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

VOLUNTARY ANNOUNCEMENT

SHANGHAI PUBLIC HEALTH CLINICAL CENTER COMPLETED PATIENT ENROLLMENT IN CLINICAL STUDY OF PD-L1 ANTIBODY ASC22 (ENVAFOLIMAB) IN COMBINATION WITH CHIDAMIDE FOR FUNCTIONAL CURE OF HIV INFECTION

This announcement is made by Ascletis Pharma Inc. (the "**Company**", 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 that the clinical study of PD-L1 antibody ASC22 (Envafolimab) in combination with Chidamide for functional cure of human immunodeficiency virus (HIV) infection has completed the enrollment of 15 HIV infected patients.

The objective of this study (ClinicalTrials.gov Identifier: NCT05129189) is to evaluate the efficacy of ASC22 (Envafolimab) combined with Chidamide on the viral reservoirs of latently infected cells in HIV patients. Ascletis BioScience Co., Ltd., a wholly-owned subsidiary of the Company incorporated in the People's Republic of China, and Shenzhen Chipscreen Biosciences Co., Ltd. provide ASC22 (Envafolimab) and Chidamide, respectively, for the clinical trial.

The study design of this trial is 1 mg/kg ASC22 (Envafolimab) subcutaneous injection once every four weeks (Q4W) in combination with 10 mg Chidamide administered orally twice a week (BIW) with 12-week treatment.

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 such as hepatitis B virus (HBV) and HIV. Latently infected cells by HIV are a major barrier to curing HIV infection. Recent data [1] demonstrated that blocking PD-1/PD-L1 pathway resulted in reversing HIV latency in the clinical trial and supported the rationale for combining PD-1/PD-L1 antibody with other drugs to reduce the HIV reservoir of latently infected cells. Chidamide is the global first approved subtype-selective histone deacetylase oral inhibitor (HDACi) mainly targeting the subtype 1, 2, 3 of Class I and subtype 10 of Class IIb histone deacetylase (HDAC), with a mechanism against epigenetic abnormality.

[1] Uldrick et al., Sci. Transl. Med. 14, eabl3836 (2022) 26 January 2022

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
September 15, 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.