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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

GANNEX'S STRATEGIC PARTNER SAGIMET ANNOUNCES RECEIPT OF FDA BREAKTHROUGH THERAPY DESIGNATION FOR ASC40 (DENIFANSTAT) FOR TREATMENT OF BIOPSY-CONFIRMED F2/F3 MASH

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 Gannex Pharma Co., Ltd. ("Gannex"), a wholly-owned subsidiary of the Company, dedicated to the research and development and commercialization of new drugs in the field of metabolic dysfunction-associated steatohepatitis (MASH), announced that its strategic partner, Sagimet Biosciences Inc. ("Sagimet", Nasdaq stock code: SGMT) received U.S. Food and Drug Administration (FDA) Breakthrough Therapy designation for ASC40 (denifanstat) for treatment of biopsy-confirmed F2/F3 MASH. ASC40 is licensed from Sagimet for the exclusive rights in the Greater China.

Treatments that receive Breakthrough Therapy designation must target a serious or life-threatening disease and preliminary clinical evidence must indicate that the drug may demonstrate a substantial improvement over existing therapies on one or more clinically significant endpoints. Drugs that receive Breakthrough Therapy designation are eligible for all the benefits of Fast Track designation, as well as intensive guidance by FDA on an efficient drug development program and organizational commitment involving FDA senior managers.

In January 2024, Sagimet announced that denifanstat achieved statistically significant results on primary and multiple secondary endpoints in a 52-week clinical trial of 168 MASH patients with stage 2 or 3 fibrosis.

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 ASC40 successfully.

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

Hangzhou, the People's Republic of China October 3, 2024

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.