**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 DENIFANSTAT (ASC40) PRE-NDA CONSULTATION WITH CHINA NATIONAL MEDICAL PRODUCTS ADMINISTRATION

– *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 Phase III randomized, double-blind, placebo-controlled, multicenter 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 it recently completed the pre-New Drug Application (NDA) consultation with China National Medical Products Administration (NMPA) for denifanstat (ASC40) for the treatment of moderate-to-severe acne vulgaris and plans to submit an NDA soon. The pre-NDA consultation was initiated from June 2025 and completed in October 2025.

Ascletis has completed the 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).

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
October 14, 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.*