction of liver fat (responder rate)	67%	18%	p<0.002
ALT (U/L)	-16.5	-4.0	p<0.05
Enhanced liver fibrosis (ELF) score*	-0.41	-0.01	p<0.05
LDL cholesterol (mg/dL)	-12.4	0.0	p<0.05

* *based upon available data (Denifanstat n=20, placebo=15)*

There were no treatment-related serious adverse events, with the majority of adverse events mild to moderate in nature (Grade 1 and 2). Additional interim data are expected in early 2023.

The FASCINATE-2 study, which was fully enrolled in August 2022, is on track for final analysis of the total patient population at 52 weeks as assessed by biopsy by the end of 2023. Primary efficacy endpoints include histological (liver biopsy) improvement in NAFLD activity score (NAS) without worsening of fibrosis or resolution of steatohepatitis without worsening of fibrosis; as well as secondary endpoints measuring biomarkers of inflammation, fibrosis and liver injury.

About ASC40 (Denifanstat)

ASC40 (Denifanstat) is an oral, selective, first-in-class fatty acid synthase inhibitor that directly targets the primary drivers of NASH by reducing excess liver fat (steatosis), decreasing inflammation and blunting fibrosis. In addition to the FASCINATE-2 trial, ASC40 (Denifanstat) is being tested in a Phase 3 clinical trial for recurrent glioblastoma and a Phase 2 study for moderate to severe acne, both in China under exclusive license by the Company through its subsidiaries.

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 ultimately commercialize 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
November 4, 2022

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