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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

ASCLETIS ANNOUNCES APPROVAL OF PHASE II CLINICAL TRIAL OF ASC22 (ENVAFOLIMAB) BY CHINA NMPA FOR IMMUNE RESTORATION/FUNCTIONAL CURE OF HIV-1 INFECTED PATIENTS

The board of directors (the “**Board**”) of Ascletis Pharma Inc. (the “**Company**” or “**Ascletis**”) is pleased to announce the approval of the Phase II clinical trial of ASC22 (Envafolelimab) by China National Medical Products Administration (NMPA) for the proposed new indication of immune restoration/functional cure of human immunodeficiency virus 1 (HIV-1) infected patients.

ASC22 (Envafolelimab) 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 developed by Ascletis, in addition to functional cure of chronic hepatitis B (CHB) patients.

HIV is estimated to infect approximately 38 million people globally, with approximately 0.69 million deaths in 2019 and approximately 1.7 million new infections occurring yearly. 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 of discontinuing antiretroviral therapy.

The Phase II study is a randomized, single-blind, placebo-controlled, multi-center clinical trial in China which evaluates the safety and efficacy of 1 mg/kg or 2.5 mg/kg ASC22 or matching placebo given once every four weeks (Q4W) in combination with cART in HIV-1 infected patients with 12-week treatment and 12-week follow-up.

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
Ascleto Pharma Inc.
歌禮製藥有限公司
Jinzi Jason WU
Chairman

Hangzhou, the People's Republic of China
November 10, 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.