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 CHINA NATIONAL MEDICAL PRODUCTS ADMINISTRATION ACCEPTANCE OF NEW DRUG APPLICATION FOR DENIFANSTAT (ASC40), A FIRST-IN-CLASS FASN INHIBITOR FOR ACNE TREATMENT

– *Denifanstat (ASC40) met all primary, key secondary and secondary efficacy endpoints (ITT analysis) and significantly improved moderate-to-severe acne vulgaris compared with placebo in a randomized, double-blind, placebo-controlled, multicenter Phase III clinical trial.*

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 that its New Drug Application (NDA) for denifanstat (ASC40), a first-in-class, once-daily oral small molecule fatty acid synthase (FASN) inhibitor for the treatment of moderate-to-severe acne vulgaris, has been accepted by the China National Medical Products Administration (NMPA).

"Acceptance of this NDA is an important milestone in our efforts to provide a potentially groundbreaking therapeutic approach for the treatment of moderate-to-severe acne," said Jinzi Jason Wu, Ph.D., Founder, Chairman of the Board and chief executive officer of Ascletis, "We are excited denifanstat (ASC40) is only one step away from the commercialization."

Ascletis has completed Phase II (NCT05104125) and Phase III (NCT06192264) studies of denifanstat (ASC40) for the treatment of moderate-to-severe acne vulgaris.

In the Phase III study, denifanstat (ASC40) met all primary, key secondary and secondary efficacy endpoints (ITT analysis) and significantly improved moderate-to-severe acne vulgaris compared with placebo. Denifanstat (ASC40) demonstrated a favorable safety and tolerability profile. All denifanstat (ASC40)-related treatment-emergent adverse events (TEAEs) were mild (Grade 1) or moderate (Grade 2). There were no denifanstat (ASC40)-related Grade 3 or 4 TEAEs and no denifanstat (ASC40)-related serious adverse events (SAEs). There were no denifanstat (ASC40)-related permanent treatment discontinuations or withdrawals observed.

The Phase III study results were presented as an oral presentation at the European Academy of Dermatology and Venereology (EADV) Congress 2025 in Paris, France on September 17, 2025 (link).

The Company recently completed the pre-NDA consultation with the China NMPA for denifanstat (ASC40) for the treatment of moderate-to-severe acne vulgaris and received positive feedback from NMPA.

Ascletis licensed denifanstat (ASC40) 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
December 10, 2025

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.