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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

IND APPROVAL OF ASC09/RITONAVIR FIXED-DOSE COMBINATION

The Board of Directors (the “**Board**”) of Ascletis Pharma Inc. (the “**Company**”) is pleased to announce that, the Company has received the Investigational New Drug (IND) approval from National Medical Products Administration (國家藥品監督管理局, the “**NMPA**”) for its human immunodeficiency virus (HIV) protease inhibitor ASC09/Ritonavir Fixed-Dose Combination (ASC09F). The IND filing for ASC09F was accepted on December 30, 2019 by the NMPA.

ASC09 has an unprecedented high genetic barrier to resistance and has completed Phase I and Phase IIa clinical trials, which have shown potent anti-viral activity. Previous clinical trials have also shown that ASC09 is safe and well-tolerated. After two weeks of treatment of mono-therapy, ASC09 demonstrated up to a 1.79 log viral load decrease (62-fold reduction of viral load in blood samples of patients). Our studies have shown that ASC09 requires seven mutations before HIV develops resistance to ASC09, indicating ASC09 to have high genetic barrier to resistance compared to other approved protease inhibitors. These characteristics make ASC09 a promising HIV drug therapy candidate for both treatment-naïve and treatment-experienced patients. ASC09 is a potential best-in-class protease inhibitor to treat HIV type-1 infections, licensed as TMC310911 from Janssen R&D Ireland in 2013 for development and commercialization in Greater China.

Ritonavir is a potent CYP3A4 inhibitor in addition to being a HIV protease inhibitor. The clinical trials have shown that a low-dose of Ritonavir can inhibit CYP3A4-mediated metabolism of other HIV protease inhibitors, increase their drug plasma concentration, boost their overall exposure, and thus increase their potency.

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 obtain further approval for, or ultimately market, ASC09F 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
April 13, 2020

As at the date of this announcement, the Board of Directors of the Company comprises Dr. Jinzi Jason WU and Mrs. Judy Hejingdao WU, as executive Directors; Dr. Ru Rong JI, Dr. Yizhen WEI, Mr. Jiong GU and Ms. Lin HUA, as independent non-executive Directors.