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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**

### **SHANGHAI PUBLIC HEALTH CLINICAL CENTER PRESENTED CLINICAL RESULTS OF ASC22 (ENVAFOLIMAB) IN COMBINATION WITH CHIDAMIDE FOR FUNCTIONAL CURE OF HIV INFECTION AT THE 12TH IAS CONFERENCE ON HIV SCIENCE**

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 that Shanghai Public Health Clinical Center presented clinical results of ASC22 (Envafolelimab) in combination with Chidamide for functional cure of human immunodeficiency virus (HIV) infection at the 12th International AIDS Society (IAS) Conference on HIV Science in Brisbane, Australia, and virtually.

Led by Jun Chen, MD, Deputy Chief Physician, Infection and Immunity, Shanghai Public Health Clinical Center, this investigator-initiated Phase II trial (ClinicalTrials.gov Identifier: NCT05129189) enrolled 15 subjects in total living with HIV who had achieved virological suppression to receive a subcutaneous injection of ASC22 (1 mg/kg) once every four weeks (Q4W) in combination with 10 mg Chidamide administered orally twice a week (BIW) during the 12-week treatment while maintaining antiretroviral therapy (ART). Subjects were followed up for 24 weeks and measured the changes in the levels of cell-associated (CA) HIV RNA, plasma HIV RNA, total and integrated HIV DNA and HIV-specific CD8+ T cell function.

The objective of this study is to evaluate the efficacy of ASC22 (Envafolelimab) combined with Chidamide on the viral reservoirs of latently infected cells in HIV-infected people. Ascletis BioScience Co., Ltd. (歌禮生物科技(杭州)有限公司), a wholly-owned subsidiary of the Company, provided ASC22 (Envafolelimab) for the clinical trial.

This Phase II study showed that combination treatment with ASC22 and Chidamide is well tolerated and effectively activated latent HIV reservoirs. There was a significant increase in CA HIV RNA at week 8 and week 12 compared to the baseline, with an average rise of 4.27-fold and 3.41-fold, respectively ( $P=0.001$ ,  $P=0.006$ ) in the subjects. The HIV CA RNA to total DNA ratios also showed the same trend ( $P=0.038$ ,  $P=0.017$ , respectively). Further investigations are warranted.

It was estimated that there were approximately 39 million people living with HIV globally with 0.63 million deaths caused by AIDS-related illnesses and 1.3 million new HIV infections in 2022<sup>[1]</sup>. 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.

<sup>[1]</sup> UNAIDS. Global HIV & AIDS statistics — FACT SHEET. 2022.

<https://www.unaids.org/en/resources/fact-sheet>

## **About International AIDS Society (IAS) Conference on HIV Science**

The International AIDS Society (IAS) Conference on HIV Science is the premier global platform to advance the HIV response. As the world's largest conference on HIV and AIDS, it sits uniquely at the intersection of science, advocacy and human rights, bringing together scientists, policy makers, healthcare professionals, people living with HIV, funders, media and communities. IAS 2023, the 12th IAS Conference on HIV Science, is scheduled to take place in Brisbane, Australia, and virtually from 23 to 26 July 2023.

**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  
July 25, 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.*