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 COMPLETES ENROLLMENT OF PHASE III TRIAL OF ASC40 (DENIFANSTAT) ONCE-DAILY ORAL TABLET FOR TREATMENT OF ACNE

– *Phase III trial enrolled a total of 480 patients with moderate to severe acne*

– *Topline results expected in the second quarter 2025*

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 completion of enrollment of 480 patients for Phase III clinical trial of ASC40 (denifanstat) once-daily oral tablet for treatment of moderate to severe acne. The first patient was enrolled on January 24, 2024.

This Phase III clinical trial is a randomized, double-blind, placebo-controlled, multicenter clinical trial in China to evaluate the safety and efficacy of ASC40 once-daily oral tablet for the treatment of moderate to severe acne vulgaris. 480 patients with moderate to severe acne vulgaris were enrolled and randomized into one active treatment arm and one placebo control arm at the ratio of 1:1 to receive 50 mg ASC40 oral tablet once daily or matching placebo for 12 weeks. Topline results are expected in the second quarter 2025.

The primary efficacy endpoints are the proportion of patients achieving treatment success at week 12, the percentage change from baseline in total lesion count at week 12, and the percentage change from baseline in inflammatory lesion count at week 12. Treatment success is defined as at least a 2-point reduction in Investigator's Global Assessment (IGA) score from baseline and a score of clear (0) or almost clear (1).

On May 2, 2023, Ascletis announced that the Phase II clinical trial for ASC40 once-daily oral tablet for the treatment of acne vulgaris met the primary and key secondary endpoints, demonstrating superior efficacy including 19.4% patients achieving treatment success at week 12 versus placebo (5.1%) and a good safety profile (Link).

ASC40 is a first-in-class, once-daily oral, selective small molecule inhibitor of fatty acid synthase (FASN). Mechanisms of ASC40 for treatment of acne are (1) direct inhibition of facial sebum production through inhibition of de novo lipogenesis (DNL) in human sebocytes, and (2) inhibition of inflammation through decreasing cytokine secretion and Th17 differentiation. ASC40 is licensed from Sagimet Biosciences Inc. (Nasdaq: SGMT) for exclusive rights in Greater China.

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 develop, manufacture and/or commercialize ASC40 (denifanstat) 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 12, 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.