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

VOLUNTARY ANNOUNCEMENT

ASCLETIS ANNOUNCES U.S. IND APPROVAL OF ASC22 (ENVAFOLIMAB) FOR IMMUNE RESTORATION/FUNCTIONAL CURE OF HIV-1 INFECTED PATIENTS

The board of directors (the "**Board**") of Ascletis Pharma Inc. (the "**Company**" or "**Ascletis**") announces the Investigational New Drug (IND) application approval of ASC22 (Envafolimab) by U.S. Food and Drug Administration (FDA) for the indication of immune restoration/functional cure of human immunodeficiency virus 1 (HIV-1) infected patients.

Human immunodeficiency virus (HIV) is estimated to infect approximately 37.7 million people globally, with approximately 0.68 million deaths in 2020 and approximately 1.5 million new infections occurring yearly[1]. In the U.S., there were approximately 1.2 million patients living with HIV at year-end 2019[2]. Combination antiretroviral therapy (cART) may lead to viremia suppression but is not curative, as nearly all HIV infected individuals experience viral rebound within weeks or months after antiretroviral therapy discontinuation.

ASC22 (Envafolimab) is a subcutaneously administered single domain antibody against PD-L1 and has the potential to restore virus-specific immune responses in patients with chronic viral infection. Immune restoration/functional cure in HIV-1 infected patients is the second indication of ASC22 that obtained IND approval from U.S. FDA, in addition to the indication of functional cure of chronic hepatitis B (CHB) patients.

The U.S. FDA approved ASC22 trial is a multi-center, randomized, single-blind, placebo-controlled, Phase I/II clinical trial to evaluate the safety, efficacy, and pharmacokinetics characteristics of ASC22 in HIV infected patients on antiretroviral therapy (ART). The objectives of this Phase I/II trial are (1) to evaluate the safety of ASC22 versus placebo in participants on suppressive ART; (2) to determine whether ASC22 1.0 mg/kg, given once every four weeks, can improve HIV-1-specific cellular immune responses; and (3) to evaluate the effects of ASC22 versus placebo on latency reversal of HIV.

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[1] UNAIDS. Global HIV & AIDS statistics — FACT SHEET. 2021. https://www.unaids.org/en/resources/fact-sheet

[2] CDC. Estimated HIV incidence and prevalence in the United States, 2015-2019. HIV Surveillance Supplemental Report 2021; 26 (No. 1).

Ascletis announced that it had obtained a global and exclusive license as of November 8, 2021 from Suzhou Alphamab Co., Ltd. (蘇州康寧傑瑞生物科技有限公司) to develop and commercialize ASC22 for all viral diseases including Hepatitis B and HIV/AIDS. Ascletis books sales globally for ASC22 of all viral diseases.

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 ASC22 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
May 11, 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.