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. FDA CLEARANCE OF CLINICAL TRIAL ON FXR AGONIST ASC42 FOR TREATMENT OF PRIMARY BILIARY CHOLANGITIS

- *ASC42 has completed Phase I trials in the U.S. and China. This approval from U.S. FDA enables Gannex to complete a critical drug-drug interaction (DDI) study to support upcoming Phase III trials in China, the U.S. and European Union*

- *Gannex expects to complete this DDI study at the beginning of Q4, 2022*

- *Currently, Phase II clinical trial of FXR agonist ASC42 in China is in progress. Gannex intends to start Phase III clinical trials in China, the U.S. and European Union after the completion of the Phase II clinical trial which is ongoing in China*

The board of directors (the "**Board**") of Ascletis Pharma Inc. (the "**Company**" or "**Ascletis**") announces that it has obtained the U.S. Food and Drug Administration (FDA) clearance for ASC42 to initiate a drug-drug interaction (DDI) study. This important DDI study is designed to provide more evidence to support upcoming Phase III clinical trials in China, the U.S. and European Union for treatment of primary biliary cholangitis (PBC). 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.

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. Previous Phase I clinical trial in the U.S. (ClinicalTrials.gov Identifier: NCT04679129) demonstrated that ASC42 might be a potentially best-in-class PBC drug candidate as low density lipoprotein cholesterol (LDL-C) levels were in normal range with no pruritus occurrence, and FXR target engagement biomarker FGF19 increased 1,780% when ASC42 was dosed at 15 mg, once daily (QD) during the 14-day treatment. Currently, Phase II clinical trial of FXR agonist ASC42 in China is in progress. Gannex intends to start a Phase III trial in China, the U.S. and European Union once the ongoing Phase II clinical trial of ASC42 for PBC in China is completed.

PBC is a chronic autoimmune cholestatic disease and frequently progresses to liver fibrosis and cirrhosis requiring liver transplantation or resulting in death. An epidemiology study indicates that there were approximately 120,000 PBC patients in the U.S. in 2014[1]. Ursodeoxycholic acid (UDCA) is the standard treatment for PBC, however, approximately 40% of PBC patients have an inadequate response to or are unable to tolerate UDCA[2]. For those patients with insufficient UDCA response or intolerance, Obeticholic Acid (OCA) is the only approved medicine in the U.S. while it has not been approved in China yet. Additionally, OCA may significantly cause pruritus and LDL-C levels to rise.

[1] Lu M, Zhou Y, Haller I V, et al. Increasing Prevalence of Primary Biliary Cholangitis and Reduced Mortality With Treatment [J]. Clin Gastroenterol Hepatol 2018, 16(8): 1342-50 e1. DOI: 10.1016/j.cgh.2017.12.033.

[2] Lindor K D, Bowlus C L, Boyer J, et al. Primary Biliary Cholangitis: 2018 Practice Guidance from the American Association for the Study of Liver Diseases [J]. Hepatology 2019, 69(1): 394-419. DOI: 10.1002/hep.30145.

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
June 8, 2022

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.