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 INITIATION OF PHASE I STUDY IN U.S. FOR ORAL AMYLIN RECEPTOR PEPTIDE AGONIST ASC36 FOR THE TREATMENT OF OBESITY

- *This trial marks the fourth Phase I peptide study for Ascletis this year.*
- *ASC36 oral tablets achieved absolute oral bioavailability of 6% to 8% at steady state in non-human primate (NHP) studies utilizing Ascletis' proprietary Peptide Oral Transport ENhancement Technology (POTENT).*
- *ASC36 oral tablets reduced mean body weight up to 13.2% from baseline after once-daily dosing for seven days in NHPs.*
- *ASC36 subcutaneous (SQ) injection demonstrated approximately 32% and 91% greater relative body weight reduction compared to eloralintide and petrelintide injection, respectively, in a head-to-head diet-induced obese (DIO) rat model.*
- *ASC36 oral tablets are expected to utilize a lower dose based on potentially better oral bioavailability and efficacy. This superior weight loss per milligram of ASC36 peptide may also provide scalability advantages in manufacturing.*

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 has initiated a U.S. Phase I study of ASC36 oral tablets (oral amylin receptor peptide agonist) for the treatment of obesity after recently receiving Investigational New Drug (IND) clearance from the U.S. Food and Drug Administration (FDA).

The Phase I study is designed to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of ASC36 following single and multiple ascending oral doses in 86 participants with obesity (body mass index (BMI) ≥ 30.0 kg/m²) or overweight (BMI ≥ 27.0 kg/m²).

"In 2026, we initiated four Phase I studies for our peptide pipeline, including ASC36 oral tablets, our fourth and most recent one, which represents a key milestone for Ascletis peptide pipeline and further validates our proprietary POTENT oral peptide delivery technology." said Jinzi Jason Wu, Ph.D., Founder, Chairman of the Board and chief executive officer of Ascletis, "ASC36 has demonstrated compelling preclinical weight-loss efficacy, favorable oral bioavailability and a prolonged half-life. We believe an effective oral amylin receptor agonist could offer a convenient, differentiated option for people with obesity. Combined with our oral small molecule and long-acting injectable programs, ASC36 further strengthens our diversified pipeline addressing the evolving treatment needs of patients with obesity and other metabolic diseases."

ASC36, an amylin receptor peptide agonist, was discovered and developed in-house utilizing Ascletis' proprietary Artificial Intelligence-assisted Structure-Based Drug Discovery (AISBDD). ASC36 oral tablet formulation was developed and optimized by Ascletis' proprietary Peptide Oral Transport ENhancement Technology (POTENT) for delivery of oral peptides.

In non-human primates (NHPs), 10 mg ASC36 oral tablet per animal dosed once daily for seven days achieved absolute oral bioavailability[1] of 8% and elimination half-life of 116 hours at steady state; 25 mg ASC36 oral tablet per animal dosed once daily for seven days achieved absolute oral bioavailability of 6% and elimination half-life of 167 hours at steady state. The long elimination half-life (116 hours to 167 hours) of ASC36 oral tablets supports once-daily and less frequent oral dosing.

ASC36 oral tablets and subcutaneous (SQ) injection demonstrated significant weight loss in NHP and diet-induced obese (DIO) rat models, respectively. In NHPs, ASC36 oral tablets reduced mean body weight up to 13.2% from baseline after once-daily dosing for seven days. ASC36 tablets also reduced food intake significantly. In a head-to-head DIO rat model, after seven days of treatment, ASC36 SQ injection demonstrated approximately 32% and 91% greater relative body weight reduction compared to eloralintide and petrelintide injection, respectively.

Based on potentially better oral bioavailability and efficacy, ASC36 oral tablets are expected to utilize a lower dose, relative to a recently FDA approved oral GLP-1R peptide agonist. This superior weight loss per milligram of ASC36 peptide may also provide scalability advantages in manufacturing.

[1] Absolute oral bioavailability: the percentage of an orally administered drug that reaches the systemic circulation (bloodstream), compared to an intravenous (IV) dose of the same drug

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 ASC36 successfully.

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

Hong Kong
September 8, 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.