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 ANNOUNCES U.S. IND APPROVAL OF ASC43F, A FIRST-IN-CLASS DUAL-TARGET FIXED-DOSE COMBINATION FOR NASH

The board of directors (the "**Board**") of Ascletis Pharma Inc. (the "**Company**") is pleased to announce the Investigational New Drug (IND) application approval by U.S. Food and Drug Administration (FDA) and initiation of global development of ASC43F, a first-in-class, fixed-dose combination (FDC) with dual targets of thyroid hormone receptor beta (THRβ) and farnesoid X receptor (FXR) for the treatment of non-alcoholic steatohepatitis (NASH). ASC43F is a drug candidate of the wholly-owned subsidiary of the Company, Gannex Pharma Co., Ltd. (甘萊製藥有限公司, "**Gannex**").

ASC43F is a single tablet, once-a-day (qd), FDC of ASC41 and ASC42. ASC41 is an oral hepatic targeting THRβ agonist prodrug under global clinical development. Previous Phase I studies in the U.S. and China have shown ASC41 to be well tolerated and to significantly reduce low density lipoprotein cholesterol (LDL-C), triglyceride (TG) and total cholesterol (TC) in overweight and obese subjects with elevated LDL-C, a population that is characteristics of NASH. ASC42 is a novel non-steroidal, selective, potent, oral FXR agonist under global clinical development. The Phase I clinical data indicated that no pruritus was observed during 14-day treatment of the once-daily human therapeutic dose of 15 mg, FXR target engagement biomarkers Fibroblast Growth Factor 19 (FGF19) increased 1,780% on Day 14 of treatment with 15 mg, once-daily and 7α-hydroxy-4-cholesten-3-one (C4) decreased 91% on Day 14 of treatment with 15 mg, once-daily.

The U.S. IND approval was based on the efficacy data in the rat NASH model after the coadministration of ASC41 and ASC42, where the combination therapy showed significant improvements on serum TG and liver TC, inflammation, ballooning, NAFLD Activity Score (NAS) and fibrosis. In addition, the data to be presented at the upcoming American Association for Study of Liver Diseases annual conference shown that the dog PK parameters of ASC42 and ASC41A, the active metabolite of ASC41, in/from ASC43F tablets remained approximately unchanged as compared to those of single ASC41 and ASC42 tablets.

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 commercialize ASC43F, ASC41 and ASC42 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
November 01, 2021

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.