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

VOLUNTARY ANNOUNCEMENT

CHINA NMPA APPROVED PHASE II AND III PROTOCOLS OF ASC42, AN FXR AGONIST, FOR TREATMENT OF PRIMARY BILIARY CHOLANGITIS

– *Gannex is expected to complete Phase II trial in 100 patients in the second half of 2022 and initiate Phase III in 140 to 210 patients after*

– *Gannex intends to start a Phase III trial in the U.S. and European Union after the completion of the Phase II study in China*

– *An epidemiology study in China showed that there were approximately 656,000 PBC patients in China in 2010 including 440,000 in females over age 40. An epidemiology study in USA indicated that there were approximately 120,000 PBC patients in USA in 2014*

The board of directors (the "**Board**") of Ascletis Pharma Inc. (the "**Company**" or "**Ascletis**") is pleased to announce that the protocols of Phase II and III clinical trials of ASC42 to treat patients with primary biliary cholangitis (PBC) has been approved by China National Medical Products Administration (NMPA). PBC is a new chronic hepatobiliary disease indication approved for clinical trials of ASC42. The other two chronic hepatobiliary disease indications approved by China NMPA and/or U.S. Food and Drug Administration (FDA) are chronic hepatitis B (CHB) and non-alcoholic steatohepatitis (NASH). ASC42 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.

With the approval of ASC42 PBC Phase II and III protocols by China NMPA, Gannex expects to complete the Phase II trial in 100 patients who have an inadequate response to or are unable to tolerate Ursodeoxycholic acid (UDCA). The Phase II study consists of three active treatment arms and one placebo control arm at the ratio of 1:1:1:1 and is expected to complete in the second half of 2022. Gannex will initiate the Phase III trial after the communications with China NMPA in terms of drug registration related matters such as Chemistry, Manufacturing and Control (CMC) and toxicology studies.

ASC42 is an in-house developed, novel non-steroidal, selective, potent Farnesoid X receptor (FXR) agonist with best-in-class potential and global intellectual property. The data from the U.S. Phase I trial of ASC42 indicated there was no pruritus observed during 14-day treatment of the once-daily human therapeutic dose of 15 mg and FXR target engagement biomarker FGF19 increased 1,780% on Day 14 of treatment with 15 mg dose. Furthermore, mean LDL-C values remained within the normal range during 14-day, once daily treatment with 15 mg.

UDCA is the only drug which is approved in China for PBC and approximately 40% PBC patients have an inadequate response to or are unable to tolerate UDCA. Obeticholic Acid (OCA), which is not approved in China, is the only approved medicine in the U.S. for PBC patients who have an inadequate response to or are unable to tolerate UDCA. However, there are significantly increased pruritus rates and LDL-C levels in patients with OCA treatment. Lack of pruritus and LDL-C level increase at the therapeutic dose makes ASC42 a potential best-in-class PBC drug. Gannex intends to start a Phase III trial in the U.S. and European Union after the completion of the Phase II study in China.

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 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 15, 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.