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 FIRST PARTICIPANT DOSED IN A GLOBAL PHASE III CLINICAL PROGRAM OF ONCE-DAILY ORAL SMALL MOLECULE GLP-1 RECEPTOR AGONIST ASC30 FOR CHRONIC WEIGHT MANAGEMENT

- *Expected to enroll approximately 4,600 participants with obesity or overweight across two pivotal trials (AURORA-1 and AURORA-2) in the U.S., Europe, and Canada.*

- *Global Phase III clinical program to investigate efficacy and safety of three maintenance doses (20 mg, 40 mg, and 60 mg) over 72 weeks in participants with obesity or overweight without type 2 diabetes (AURORA-1) and with type 2 diabetes (AURORA-2).*

- *Topline data from the AURORA Phase III clinical program are expected in the third quarter of 2028, with a U.S. Food and Drug Administration (FDA) New Drug Application (NDA) submission expected by the end of 2028 and European Medicines Agency (EMA) Marketing Authorisation Application (MAA) submission 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.*

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 the first participant has been dosed in a global Phase III clinical program of ASC30 for chronic weight management. ASC30 is an investigational, proprietary once-daily oral small molecule glucagon-like peptide-1 receptor (GLP-1R) agonist being developed for chronic weight management and diabetes.

The global Phase III clinical program consists of two pivotal, multicenter, randomized, double-blind, placebo-controlled Phase III trials, AURORA-1 (NCT07743463) and AURORA-2 (NCT07743450), evaluating the long-term efficacy, safety, and tolerability of ASC30 once-daily oral tablets in approximately 4,600 participants across clinical sites in the U.S., Europe, and Canada.

"Obesity is a complex, chronic disease associated with over 200 comorbidities and represents an immense global public health burden. While injectable incretin therapies have transformed obesity care, there remains substantial unmet need for an oral small molecule that is effective, well-tolerated, and convenient enough to expand patient access and support long-term adherence." said Jinzi Jason Wu, Ph.D., Founder, Chairman of the Board and chief executive officer of Ascletis, "Dosing the first participant in our AURORA global Phase III clinical program marks a transformative milestone for Ascletis. ASC30 enters this pivotal stage backed by a competitive Phase II weight loss profile, favorable gastrointestinal tolerability, and no observed hepatic safety signals. We believe this foundation supports ASC30's potential as a category-leading oral therapy, with the goal of bringing patients a once-daily oral GLP-1 option approved globally."

Ascletis expects to report topline data from the AURORA Phase III clinical program in the third quarter of 2028. The Company expects to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) by the end of 2028 and a Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) in early 2029. Ascletis maintains a strong balance sheet with sufficient cash on hand to support operations into 2029, fully funding the program beyond the planned U.S. and European regulatory submissions.

Ascletis has one of the most comprehensive and leading oral small molecule portfolios for obesity. In addition to the AURORA global Phase III monotherapy program, Ascletis is also developing the first tirzepatide-like oral small molecule dual agonist fixed-dose combination GLP-1/GIP (ASC30_48FDC), the first tirzepatide/eloralintide-like oral small molecule triple agonist fixed-dose combination GLP-1/GIP/amylin (ASC30_48_39FDC), and a fixed-dose combination of our small molecule oral GLP-1 and oral amylin (ASC30_39FDC).

About the ASC30 Global Phase III Clinical Program

The ASC30 global Phase III clinical program consists of two pivotal, multicenter, randomized, double-blind, placebo-controlled Phase III trials, AURORA-1 (NCT07743463) and AURORA-2 (NCT07743450), which are designed to evaluate the long-term efficacy, safety, and tolerability of once-daily oral ASC30 compared to placebo in approximately 4,600 adults living with obesity or overweight, with treatment duration of 72 weeks and across both pivotal trials:

AURORA-1 (NCT07743463): A pivotal trial evaluating efficacy and safety of once-daily oral ASC30 in participants with obesity (body mass index (BMI) ≥ 30 kg/m^2) or overweight (BMI ≥ 27 kg/m^2 with at least one weight-related comorbidity), excluding type 2 diabetes. Participants are randomized to one of three maintenance doses of ASC30 (20 mg, 40 mg, or 60 mg) or placebo. The primary endpoint is the percentage change in body weight from baseline to Week 72.

AURORA-2 (NCT07743450): A pivotal trial evaluating efficacy and safety of once-daily oral ASC30 in participants with obesity or overweight (BMI ≥ 27 kg/m^2) and with type 2 diabetes. Participants are randomized to one of three maintenance doses of ASC30 (20 mg, 40 mg, or 60 mg), or placebo. The primary endpoint is the percentage change in body weight from baseline to Week 72.

About ASC30

ASC30 was discovered and developed in-house by Ascletis as an investigational oral small molecule GLP-1R fully biased agonist. It serves as the primary pillar of Ascletis' comprehensive, industry-leading oral small molecule obesity portfolio, which also includes fixed-dose combinations spanning GLP-1, GIP, and amylin targets (such as ASC30_48FDC, ASC30_48_39FDC and ASC30_39FDC) to provide convenient, one-pill, once-daily treatment options for people living with obesity and other metabolic diseases.

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, ASC30_48FDC, ASC30_48_39FDC and/or ASC30_39FDC successfully.

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

Hong Kong
August 30, 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.