Ascletis Pharma Inc.
歌禮製藥有限公司
(incorporated in the Cayman Islands with limited liability)
(Stock Code: 1672)

INSIDE INFORMATION

ASCLETIS ANNOUNCES POSITIVE INTERIM RESULTS FROM FIRST TWO COHORTS OF U.S. PHASE IB MULTIPLE ASCENDING DOSE STUDY OF SMALL MOLECULE ORAL GLP-1R AGONIST ASC30

- *ASC30 oral once-daily tablet demonstrated a 6.3% mean body weight reduction from baseline after 28-day treatment in multiple ascending dose (MAD) cohort 2 (weekly titrations of 2 mg, 10 mg, 20 mg, and 40 mg).*

- *ASC30 oral once-daily tablet also demonstrated a 4.3% mean body weight reduction from baseline after 28-day treatment in MAD cohort 1 (weekly titrations of 2 mg, 5 mg, 10 mg, and 20 mg).*

- *0.1% mean body weight reduction from baseline was observed after 28-day treatment with matching placebo tablets.*

This announcement is made by Ascletis Pharma Inc. (the "**Company**" or "**Ascletis**") pursuant to Rule 13.09(2) of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the "**Listing Rules**") and the Inside Information Provisions (as defined in the Listing Rules) under Part XIVA of the Securities and Futures Ordinance (Chapter 571 of the Laws of Hong Kong).

The board (the "**Board**") of directors (the "**Directors**") of the Company announces positive interim results from the first two cohorts of its randomized, double-blind, placebo-controlled Phase Ib multiple ascending dose (MAD) study (NCT06680440), conducted in the U.S., of ASC30 oral once-daily tablet in patients with obesity (body mass index (BMI): 30-40 kg/m^2). The Phase Ib MAD study consists of 3 cohorts, with eight patients in each cohort on ASC30 tablets and two patients in each cohort on matching placebo. Cohort 1 had four dose levels (2 mg, 5 mg, 10 mg, and 20 mg). Patients in cohort 1 received each dose level of ASC30 or placebo for seven days in a sequential manner. The average daily dose over the 28-day treatment period was 9.25 mg ASC30 for cohort 1. Cohort 2 had four dose levels (2 mg, 10 mg, 20 mg, and 40 mg). Patients in cohort 2 received each dose level of ASC30 or placebo for seven days in a sequential manner. The average daily dose over the 28-day treatment period was 18 mg ASC30 for cohort 2.

Mean body weight reductions from baselines were 4.3% and 6.3% for MAD cohorts 1 and 2, respectively, after 28-day treatment with ASC30 oral once-daily tablets. Placebo-adjusted mean body weight reductions from baselines were 4.2% and 6.2% for MAD cohorts 1 and 2, respectively.

ASC30 was generally well tolerated in MAD cohorts 1 and 2, with a favorable safety profile. There were no serious adverse events (SAEs). All gastrointestinal (GI)-related adverse events (AEs) were mild (grade 1) or moderate (grade 2). Weekly titrations of ASC30 improved GI tolerability. In MAD cohort 1, there were no incidences of vomiting. No clinically significant changes in liver enzymes including alanine aminotransferase (ALT), aspartate aminotransferase (AST) and total bilirubin (TBL) were observed. There were no clinically significant findings in laboratory tests, vital signs, ECGs (electrocardiograms, including QTc intervals), and physical exams.

Detailed results will be presented at a future medical conference.

ASC30 was discovered and developed in-house at Ascletis as a first and only investigational small molecule GLP-1 receptor (GLP-1R) biased agonist designed to be dosed once daily orally and once monthly subcutaneously for the treatment of obesity.

Reference is made to the announcement of the Company dated January 21, 2025, in which Ascletis announced positive topline results from its U.S. single ascending dose (SAD) study (NCT06680440) of ASC30 oral tablet in patients with obesity (BMI: 30-40 kg/m^2). The SAD study consisted of five cohorts (2 mg, 5 mg, 10 mg, 20 mg, and 40 mg) with a total of 40 patients with obesity under fasting conditions.

ASC30 Oral Tablet U.S. Phase Ib MAD Study Update

The ASC30 oral tablet MAD study is designed as a randomized, double-blind, placebo-controlled study consisting of three cohorts. Patients with obesity receive either ASC30 oral tablet or matching placebo once daily for 28 days, with weekly titrations. Cohort 1 (2 mg, 5 mg, 10 mg, and 20 mg) and cohort 2 (2 mg, 10 mg, 20 mg, and 40 mg) have been completed. Cohort 3 (5 mg, 15 mg, 30 mg, and 60 mg) is expected to be completed by the end of March 2025, and topline results will be available soon after.

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 compound patent protection until 2044.

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.

Shareholders and potential investors of the Company are advised to exercise caution when dealing in the securities of the Company.

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
February 19, 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.