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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 POSITIVE TOPLINE RESULTS FROM U.S. PHASE I STUDY OF ASC50, A POTENTIAL BEST-IN-CLASS ORAL SMALL MOLECULE IL-17 INHIBITOR

- *The elimination half-life of ASC50 after a single oral dose was 43, 89, 91, 87, 104, and 85 hours for 10 mg, 30 mg, 100 mg, 200 mg, 400 mg, and 600 mg, respectively, supporting once-daily or potentially once-weekly oral dosing.*
- *ASC50 had strong target engagement after a single oral dose, indicated by elevated plasma interleukin-17A (IL-17A) levels, which continued until day 7 for higher doses of ASC50.*
- *ASC50 demonstrated a dose-proportional pharmacokinetic profile from 10 mg to 600 mg in single ascending dose study in healthy participants.*
- *ASC50 was safe and well tolerated at all dose levels.*
- *The Company will host a conference call in Mandarin at 8:00 p.m. China Standard Time on December 15, 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 positive topline results from a randomized, double-blind, placebo-controlled Phase I clinical trial in the U.S., evaluating the safety, tolerability, pharmacokinetics and peripherally circulating interleukin-17A (IL-17A) target engagement profile of ASC50 ([NCT07024602](#)) in a single ascending dose (SAD) study in healthy participants. Forty-six healthy participants received 10 mg, 30 mg, 100 mg, 200 mg, 400 mg, or 600 mg of ASC50 or matching placebo. The objectives of the study included safety, tolerability, pharmacokinetics and target engagement.

Key Findings

- The elimination half-life of ASC50 after a single oral dose was 43, 89, 91, 87, 104, and 85 hours for 10 mg, 30 mg, 100 mg, 200 mg, 400 mg, and 600 mg, respectively, supporting once-daily or potentially once-weekly oral dosing.
- ASC50 had strong target engagement after a single oral dose, indicated by elevated plasma IL-17A levels, which continued until day 7 for higher doses of ASC50.
- ASC50 demonstrated a dose-proportional pharmacokinetic profile from 10 mg to 600 mg.
- Following oral dosing in non-human primates (NHPs) in head-to-head studies, ASC50 demonstrated higher absolute oral bioavailability, higher drug exposure, longer half-life and lower clearance than LY4100511 (DC-853), an oral small molecule interleukin-17 (IL-17) inhibitor currently in clinical development.
- ASC50 was safe and well tolerated in the SAD study. All adverse events (AEs) were mild (Grade 1) and transient. No serious adverse events (SAEs) were reported. There was no discontinuation in the study. No hepatic safety signal was detected.

Based on the favorable safety, tolerability, pharmacokinetics and strong target engagement, ASC50 has progressed into the next phase clinical development (multiple ascending dose study) in participants with mild to moderate plaque psoriasis.

ASC50 is an in-house discovered and developed oral small molecule inhibitor targeting IL-17, an important biologically and commercially validated target for multiple autoimmune and inflammatory diseases, including psoriasis. ASC50 is a new chemical entity (NCE), with U.S. and global patent protection through 2043 (excluding potential patent extensions).

“These data demonstrate a favorable safety profile as well as a dose-dependent and differentiated pharmacokinetic profile of ASC50,” said Jinzi Jason Wu, Ph.D., Founder, Chairman of the Board and chief executive officer of Ascletois. “We are encouraged by these data as ASC50 is the first oral small molecule drug candidate in immunology developed from our Artificial Intelligence-assisted Structure-Based Drug Discovery (AISBDD) technology. These findings underscore ASC50’s potential as a best-in-class oral small molecule IL-17 inhibitor.”

Conference Call

Ascletois will host a conference call in Mandarin at 8:00 p.m. China Standard Time on December 15, 2025. A live webcast of the call will be available via Tencent Meeting/VooV Meeting, with the Meeting ID: 889-752-167, or access links of:

Chinese Mainland: <https://meeting.tencent.com/dm/eb7KovQX2hYD>; or

International: <https://voovmeeting.com/dm/eb7KovQX2hYD>.

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 ASC50 successfully.

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

Hong Kong
December 15, 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.