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 ANNOUNCES STRATEGIC DECISIONS ON FXR AGONIST ASC42

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 (the "**Board**") of directors (the "**Directors**") of the Company announces the strategic decisions on farnesoid X receptor (FXR) agonist ASC42.

After thorough analysis of the Phase II trial data of ASC42 for primary biliary cholangitis (PBC) (ClinicalTrials.gov: NCT05190523), the Company made a strategic decision not to pursue further clinical trials of ASC42 for PBC indication. This decision is based on the efficacy and safety data from the 12-week Phase II study, which consisted of three ASC42 active treatment arms (5 mg, 10 mg and 15 mg QD) and one placebo control arm. The results indicated that ASC42 did not show competitiveness to new PBC drug candidates currently in development and registrational stages.

Furthermore, the Company also decided not to pursue further clinical studies of ASC42 as an FXR agonist in combination for non-alcoholic steatohepatitis (NASH) (ASC43F) and clinical studies of ASC42 for hepatitis B virus (HBV) indication.

As of December 31, 2023, the Group had cash and cash equivalent and time deposits of approximately RMB2.3 billion. These strategic decisions are part of the Company's efforts to continue to evaluate and optimize its research & development pipeline to increase efficiency and preserve cash. The savings from discontinuing these planned clinical trials will be used to accelerate clinical development of ASC41 and ASC40 for NASH indication and in-house discovery for global first-in-class or best-in-class drug candidates. The positive interim results from ASC41 Phase II trial in biopsy-confirmed NASH patients demonstrated ASC41 as a potential best-in-class thyroid hormone receptor β (THRβ) agonist. As a first-in-class FASN inhibitor, the Phase IIb study showed ASC40 (denifanstat) achieved statistically significant results for both NASH resolution and fibrosis improvement in biopsy-confirmed NASH patients with stage 2 or 3 fibrosis after 52-week treatment.

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 ASC41 or 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
April 3, 2024

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.