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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 RECEIVED CHINA IND APPROVAL OF ITS FXR AGONIST ASC42 FOR CHRONIC HEPATITIS B INDICATION

– *Chronic hepatitis B is ASC42's second indication following the approval of NASH indication*

– *In vivo HBV infection mouse model results indicated that ASC42 significantly inhibited HBsAg and HBV pgRNA, biomarkers for functional cure of chronic hepatitis B*

– *ASC42 in combination with ASC22 (PD-L1 antibody) or pegylated interferon may have synergistic effect, leading to the potentially high rate of functional cure of chronic hepatitis B*

The board of directors (the "**Board**") of Ascletis Pharma Inc. (the "**Company**") is pleased to announce that China National Medical Products Administration (NMPA) has approved the Investigational New Drug (IND) application for its drug candidate ASC42 to conduct clinical trials for chronic hepatitis B (CHB) indication.

ASC42 is an in-house developed, selective, potent farnesoid X receptor (FXR) agonist. ASC42 is an oral tablet formulation developed with in-house proprietary technology and is stable at room temperature.

Both in vitro primary human hepatocyte (PHH) cells and in vivo AAV/HBV mouse studies demonstrated that ASC42 significantly inhibited serum hepatitis B surface antigen (HBsAg) and HBV pregenomic RNA (pgRNA), indicating that ASC42 has therapeutic potential to functionally cure CHB.

Nucleot(s)ide analogues (direct antiviral drugs) inhibit only reverse transcription of HBV RNA into HBV DNA and do not inhibit the transcription of HBV cccDNA (covalently closed circular DNA) into HBV RNA, thus have no inhibitory effect on HBsAg. As an FXR agonist, ASC42 has unique mechanism of action against HBV: ASC42 inhibits the transcription of HBV cccDNA into HBV RNA, which in turn inhibits the translation of HBV RNA into HBsAg. ASC42 may also reduce HBV cccDNA stability.

ASC42 is the second investigational new drug of the Company for HBV functional cure. Another investigational new drug for HBV functional cure is PD-L1 antibody ASC22, which is currently in Phase IIb study and has demonstrated good safety and preliminary efficacy in HBsAg reduction in Phase IIa study.

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 ASC42 and 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
June 7, 2021

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.