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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 IND APPROVAL OF ASC10 FOR MONKEYPOX INDICATION BY U.S. FDA**

- *Based on available data, ASC10 at the dosage of 800 mg twice daily was approved by the U.S. Food and Drug Administration (FDA) to conduct a Phase Ib study in patients with monkeypox virus disease*
- *Preclinical studies show that ASC10-A, active metabolite of double prodrug ASC10, has potent antiviral activities against both monkeypox and SARS-CoV-2 viruses*

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 ASC10 for monkeypox indication. Based on available data, 800 mg ASC10 twice daily was approved by U.S. FDA to conduct a Phase Ib, randomized, double blind, placebo-controlled study to evaluate safety, tolerability, efficacy and pharmacokinetics of ASC10 tablets in patients with monkeypox virus disease.

ASC10 is an oral double prodrug. After oral administration, both ASC10 and single prodrug molnupiravir are rapidly and completely converted *in vivo* into the same active metabolite ASC10-A, also known as  $\beta$ -D-N4-hydroxycytidine (NHC) or EIDD-1931.

Preclinical studies show that ASC10-A has broad spectrum antiviral activities including potent activities against both monkeypox and SARS-CoV-2 viruses. Ascletis has filed multiple patent applications globally for ASC10 and its use in viral diseases including monkeypox virus infection.

Monkeypox virus is an orthopoxvirus that causes a disease with symptoms similar to smallpox<sup>[1]</sup>. As of November 15, 2022, over 79,000<sup>[2]</sup> confirmed cases have been reported globally and monkeypox virus has spread in 110 countries<sup>[2]</sup> according to data from World Health Organization (WHO). In particular, a total of 28,947<sup>[3]</sup> confirmed monkeypox cases have been reported in the U.S. WHO assesses the risk of monkeypox virus in the Region of the Americas as high<sup>[2]</sup>.

Data from *in vitro* antiviral cellular assay with infectious monkeypox virus, a study sponsored by Ascletis and conducted at IIT Research Institute (IITRI) of Illinois Institute of Technology in Chicago, U.S, showed that ASC10-A has potent antiviral activity against monkeypox virus, suggesting that ASC10 has the potential to be an effective treatment of monkeypox virus infection. Researchers from National Institute of Infectious Diseases, Tokyo, Japan, tested 132 drugs and the results showed that molnupiravir (active metabolite ASC10-A) and other two drugs have potent cellular antiviral activity in the infectious monkeypox virus assay<sup>[4]</sup>. The rest of 129 drugs such as remdesivir, favipiravir, sofosbuvir and ribavirin, etc. do not have antiviral activities against monkeypox virus<sup>[4]</sup>.

<sup>[1]</sup> [https://www.who.int/health-topics/monkeypox/#tab=tab\\_1](https://www.who.int/health-topics/monkeypox/#tab=tab_1)

<sup>[2]</sup> [https://worldhealthorg.shinyapps.io/mpx\\_global/](https://worldhealthorg.shinyapps.io/mpx_global/)

<sup>[3]</sup> <https://www.cdc.gov/poxvirus/monkeypox/response/2022/index.html>

<sup>[4]</sup> Daisuke Akazawa, Hirofumi Ohashi, Takayuki Hishiki, et al. Potential anti-monkeypox virus activity of atovaquone, mefloquine, and molnupiravir, and their potential use as treatments. bioRxiv preprint. <https://doi.org/10.1101/2022.08.02.502485>

**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 ASC10 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 16, 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.*