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 POSITIVE TOPLINE RESULTS FROM ITS PHASE III OPEN-LABEL STUDY OF DENIFANSTAT (ASC40), A FIRST-IN-CLASS, ONCE-DAILY ORAL FASN INHIBITOR FOR ACNE

- *Denifanstat (ASC40), a once-daily oral fatty acid synthase (FASN) inhibitor, demonstrated favorable safety and tolerability in a Phase III open-label study*

- *The exceptional efficacy of denifanstat (ASC40) observed in the Company's previously reported placebo-controlled Phase III trial coupled with a favorable safety profile in two Phase III trials provide a potential major break-through for the treatment of acne*

- *New Drug Application for denifanstat (ASC40) for acne was recently accepted by the China National Medical Products Administration*

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 positive topline results from the Phase III open-label study (NCT06248008) evaluating denifanstat (ASC40), a first-in-class, once-daily oral small molecule fatty acid synthase (FASN) inhibitor, in patients with moderate-to-severe acne vulgaris.

This recently completed second Phase III study was an open-label, multicenter study in China designed to evaluate the long-term safety of denifanstat (ASC40) in 240 patients with moderate to severe acne vulgaris. All the 240 patients, previously treated with denifanstat (ASC40) or placebo for 12 weeks, received denifanstat (ASC40) once daily for 40 weeks. The primary endpoints included: (1) incidence of treatment-emergent adverse events (TEAEs); (2) incidence of serious adverse events (SAEs); and (3) incidence of discontinuation due to adverse events (AEs). Denifanstat (ASC40) demonstrated a favorable safety and tolerability profile. Most TEAEs were mild (grade 1) and moderate (grade 2). There were no denifanstat (ASC40)-related grade 3 or 4 AEs and no denifanstat (ASC40)-related SAEs. No deaths were reported.

Reference is made to the Company's announcement dated June 4, 2025, in which it announced that denifanstat (ASC40) met all primary, key secondary, and secondary endpoints in the 480-patient randomized, double-blind, placebo-controlled Phase III clinical trial (NCT06192264) for the treatment of moderate to severe acne vulgaris.

The mechanisms of action of denifanstat (ASC40) for the treatment of acne are (1) direct inhibition of sebum production, through inhibition of de novo lipogenesis (DNL) in human sebocytes; and (2) inhibition of inflammation, through decreasing cytokine secretion and Th17 differentiation. Denifanstat (ASC40)'s unique mechanism of action directly reduces one of the main underlying causes of acne which is the overproduction of sebum. This sets denifanstat (ASC40) apart as most other acne treatments do not treat the underlying cause of the condition.

Denifanstat (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

Hong Kong
January 29, 2026

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.