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 IND APPROVAL OF ORAL 3CLPRO INHIBITOR ASC11 FOR COVID-19 BY U.S. FDA

- *The Phase I clinical trial will consist of 3 cohorts in healthy subjects, including single- and multiple-dose escalation studies and food effect study. The objective of Phase I trial is to find a right dose to move into the pivotal Phase II/III in COVID-19 patients*

- *In antiviral cellular assays with infectious SARS-CoV-2, ASC11 demonstrated much higher potency against SARS-CoV-2 than other 3-chymotrypsin like protease (3CLpro) inhibitors including Nirmatrelvir, S-217622, PBI-0451 and EDP-235*

- *Ascletis has filed global patent applications for ASC11 and related compounds and their use in viral disease*

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 the U.S. Food and Drug Administration (FDA) has approved the Investigational New Drug (IND) application of ASC11, an oral inhibitor drug candidate targeting 3-chymotrypsin like protease (3CLpro) for COVID-19.

U.S. FDA has approved to study safety, tolerability and pharmacokinetics of ASC11 at various doses in healthy subjects co-dosed with 100 mg ritonavir tablets. Both ASC11 and ritonavir tablets are manufactured by Ascletis.

The Phase I clinical trial will consist of 3 cohorts in healthy subjects, including single- and multiple-dose escalation studies and food effect study. The objective of Phase I trial is to find a right dose to move into the pivotal Phase II/III in COVID-19 patients.

In antiviral cellular assays with infectious SARS-CoV-2, ASC11 demonstrated much higher potency against SARS-CoV-2 than other 3CLpro inhibitors including Nirmatrelvir, S-217622, PBI-0451 and EDP-235. ASC11 remains potent antiviral activity against various popular Omicron variants such as BA.1 and BA.5. In the animal model with infectious SARS-CoV-2, ASC11 also showed potent antiviral activity.

ASC11 is an in-house discovered oral small molecule drug candidate using various proprietary technologies including molecular docking. Ascletis has filed global patent applications for ASC11 and related compounds and their use in viral disease.

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 ASC11 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
November 23, 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.