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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 PRESENTED RESULTS FROM COHORTS 1 AND 2 OF 28-DAY MULTIPLE ASCENDING DOSE STUDY OF ITS ORAL SMALL MOLECULE GLP-1R AGONIST ASC30 AT THE 61ST EUROPEAN ASSOCIATION FOR THE STUDY OF DIABETES (EASD) ANNUAL MEETING

- *ASC30 once-daily oral tablet demonstrated up to 6.5% placebo-adjusted mean body weight reduction from baseline after 28-day treatment.*

- *ASC30 tablet's higher efficacy is supported by its higher oral drug exposures.*

- *ASC30 is safe and well tolerated with only mild-to-moderate gastrointestinal (GI) adverse events (AEs). There was no vomiting incidence in multiple ascending dose (MAD) cohort 1 due to 2 mg to 5 mg weekly titration strategy.*

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 results from cohorts 1 and 2 of 28-day multiple ascending dose (MAD) study of its oral small molecule GLP-1 receptor (GLP-1R) agonist ASC30 (NCT06680440) were presented in the short oral discussion session event A at the 61st European Association for the Study of Diabetes (EASD) Annual Meeting in Vienna, Austria on September 16, 2025.

The Phase Ib MAD study is a randomized, double-blind, placebo-controlled study, conducted in the U.S., to evaluate safety and tolerability, various titration schemes, pharmacokinetics (PK) and preliminary efficacy of ASC30 once-daily oral tablet in participants with obesity (body mass index (BMI): 30-40 kg/m^2).

ASC30 once-daily oral tablet demonstrated a 6.5% placebo-adjusted mean body weight reduction from baseline after 28-day treatment in MAD cohort 2 (weekly titrations of 2 mg, 10 mg, 20 mg, and 40 mg). ASC30 once-daily oral tablet also demonstrated a 4.5% placebo-adjusted 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). No sign of plateau was observed at Day 29.

20 mg and 40 mg ASC30 demonstrated superior oral PK profile at steady state. Higher area under the curve (AUC) positively correlated with greater body weight reduction. Table 1 summarizes the PK profile of ASC30.

Table 1. PK profile of ASC30

		MAD cohort 1 (N = 8)	MAD cohort 2 (N = 8)
Dose level (mg)		2, 5, 10, 20	2, 10, 20, 40
Day 28 (steady state)	T_{max} (h)	8.000 (2.00-8.00)	8.000 (3.00-24.00)
	C_{max} (ng/mL)	272±101	397±274
	AUC_{0-24h} (h*ng/mL)	3,560±1,440	5,060±2,080
	$T_{1/2}$ (h)	41.9±12.9	35.7±13.7

Notes: PK: pharmacokinetics; MAD: multiple ascending dose; T_{max}: time to maximum concentration, shown as median (range); C_{max}: maximum concentration, shown as mean±standard deviation; AUC_{0-24h}: area under the curve over 0-24 hours, shown as mean±standard deviation; $T_{1/2}$: half-life, shown as mean±standard deviation.

ASC30 is safe and well tolerated with only mild to moderate gastrointestinal (GI) adverse events (AEs). During 28-day treatment and 7-day follow up, MAD cohort 1 (2 mg, 5 mg, 10 mg, and 20 mg) had zero incidence of vomiting. Although vomiting events occurred in MAD cohort 2 (2 mg, 10 mg, 20 mg, and 40 mg), most of these vomiting events occurred during 10 mg titration week and no vomiting event was reported during 2 mg titration week. Taken together, the data suggest that weekly titration from 2 mg to 5 mg represents an appropriate escalation pace and provided key evidence to inform the titration schemes for the Phase IIa study design.

No serious adverse events (SAEs) were reported. There were no Grade 3 or higher AEs observed. There were no elevations of liver enzymes including alanine aminotransferase (ALT), aspartate aminotransferase (AST) and total bilirubin (TBL) during the treatment. There were no abnormal findings in laboratory tests, vital signs, ECGs (electrocardiograms, including QTc intervals), and physical exams.

Detailed data presented at the 61st EASD Annual Meeting can be found at Ascletis' website (link).

"We're very excited that we presented in an oral session the clinical data of ASC30 oral tablet at this year's EASD Annual Meeting," said Jinzi Jason Wu, Ph.D., Founder, Chairman of the Board and chief executive officer of Ascletis. "ASC30 oral tablet has shown promising efficacy and safety data, which once again demonstrated our strong R&D capabilities to develop more differentiated options for the treatment of obesity. We're looking forward to reporting topline results from ASC30 oral tablet 13-week Phase IIa study in the fourth quarter this year."

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 without patent extensions.

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.

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

Hong Kong
September 17, 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.