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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' ORAL SMALL MOLECULE GLP-1, ASC30, DEMONSTRATED PLACEBO-ADJUSTED HBA1C REDUCTION OF 1.7% AT 12 WEEKS FROM ITS U.S. PHASE II STUDY IN PARTICIPANTS WITH DIABETES

- *ASC30 reduced HbA1c by a placebo-adjusted 1.7%, 1.6% and 1.7% from baseline for 40 mg, 60 mg and 80 mg, respectively, at 12 weeks, the primary endpoint.*
- *ASC30 achieved placebo-adjusted weight reduction of 4.4%, 3.8% and 4.0% from baseline for 40 mg, 60 mg and 80 mg, respectively and no plateau was observed, at 13 weeks, a secondary endpoint.*
- *ASC30 titrated weekly to maintenance doses (40 mg, 60 mg and 80 mg) demonstrated favorable safety and tolerability, with zero study discontinuations due to gastrointestinal adverse events.*
- *No hepatic safety signal was observed.*

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 its U.S. Phase II study (NCT07321678) evaluating ASC30, an oral small molecule GLP-1 receptor (GLP-1R) agonist, for the treatment of type 2 diabetes mellitus (T2D). This Phase II study is a 13-week U.S. study evaluating the efficacy, safety and tolerability of oral small molecule GLP-1R agonist ASC30, a once-daily tablet, in 100 participants with diabetes. The primary endpoint is HbA1c reduction from baseline at 12 weeks; one of the secondary endpoints are body weight loss from baseline at 13 weeks. ASC30 (40 mg, 60 mg, 80 mg) met the primary and all secondary endpoints, delivering significant HbA1C reduction and weight loss as well as improvements in multiple cardiovascular risk factors. T2D is the second indication in development for ASC30, in addition to obesity.

For the primary endpoint, ASC30 demonstrated statistically significant and clinically meaningful HbA1c reduction in participants with diabetes compared to placebo ($p < 0.0001$). Placebo-adjusted HbA1c reductions from baseline were 1.7%, 1.6% and 1.7% (least squares mean) for 40 mg (n=20), 60 mg (n=29) and 80 mg (n=28), respectively, at 12 weeks, using the efficacy estimand ^[1]. Participants had an average HbA1c of 8.3% at baseline.

For the secondary endpoint of body weight reduction, ASC30 demonstrated statistically significant and clinically meaningful body weight reduction compared to placebo ($p = 0.001$ to 0.003). Placebo-adjusted body weight reduction from baseline was 4.4%, 3.8% and 4.0% (least squares mean) for 40 mg ($n=20$), 60 mg ($n=29$) and 80 mg ($n=28$), respectively and no plateau was observed, at 13 weeks, using the efficacy estimand. Participants had an average body weight of 93.7 kg at baseline.

Although titration (once weekly) was fast in the study, ASC30 continued to demonstrate favorable gastrointestinal (GI) tolerability. ASC30 titrated weekly to maintenance doses (40 mg, 60 mg and 80 mg) demonstrated favorable safety and GI tolerability, with zero study discontinuations due to GI adverse events (AEs). The favorable GI tolerability in diabetic participants was consistent with the finding from studies in obese or overweight participants. It is anticipated that GI tolerability will significantly improve in the Phase III diabetic program when titration is slowed down to once every four weeks. There was only one study discontinuation (1/80, 1.3%, hiccup) due to any AEs. The placebo group had zero study discontinuation due to any AEs.

In this ASC30 U.S. Phase II diabetic study, all drug-related AEs were only grade 1 (mild) and grade 2 (moderate) in severity. There were no drug-related serious AEs (SAEs).

The overall safety profile of ASC30 in diabetic participants was consistent with that observed in another Phase II study ([NCT07002905](#)) in participants with obesity or overweight. No hepatic safety signal was observed. There were no elevations of alanine transaminase (ALT), aspartate aminotransferase (AST), or total bilirubin (TBL) during the treatment period. For all other safety signals, ASC30 demonstrated a favorable safety profile in diabetic participants.

“These data demonstrate that ASC30 has the potential to be a best-in-class oral small molecule GLP-1 for diabetes, in addition to a best-in-class oral small molecule GLP-1 for obesity as demonstrated by the efficacy and tolerability from our U.S. Phase II study in participants with obesity or overweight,” said Jinzi Jason Wu, Ph.D., Founder, Chairman of the Board and chief executive officer of Ascletis, “The combination of significant HbA1c reductions, weight loss and favorable tolerability reinforces our confidence in advancing ASC30 as a once-daily oral treatment option for patients with type 2 diabetes.”

ASC30 was discovered and developed in-house at Ascletis as an investigational small molecule GLP-1R fully biased agonist. The ASC30 global Phase III program for obesity has two pivotal trials (AURORA-1 [NCT07743463](#) and AURORA-2 [NCT07743450](#)) in the U.S., Europe, and Canada and is currently enrolling approximately 4,600 participants with obesity or overweight. Topline data from the ASC30 global Phase III clinical program for obesity are expected in the third quarter of 2028, with a U.S. Food and Drug Administration (FDA) New Drug Application (NDA) submission for obesity expected by the end of 2028 and a European Medicines Agency (EMA) Marketing Authorisation Application (MAA) submission for obesity expected in early 2029. ASC30 has the potential to become the second oral small molecule GLP-1 receptor agonist available in the U.S. and Europe, if approved.

^[1] The efficacy estimand is the primary estimand which evaluates the treatment effect of all randomized eligible participants while adhering to treatment.

About the U.S. Phase II Study with ASC30 for the Treatment of Diabetes

The Phase II study is a 13-week, randomized, double-blind, placebo-controlled and multi-center study to evaluate the efficacy, safety, and tolerability of ASC30 tablets in participants with type 2 diabetes mellitus ($7.0\% \leq \text{HbA1c} \leq 10.5\%$ at baseline). The primary endpoint of the Phase II study is the change from baseline in HbA1c at 12 weeks in the treatment group compared with the placebo group. Secondary endpoints include the change from baseline in body weight at 13 weeks in the treatment group compared with placebo group. The Phase II study enrolled 100 participants with type 2 diabetes mellitus at multiple sites across the U.S. The participants were randomly assigned in a ratio of approximately 2:3:3:2 to 40 mg, 60 mg and 80 mg ASC30 tablets and matching placebo tablets, respectively. ASC30 was titrated weekly from 1 mg to maintenance doses of 40 mg, 60 mg and 80 mg.

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
October 29, 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.