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 PRESENTED PHASE III STUDY RESULTS OF FIRST-IN-CLASS FASN INHIBITOR DENIFANSTAT (ASC40) FOR ACNE TREATMENT IN THE LATE BREAKING NEWS SESSIONS OF THE EUROPEAN ACADEMY OF DERMATOLOGY AND VENEREOLOGY (EADV) CONGRESS 2025

- *Denifanstat (ASC40) met all primary, key secondary and secondary efficacy endpoints (ITT analysis) and significantly improved moderate-to-severe acne compared with placebo.*

- *Denifanstat (ASC40) demonstrated a favorable safety and tolerability profile. Treatment emergent adverse events (TEAEs) in the denifanstat (ASC40) group were comparable to placebo: 58.6% versus 56.3%. The majority of TEAEs were mild (Grade 1) or moderate (Grade 2).*

- *Pre-New Drug Application (NDA) consultation of denifanstat (ASC40) with the China National Medical Products Administration (NMPA) is ongoing and feedback received from NMPA so far is encouraging. Ascletis plans to submit an NDA for denifanstat (ASC40) for the treatment of moderate to severe acne vulgaris to NMPA after completing its pre-NDA consultation.*

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 the oral presentation of the Phase III study results of denifanstat (ASC40) for the treatment of moderate to severe acne vulgaris (NCT06192264) was presented in the Late Breaking News sessions of the European Academy of Dermatology and Venereology (EADV) Congress 2025 in Paris, France on September 17, 2025.

Details of the Oral Presentation

Title: First-in-Class FASN Inhibitor Denifanstat Achieved All Endpoints in the Treatment of Acne Vulgaris: Results from a Phase III Randomised Placebo Controlled Trial

Presenter: Dr. Leihong (Flora) XIANG, M.D and Ph.D., Principal Investigator of denifanstat (ASC40) Phase III study, Department of Dermatology, Huashan Hospital, Fudan University

The Phase III clinical trial was a randomized, double-blind, placebo-controlled, multicenter clinical trial in China to evaluate the safety and efficacy of denifanstat (ASC40) once-daily oral tablet in 480 patients with moderate to severe acne vulgaris. Patients were enrolled and randomized into one active treatment arm and one placebo control arm at the ratio of 1:1 to receive 50 mg denifanstat (ASC40) oral tablet once daily or matching placebo for 12 weeks. Baseline characteristics were well balanced between denifanstat (ASC40) and placebo arms.

Primary endpoints included the percent treatment success, defined as an Investigator's Global Assessment (IGA) score of 0 (clear) or 1 (almost clear) with at least a 2-point decrease in IGA from baseline at week 12, the percent reductions from baseline to week 12 in total lesion count (TLC), and the percent reduction from baseline to week 12 in inflammatory lesion count (ILC).

After 4-week treatment, the denifanstat (ASC40) group already showed statistically significant improvements ($p<0.05$) over placebo in multiple efficacy endpoints, including treatment success, TLC, ILC, and non-inflammatory lesion count (NILC).

After 12-week treatment, denifanstat (ASC40) met all primary, key secondary and secondary efficacy endpoints. Table 1 summarizes efficacy results from the Phase III study versus placebo (intent-to-treat, ITT analysis).

Table 1. Efficacy results from the Phase III study versus placebo (intent-to-treat, ITT analysis)

Efficacy endpoints[1]	50 mg denifanstat (ASC40), oral, once daily (n=240)	Placebo, oral, once daily (n=240)	Placebo adjusted	*P* value
Primary endpoints				
Percent treatment success[2]	33.17	14.58	18.59	<0.0001
Percent reduction from baseline in TLC	57.38	35.42	21.96	<0.0001
Percent reduction from baseline in ILC	63.45	43.21	20.24	<0.0001
Key secondary endpoint				
Percent reduction from baseline in NILC	51.85	28.94	22.91	<0.0001
Secondary endpoints				
Absolute reduction from baseline in TLC	58.25	36.17	22.08	<0.0001
Absolute reduction from baseline in ILC	26.56	18.42	8.14	<0.0001

Notes:

(1) All efficacy endpoints are least square means.

(2) Treatment success is defined as an Investigator's Global Assessment (IGA) score of 0 (clear) or 1 (almost clear) with at least a 2-point decrease in IGA from baseline at week 12.

(3) TLC: total lesion count; ILC: inflammatory lesion count; NILC: non-inflammatory lesion count.

Denifanstat (ASC40) demonstrated a favorable safety and tolerability profile following 12 weeks of once-daily oral administration at 50 mg. The incidence rates of treatment-emergent adverse events (TEAEs) were comparable between denifanstat (ASC40) and placebo: 58.6% versus 56.3%. No incidence rates of TEAEs related to study drug in any category exceeded 10%. Only two categories of TEAEs had an incidence rate of more than 5% (6.3% dry skin in denifanstat (ASC40)-related patients versus 2.9% in the placebo group; 5.9% xerophthalmia in denifanstat (ASC40)-related patients versus 3.8% in the placebo group). The majority of TEAEs were mild (Grade 1) or moderate (Grade 2). All denifanstat (ASC40)-related 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 AEs (SAEs). No deaths were reported. No denifanstat (ASC40)-related permanent treatment discontinuations or withdrawals were observed.

Detailed data presented at the EADV Congress 2025 can be found at Ascletis' website (link).

"Denifanstat (ASC40) is an innovative and potentially meaningful advancement for the treatment of acne and we're very pleased that we have presented these results to the dermatology community at this year's EADV Congress," said Jinzi Jason Wu, Ph.D., Founder, Chairman of the Board and chief executive officer of Ascletis. "Denifanstat (ASC40) has a new mechanism of action for acne treatment and demonstrated statistically significant and clinically meaningful improvement compared to placebo in all primary and secondary endpoints in the Phase III study, as well as a favorable safety and tolerability profile."

Pre-New Drug Application (NDA) consultation of denifanstat (ASC40) with the China National Medical Products Administration (NMPA) is ongoing and feedback received from NMPA so far is encouraging. Ascletis plans to submit an NDA for denifanstat (ASC40) for the treatment of moderate to severe acne vulgaris to NMPA after completing its pre-NDA consultation.

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 denifanstat (ASC40) successfully.

By order of the Board
Ascletis Pharma Inc.
歌禮製藥有限公司
Jinzi Jason WU
Chairman

Hong Kong
September 18, 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.