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 CO-FORMULATION OF ASC36, ONCE-MONTHLY NEXT-GENERATION AMYLIN RECEPTOR AGONIST AND ASC35, ONCE-MONTHLY NEXT-GENERATION GLP-1R/GIPR DUAL AGONIST FOR CLINICAL DEVELOPMENT

- *Using Ascletis' proprietary Ultra-Long-Acting Platform technology, co-formulation of ASC36, a once-monthly subcutaneously administered amylin receptor peptide agonist and ASC35, a once-monthly subcutaneously administered GLP-1R/GIPR dual peptide agonist, demonstrated a comparable pharmacokinetic (PK) profile to ASC36 and ASC35 dosed alone in head-to-head non-human primate studies.*

- *ASC36 monotherapy demonstrated approximately 32% greater relative body weight reduction compared to eloralintide monotherapy in a head-to-head diet-induced obese (DIO) rat study, while ASC35 monotherapy demonstrated approximately 71% greater relative body weight reduction compared to tirzepatide monotherapy in a head-to-head DIO mouse study.*

- *Co-formulation of ASC36 and ASC35 demonstrated approximately 51% greater relative body weight reduction compared to the co-formulation of eloralintide and tirzepatide in a head-to-head DIO rat study.*

- *Co-formulation of ASC36 and ASC35 had excellent chemical and physical stability with no aggregation or precipitation caused by fibrillation at neutral pH.*

- *Submission of an Investigational New Drug Application to the U.S. Food and Drug Administration for co-formulation of ASC36 and ASC35 is expected in the second quarter of 2026.*

- *The Company will host a conference call in Mandarin at 10:00 a.m. China Standard Time on November 13, 2025.*

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 the co-formulation of ASC36, a once-monthly next-generation amylin receptor agonist and ASC35, a once-monthly next-generation GLP-1R/GIPR dual agonist for clinical development. Ascletis expects to submit an Investigational New Drug Application (IND) to the U.S. Food and Drug Administration (FDA) for co-formulation of ASC36 and ASC35 for the treatment of obesity in the second quarter of 2026.

Both ASC36, a once-monthly next-generation amylin receptor agonist, and ASC35, a once-monthly next-generation GLP-1R/GIPR dual agonist, were discovered and developed in-house utilizing Ascletis' Artificial Intelligence-Assisted Structure-Based Drug Discovery (AISBDD) and Ultra-Long-Acting Platform (ULAP) technologies. Ascletis has successfully co-formulated ASC36 and ASC35 in the proprietary ultra-long-acting formulation to enable once monthly subcutaneous (SQ) administration using its ULAP technology. Co-formulation of ASC36 and ASC35 had excellent chemical and physical stability with no aggregation or precipitation caused by fibrillation at neutral pH. Some of amylin receptor peptide agonists aggregate or precipitate at neutral pH, which leads to loss of potency, turbidity/particles, device clogging, and higher immunogenicity risk.

In head-to-head non-human primate (NHP) studies, co-formulation of ASC36 and ASC35 demonstrated a comparable pharmacokinetic profile to ASC36 and ASC35 dosed alone, supporting once-monthly SQ dosing.

ASC36 monotherapy demonstrated approximately 32% greater relative body weight reduction compared to eloralintide monotherapy in a head-to-head diet-induced obese (DIO) rat study. ASC35 monotherapy demonstrated approximately 71% greater relative body weight reduction compared to tirzepatide monotherapy in a head-to-head DIO mouse study. The co-formulation of ASC36 and ASC35 demonstrated approximately 51% greater relative body weight reduction compared to the co-formulation of eloralintide and tirzepatide in a head-to-head DIO rat study (Table 1).

Table 1. ASC36 monotherapy and co-formulation of ASC36 and ASC35 demonstrated statistically and significantly more weight loss than eloralintide monotherapy and the co-formulation of eloralintide and tirzepatide in DIO rats after 7-day treatment

Group	Dosing	Total body weight change from baseline	Greater relative weight loss versus eloralintide monotherapy or co-formulation of eloralintide and tirzepatide
Obese rats treated with vehicle	Vehicle, SQ, Q2D	-0.5%	–
Obese rats treated with ASC36 monotherapy	5 nmol/kg, SQ, Q2D	-9.6% (p =0.028 vs eloralintide monotherapy)	32% (vs eloralintide monotherapy)
Obese rats treated with eloralintide monotherapy	5 nmol/kg, SQ, Q2D	-7.3%	–
Obese rats treated with co-formulation of ASC36 and ASC35	5 nmol/kg ASC36/ 8 nmol/kg ASC35, SQ, Q2D	-14.5% (p <0.0001 vs eloralintide monotherapy; p <0.0001 vs co-formulation of eloralintide and tirzepatide)	99% (vs eloralintide monotherapy) 51% (vs co-formulation of eloralintide and tirzepatide)
Obese rats treated with co-formulation of eloralintide and tirzepatide	5 nmol/kg eloralintide/ 8 nmol/kg tirzepatide, SQ, Q2D	-9.6%	–

Note: DIO rats/obese rats: diet-induced obese rats; SQ: subcutaneous; Q2D: once every two days.

"Based on these encouraging preclinical data, we believe the co-formulation of ASC36 and ASC35 has the potential to lead to greater weight loss reduction in people with obesity than single-agent therapies can achieve alone," said Jinzi Jason Wu, Ph.D., Founder, Chairman of the Board and chief executive officer of Ascletis, "The growing body of evidence reinforces our platform technologies' ability to design, optimize and develop multiple once-monthly SQ ultra-long-acting peptides."

Monotherapy and Co-formulation Therapies with ASC36

Ascletis is developing ASC36 as the cornerstone of its once-monthly therapies for the treatment of cardio-metabolic diseases including obesity. With the potential for better efficacy and improved tolerability to GLP-1 therapies, ASC36 is an ideal drug candidate to develop as a monotherapy and co-formulations with other long-acting agents such as ASC35 and potentially ASC47, an adipose-targeted thyroid hormone receptor beta (THRβ) agonist.

Ascletis' AISBDD and ULAP technologies enable the Company to design, optimize and develop multiple once-monthly SQ ultra-long-acting peptides, including ASC35 and ASC36. Based on the properties of peptides, the Company can design, through its proprietary ULAP technology, various slow-release constants (k) for peptides in SQ depots to precisely release injected peptides over desired dosing intervals to reduce peak-to-trough ratios and improve clinical outcomes.

Conference Call

Ascletis will host a conference call in Mandarin at 10:00 a.m. China Standard Time on November 13, 2025. A live webcast of the call will be available via Tencent Meeting/VooV Meeting, with the Meeting ID: 573-120-481, or access links of:

Chinese Mainland: https://meeting.tencent.com/dm/uIyhG5Mtu3op; or

International: https://voovmeeting.com/dm/uIyhG5Mtu3op.

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, ASC36 and/or ASC47 successfully.

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

Hong Kong
November 13, 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.