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 ANNOUNCED FIRST SUBJECT DOSED IN THE PHASE II CLINICAL TRIAL OF ASC22 (ENVAFOLIMAB) FOR IMMUNE RESTORATION/FUNCTIONAL CURE OF HIV-1 INFECTION

– *The Phase II clinical study in China is currently expected to be completed in early 2023 with an expected enrollment of 30 subjects*

The board of directors (the "**Board**") of Ascletis Pharma Inc. (the "**Company**" or "**Ascletis**") announces that the first subject has been dosed in the China Phase II clinical trial of ASC22 (Envafolimab) in combination with anti-retroviral therapy (ART) for immune restoration/functional cure of human immunodeficiency virus 1 (HIV-1) infection.

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. In addition to the indication of immune restoration/functional cure of HIV-1 infection, Ascletis has developed another indication of ASC22, that is, the one on functional cure of chronic hepatitis B.

This Phase II study (ClinicalTrials.gov Identifier: NCT05330143) is a randomized, single-blind, placebo-controlled, multi-center clinical trial in China to evaluate the safety and efficacy of ASC22 for treatment of HIV-1 infection at the dosage of 1 mg/kg or 2.5 mg/kg or placebo in combination with ART once every four weeks (Q4W) during 12-week treatment and 12-week follow-up.

Subjects of ASC22 arm will be subcutaneously administered with 1 mg/kg or 2.5 mg/kg plus standard ART including Integrase inhibitors (INSTIs) Q4W for 12 weeks. In placebo arm, subjects will be given 0.9% saline plus ART Q4W for 12 weeks. The changes of CD4/CD8 ratio from baseline will be recorded at Week 4, Week 8 and Week 12 as the primary outcome measures.

It was estimated that there were approximately 37.7 million people living with HIV globally with 0.68 million deaths and 1.5 million new infections in 2020[1]. Combination ART can suppress the virus in blood, but it is not curative, as nearly all HIV infected individuals will experience viral rebound within weeks or months when ART is discontinued.

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

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
June 28, 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.