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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 U.S. FDA IND CLEARANCE FOR 13-WEEK PHASE II STUDY OF ITS ORAL SMALL MOLECULE GLP-1, ASC30, IN PARTICIPANTS WITH DIABETES

- *The Phase II study for diabetes is a 13-week, randomized, double-blind, placebo-controlled and multi-center study to evaluate the efficacy, safety, and tolerability of ASC30 in participants with diabetes. Enrollment is expected to begin in the first quarter of 2026.*
- *ASC30 demonstrated placebo-adjusted weight loss of 7.7% in a recently completed 13-week U.S. Phase II study in participants with obesity or overweight, with better gastrointestinal tolerability. 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 that it recently received the Investigational New Drug (IND) clearance from the U.S. Food and Drug Administration (FDA) for the Phase II study of its oral small molecule GLP-1, ASC30, in participants with 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 in participants with type 2 diabetes mellitus. The primary endpoint of the Phase II study is the mean change from baseline in HbA1c up to 13 weeks in the treatment group compared with the placebo group. Secondary endpoints include the mean change from baseline in fasting blood glucose up to 13 weeks in the treatment group compared with the placebo group, the mean change from baseline in body weight up to 13 weeks in the treatment group compared with placebo group, and safety and tolerability. The Phase II study will enroll approximately 100 participants with type 2 diabetes mellitus at multiple sites across the U.S. Participants will be 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 will be titrated weekly from 1 mg to target doses of 40 mg, 60 mg and 80 mg. Enrollment is expected to begin in the first quarter of 2026.

Ascletis recently completed its 13-week Phase II study evaluating ASC30, an oral small molecule GLP-1 receptor (GLP-1R) agonist for the treatment of obesity ([NCT07002905](#)) in 125 participants with obesity or overweight with at least one weight-related comorbidity at multiple sites across the U.S. At the 13-week primary endpoint, ASC30 once-daily tablets showed statistically significant, clinically meaningful and dose-dependent placebo-adjusted mean body weight reductions of 5.4%, 7.0% and 7.7% for 20 mg, 40 mg and 60 mg, respectively. No plateau was observed for weight loss. The vomiting rate of ASC30 titrated weekly to target dose was approximately half of the published vomiting rate observed with orforglipron titrated weekly. The gastrointestinal tolerability of ASC30 titrated weekly was comparable to published results of orforglipron titrated every four weeks in the Phase III ATTAIN-1 study. The total treatment discontinuation rate due to adverse events for the ASC30 Phase II study for obesity or overweight was 4.8%.

ASC30 was discovered and developed in-house at Ascletis as a first and only investigational small molecule GLP-1R fully biased agonist designed to be dosed once daily orally and once monthly to once quarterly subcutaneously for the treatment of obesity, diabetes and other metabolic diseases.

“IND clearance for this Phase II study for diabetes is a significant milestone for Ascletis as we continue to build upon the data for ASC30,” said Jinzi Jason Wu, Ph.D., Founder, Chairman of the Board and chief executive officer of Ascletis, “Furthermore, the FDA’s clearance of our IND expands entry for ASC30 into clinical development for the large diabetes treatment market.”

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
January 5, 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.