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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 U.S. PHASE II, 24-WEEK STUDY FOR ITS ULTRA-LONG-ACTING SUBCUTANEOUS DEPOT FORMULATIONS OF SMALL MOLECULE GLP-1R AGONIST ASC30 FOR OBESITY

- *ASC30 subcutaneous (SQ) depot formulation achieved statistically significant and clinically meaningful placebo-adjusted mean weight loss of 7.5% at week 16 after three monthly doses.*

- *ASC30 SQ depot formulation maintained weight loss for the four months following the third and final monthly dose, suggesting potential quarterly dosing as a maintenance therapy.*

- *ASC30 demonstrated a safety and tolerability profile consistent with the GLP-1 drug class.*

- *ASC30 SQ depot formulation is the first GLP-1 to achieve drug class consistent weight loss with once-monthly injection without requiring lead-in weekly injections, and to maintain weight loss up to four months after the last dose.*

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 a U.S. Phase II, 24-week study for its subcutaneous (SQ) depot formulations of small molecule GLP-1 receptor (GLP-1R) agonist ASC30 for obesity (NCT06679959). All 65 participants enrolled in three cohorts utilizing two formulations (A1 and A2) were obese or overweight with at least one weight-related comorbidity.

The Phase II study achieved its primary endpoint, with patients receiving three doses of once-monthly ASC30 SQ depot formulation A1 demonstrating a statistically significant ($p < 0.05$ vs placebo) and clinically meaningful placebo-adjusted mean weight loss of 6.3% at week 12. Additionally, ASC30 SQ depot formulation A1 achieved a statistically significant ($p < 0.05$ vs placebo) and clinically meaningful placebo-adjusted mean weight loss of 7.5% at week 16 after 3 monthly doses.

The Phase II study was a randomized, double-blind, placebo-controlled and multi-center 24-week study conducted in the U.S. to evaluate the safety, tolerability and efficacy in 65 participants with obesity (body mass index (BMI) ≥ 30 kg/m^2) or overweight (BMI ≥ 27 kg/m^2 but < 30 kg/m^2) with at least one weight-related comorbidity. All 65 participants were given three monthly ASC30 SQ depot doses or matching placebo at day 1, day 29 (week 4) and day 57 (week 8), without requiring lead-in weekly doses. The maintenance period was 16 weeks, starting from week 8 to week 24. The study evaluated two SQ depot formulations of ASC30 (A1 and A2). The study objective was to evaluate the potential for once-monthly dosing for treatment therapy and once-quarterly dosing for maintenance therapy. ASC30 SQ depot formulation A1 was previously studied in the 12-week Phase Ib single dose study (NCT06679959) and demonstrated an observed half-life of 46 days to 75 days. No human studies of ASC30 SQ depot formulation A2 were conducted previously. Formulation A1 achieved therapeutic drug exposures in obese patients in this study while formulation A2 did not.

For ASC30 SQ depot formulation A1, all participants were given three SQ doses of 400 mg each with a four-week dosing interval at day 1, day 29 (week 4) and day 57 (week 8). ASC30 SQ depot formulation A1 achieved placebo-adjusted mean body weight loss of 2.7%, 5.5%, 6.3%, and 7.5% at week 4, week 8, week 12 and week 16, respectively. The data demonstrate that ASC30 SQ depot formulation A1 can be dosed once monthly and potentially once every two months for the treatment of obesity without requiring a weekly lead-in dosing period.

This Phase II study also evaluated the potential for ASC30 SQ depot formulation A1 to be used as a maintenance therapy. Patients in the study were evaluated for duration of effect for 16 weeks following the final dose on week 8. ASC30 SQ depot formulation A1 achieved therapeutic drug exposures over this 16-week maintenance period after the final dose. Placebo-adjusted mean weight loss was 5.5% at week 8, 6.4% at week 20 (three months following the final dose), and 5.8% at week 24 (four months following the final dose). These results demonstrate that ASC30 SQ depot formulation A1 has the potential to be an effective once-quarterly maintenance therapy for obesity.

ASC30 SQ depot formulations A1 and A2 were safe and well tolerated, demonstrating a safety and tolerability profile consistent with the GLP-1 drug class. There were no discontinuations due to adverse events (AEs) for either ASC30 SQ depot formulations A1 and A2 or placebo-treated participants. All AEs, including injection site AEs, were mild to moderate in severity. All gastrointestinal (GI) AEs were mild (grade 1) with no moderate (grade 2) or above GI AEs. No hepatic safety signal was observed. In addition, there were no abnormal findings in laboratory tests, vital signs, ECGs (electrocardiograms, including QTc intervals), and physical exams.

"We are very excited to observe this statistically significant and clinically meaningful weight loss in obese patients treated with ASC30 long acting SQ depot formulation. ASC30 is the first and only incretin that has demonstrated effective weight loss with once-daily oral dosing, once-monthly SQ dosing for treatment therapy and once-quarterly SQ dosing for maintenance therapy in two Phase II studies for obesity," said Jinzi Jason Wu, Ph.D., Founder, Chairman of the Board and chief executive officer of Ascletis. "This competitive efficacy, combined with a well-tolerated safety profile of the long-acting formulation of ASC30, reinforces our confidence in expanding clinical development program for ASC30 SQ depot formulation for both once-monthly treatment therapy and once-quarterly maintenance therapy. Furthermore, the data from this 24-week study with our proprietary SQ depot formulation validate Ascletis' Ultra-Long-Acting Platform (ULAP) technology for the development of once-monthly to once-quarterly therapies for chronic weight management."

ASC30 was discovered and developed in-house at Ascletis as the first and only investigational small molecule GLP-1R biased agonist designed to be administered once daily orally and once monthly to once quarterly subcutaneously as a treatment therapy and a maintenance therapy for chronic weight management.

About ASC30

ASC30 is an investigational GLP-1R biased small molecule agonist and has unique and differentiated properties that enable the same small molecule for both oral tablet and subcutaneous injection administrations. ASC30 is a new chemical entity (NCE), with U.S. and global patent protection through 2044 (excluding potential patent extensions).

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 ASC30 successfully.

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

Hong Kong
March 10, 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.