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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 PHASE I STUDY OF ONCE-MONTHLY SUBCUTANEOUSLY ADMINISTERED GLP-1R/GIPR DUAL PEPTIDE AGONIST, ASC35, FOR THE TREATMENT OF OBESITY

- *Phase I trial consists of two parts. Part A is a single ascending dose (SAD) study of ASC35 once-monthly Self-Assembling Lipid Depot (SALD) formulation; Part B is a head-to-head study of multiple ascending doses (MAD) of ASC35 once-monthly SALD formulation compared to the U.S. Food and Drug Administration (FDA)-authorized tirzepatide once-weekly formulation.*
- *In head-to-head non-human primate (NHP) studies, the average observed half-life of ASC35 was approximately six-fold longer than tirzepatide, which supports once-monthly subcutaneous (SQ) dosing in humans.*
- *In a head-to-head diet-induced obese (DIO) mouse study, ASC35 demonstrated approximately 71% greater relative body weight reduction compared to tirzepatide.*

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 Investigational New Drug (IND) clearance from the U.S. Food and Drug Administration (FDA) for the Phase I study of ASC35, a potentially best-in-class, once-monthly subcutaneously administered GLP-1 receptor (GLP-1R)/GIP receptor (GIPR) dual peptide agonist, for the treatment of obesity.

The Phase I trial is a randomized, double-blind, placebo-controlled clinical trial designed to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of ASC35 following single and multiple ascending doses in 84 participants with obesity (body mass index (BMI) ≥ 30.0 kg/m²) or overweight (BMI ≥ 27.0 kg/m²) with weight-related comorbidities. The Phase I trial consists of two parts. Part A is a single ascending dose (SAD) study of ASC35 once-monthly Self-Assembling Lipid Depot (SALD) formulation; Part B is a head-to-head study of multiple ascending doses (MAD) of ASC35 once-monthly SALD formulation compared to the U.S. FDA-approved tirzepatide once-weekly formulation.

ASC35 was discovered and developed in-house utilizing Ascletis' Artificial Intelligence-Assisted Structure-Based Drug Discovery (AISBDD) technology. ASC35 once-monthly SALD formulation was developed utilizing Ascletis' Ultra-Long-Acting Platform (ULAP) technology.

SALD formulation is a low-viscosity solution which is composed of lipids, biocompatible organic solvents, and the active pharmaceutical ingredient (API). The low-viscosity solution can be easily administered into the subcutaneous tissue using an injection pen/auto-injector with a fine needle as thin as 29 gauge. After subcutaneous (SQ) administration, the solution transforms into a gel-like depot in the tissue. Under the action of enzymes in the tissue, the depot slowly degrades, releasing the API over a one-month or longer period.

In head-to-head non-human primate (NHP) studies, ASC35 SALD formulation with SQ administration exhibited an average observed half-life of approximately six-fold longer than tirzepatide in its FDA-authorized SQ formulation. The longer observed half-life and a flatter pharmacokinetic profile of ASC35 in NHPs compared to other peptide incretins may also translate into a better gastrointestinal tolerability in humans.

In head-to-head NHP studies, drug exposures of ASC35 intravenous (I.V.) and SQ administration were approximately 80% and 70% greater than tirzepatide I.V. and SQ administration, respectively.

In a head-to-head diet-induced obese (DIO) mouse study, which is well established as being highly predictive of human efficacy, dosed with equal molar concentrations of ASC35 and tirzepatide, ASC35 demonstrated a relative greater efficacy of 71% compared to tirzepatide.

ASC35 was approximately four-fold more potent than tirzepatide for both GLP-1R and GIPR *in vitro*. Combination of all preclinical studies suggests ASC35 is more efficient on a per-milligram peptide basis compared to tirzepatide.

“The FDA’s IND clearance for ASC35 once-monthly utilizing our proprietary SALD formulation is an exciting and significant milestone for Ascletis’ peptide pipeline to treat obesity as we advance multiple once-monthly to once-quarterly SQ administered peptides into the clinic,” said Jinzi Jason Wu, Ph.D., Founder, Chairman of the Board and chief executive officer of Ascletis, “ASC35’s potential for superior weight loss combined with a more versatile and patient-friendly once-monthly SQ injection will address a major unmet need in the rapidly growing obesity 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 ASC35 successfully.

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

Hong Kong
June 23, 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.