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 POSTER PRESENTATION OF PHASE II STUDY TOPLINE RESULTS OF FASN INHIBITOR ASC40 FOR TREATMENT OF ACNE AT EADV CONGRESS 2023

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 of directors (the "**Board**") of the Company announces the poster presentation of Phase II study topline results of ASC40, a first-in-class fatty acid synthase (FASN) inhibitor for treatment of acne, at the European Academy of Dermatology and Venereology (EADV) Congress 2023 in Berlin, Germany. The summary of the poster is shown as below:

Title: ASC40, an oral once-daily fatty acid synthase (FASN) inhibitor, in patients with acne vulgaris: topline results from a Phase II randomized, double-blind, placebo-controlled, multicenter trial

Presenter: Jinzi J. Wu, Ph.D.

Principal Investigator: Professor Leihong Xiang, Huashan Hospital, Fudan University

Poster ID: P0053

Part of Session: Acne and related disorders, hidradenitis suppurativa

Study Design:

This Phase II trial (ClinicalTrials.gov: NCT05104125) was a randomized, double-blind, placebo-controlled, multicenter study. 180 patients with moderate to severe acne vulgaris were randomized into three active treatment arms and one placebo control arm at the ratio of 1:1:1:1 to receive ASC40 (25 mg, 50 mg or 75 mg tablet) or matching placebo tablet orally, once daily for 12-week treatment and 2-week follow-up. Efficacy and safety of 12-week treatment of ASC40 or placebo were assessed.

Results:

Table 1 summarized the topline data of primary and key secondary efficacy endpoints at Week 12 versus baseline. Overall, all three doses of ASC40 demonstrated good efficacy compared to placebo. The efficacy of ASC40 seemed maxed out at 50 mg dose.

Table 1. Primary and key secondary efficacy endpoints of 25 mg, 50 mg and 75 mg ASC40, oral, once daily tablet for 12 weeks vs placebo (n=179)

Endpoint	25 mg ASC40, oral, once daily, 12 weeks (n=45)	50 mg ASC40, oral, once daily, 12 weeks (n=44)	75 mg ASC40, oral, once daily, 12 weeks (n=45)	Placebo, oral, once daily, 12 weeks (n=45)
% change from baseline in total lesion count at week 12 (primary endpoint)[§]	-53.2	-61.3	-53.1	-34.2
P value vs placebo	0.005	0.008	0.008	NA
Absolute change from baseline in total lesion count at week 12 (key secondary endpoint)[§]	-56.0	-60.5	-46.0	-37.0
P value vs placebo	0.024	0.030	0.083	NA
% change from baseline in inflammatory lesion count at week 12 (key secondary endpoint)[§]	-54.4	-65.0	-60.0	-31.4
P value vs placebo	0.006	0.003	0.029	NA
Absolute change from baseline in inflammatory lesion count at week 12 (key secondary endpoint)[§]	-25.0	-26.0	-22.0	-13.0
P value vs placebo	0.007	0.003	0.032	NA

Note: § Data are medians.

Conclusion:

Topline results of this study showed that oral ASC40, once daily, 12-week treatment was safe and well tolerated. ASC40 improved significantly in total lesion, inflammatory lesion, and IGA (Investigator's Global Assessment) treatment success. Based on efficacy and safety assessment of this Phase II study, the Phase III clinical trial is warranted and will be initiated soon.

About EADV

The European Academy of Dermatology and Venereology (EADV) has over 8,500 members and an active community of more than 14,000 professionals around the world. The EADV Congress is the annual international congress for the latest scientific advances and research in dermatology & venereology, bringing together healthcare professionals, organisations and industry from around the world to maximise impact. This year's event will be held in Berlin, Germany from October 11 to 14.

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 commercialize ASC40 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
October 11, 2023

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.