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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 ANNOUNCES THE COMPLETION OF PATIENT ENROLLMENT FOR PHASE II CLINICAL TRIAL OF ASC42, AN FXR AGONIST, FOR PRIMARY BILIARY CHOLANGITIS

– *Gannex is expected to release topline data of the Phase II clinical trial by the end of 2023*

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 of directors (the "**Board**") of the Company announces the completion of enrollment of 98 patients with primary biliary cholangitis (PBC) in the Phase II clinical trial of ASC42, a novel Farnesoid X receptor (FXR) agonist. 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.

The 12-week Phase II study (ClinicalTrials.gov Identifier: NCT05190523) consists of three ASC42 active treatment arms (5 mg, 10 mg and 15 mg) and one placebo control arm and enrolled a total of 98 patients who have an inadequate response to or are unable to tolerate Ursodeoxycholic acid (UDCA). Topline data are expected to be available by the end of 2023.

ASC42 is an in-house developed, novel non-steroidal, selective, potent FXR agonist with best-in-class potential and global intellectual property. The data from the U.S. Phase I trial of ASC42 indicated that there was no pruritus observed during 14-day treatment of the once-daily human therapeutic dose of 15 mg and FXR target engagement biomarker Fibroblast Growth Factor 19 (FGF19) increased by 1,780% on Day 14 of treatment at the dose of 15 mg. Furthermore, mean low density lipoprotein cholesterol (LDL-C) values remained within the normal range during 14-day, once-daily treatment at the dose of 15 mg.

UDCA is the only drug which is approved in China for PBC and approximately 40% of PBC patients have an inadequate response to or are unable to tolerate UDCA[1]. 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[2]. Absence of pruritus and mean LDL-C values within the normal range at the therapeutic dose make ASC42 a potential best-in-class PBC drug candidate.

An epidemiology study in China in 2010 showed that there were approximately 656,000 PBC patients in China including 440,000 in females over age 40[3]. An epidemiology study in the U.S. indicated that there were approximately 120,000 PBC patients in the U.S. in 2014[4].

[1] 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.

[2] Nevens, Frederik et al. "A Placebo-Controlled Trial of Obeticholic Acid in Primary Biliary Cholangitis." The New England journal of medicine vol. 375,7 (2016): 631-43. doi:10.1056/NEJMoa1509840.

[3] Chinese Rheumatology Association (中華醫學會風濕病學分會), "Recommendations for diagnosis and treatment of primary biliary cholangitis in China (2021)"(原發性膽汁性膽管炎診療規範(2021)) J. Zhong Hua Nei Ke Za Zhi. (中華內科雜誌), 2021, 60(8): 709-15. DOI: 10.3760/cma.j.cn112138-20210520-00360.

[4] 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.

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
July 20, 2023

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.