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 PD-L1 SMALL MOLECULE INHIBITOR ASC61 FOR TREATMENT OF ADVANCED SOLID TUMORS BY CHINA NMPA

– *While the ASC61 Phase I study is ongoing in the U.S., the Investigational New Drug (IND) approval in China will accelerate the global development of ASC61, an in-house developed oral PD-L1 small molecule inhibitor*

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 the approval of the Investigational New Drug (IND) application by China National Medical Products Administration (NMPA) for the in-house developed oral PD-L1 small molecule inhibitor, ASC61, for the treatment of advanced solid tumors. While the ASC61 Phase I dose escalation study is ongoing in the U.S., IND approval in China will accelerate the global development of ASC61.

ASC61 is an oral small molecule inhibitor prodrug. Its active metabolite, ASC61-A, is a potent and highly selective inhibitor which blocks PD-1/PD-L1 interaction through inducing PD-L1 dimerization and internalization. As a single agent, ASC61 demonstrated significant antitumor efficacy in multiple animal models including humanized mouse model. Preclinical studies showed that ASC61 has good safety and pharmacokinetic profiles in animal models.

In a head-to-head comparison study using the human PD-L1 expressing cells and fresh peripheral blood mononuclear cells (PBMCs) co-culture assay, ASC61-A treatment induced secretion of IFNγ in a concentration dependent manner, with an EC_{50} of 2.86 nM. Maximal levels of IFNγ induced by ASC61-A were similar to that induced by Keytruda, a marketed PD-1 antibody.

Compared with PD-1/PD-L1 antibody injections, the oral PD-L1 inhibitor ASC61 has the following benefits: (1) higher patient compliance with easy and safe administration with no need of hospital visits for injections; (2) ease of all oral combination therapies with other oral anti-tumor drugs; (3) easier to manage immune-related adverse effects (irAEs) with dose adjustment; (4) relatively lower cost; and (5) higher permeability to distribute into targeted tissues.

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 ASC61 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 17, 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.