Ascletis Pharma Inc.
歌禮製藥有限公司
(incorporated in the Cayman Islands with limited liability)
(Stock Code: 1672)

VOLUNTARY ANNOUNCEMENT

FIRST SUBJECT DOSED IN THE U.S. PHASE I TRIAL FOR ASC43F ONLY HALF A MONTH AFTER IND APPROVAL BY THE U.S. FDA

– *Demonstrating execution excellence of Gannex clinical team*

– *ASC43F is a first-in-class dual targeting fixed-dose combination for NASH*

– *Animal studies showed that dual targeting THRβ and FXR has synergies on reducing liver fat, inflammation and fibrosis*

The board of directors (the "**Board**") of Ascletis Pharma Inc. (the "**Company**" or "**Ascletis**") is pleased to announce dosing of the first subject in the U.S. Phase I trial for ASC43F, a first-in-class, fixed-dose combination (FDC) oral tablet with dual targets of thyroid hormone receptor beta (THRβ) and farnesoid X receptor (FXR) for the treatment of non-alcoholic steatohepatitis (NASH). The U.S. Phase I trial is an open-label, single-dose study to evaluate the safety, tolerability and pharmacokinetics of ASC43F in healthy subjects. ASC43F is a drug candidate of Gannex Pharma Co., Ltd. (甘萊製藥有限公司, "**Gannex**"), a wholly-owned subsidiary of the Company.

ASC43F is a single tablet, once-a-day (QD), FDC of 5 mg ASC41 (THRβ agonist) and 15 mg ASC42 (FXR agonist). Previous Phase I studies in the U.S. and China have shown ASC41 to be well tolerated, has favorable PK profiles in both healthy volunteers and patients with NAFLD, and significantly reduces 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.

The Phase I clinical data indicated that ASC42 is safe and well tolerated, with no pruritus observed and LDC-C values remained within normal range during 14-day treatment of the once-daily human therapeutic dose of 15mg. FXR target engagement biomarkers Fibroblast Growth Factor 19 (FGF19) increased 1,780% and 7α-hydroxy-4-cholesten-3-one (C4) decreased 91% on Day 14 of treatment with 15 mg, once-daily.

Animal studies showed that PK parameters of ASC42 and ASC41A, the active metabolite of ASC41, in or from ASC43F tablets remained approximately unchanged as compared to the PK parameters 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 ASC41, ASC42 and ASC43F 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 18, 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.