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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**

## SUSTAINED HEPATITIS B SURFACE ANTIGEN LOSS IN CHRONIC HEPATITIS B PATIENTS WITH SUBCUTANEOUS PD-L1 ANTIBODY ASC22 TREATMENT: INTERIM RESULTS OF PHASE IIb STUDY

- Hepatitis B Surface Antigen (HBsAg) loss was assessed in 44 patients who completed 24-week treatment of 1 mg/kg ASC22 (n=33) or Placebo (n=11) + nucleos(t)ide analogs (NAs).
- 16 out of 33 patients treated with ASC22 had baseline HBsAg ≤ 500 IU/mL, 19% (3/16) of patients obtained HBsAg loss and no rebound after the last dosing of ASC22, indicating HBV functional cure.

The board of directors (the "Board") of Ascletis Pharma Inc. (the "Company") is pleased to announce that the interim results of 44 chronic hepatitis B (CHB) patients from a Phase IIb trial of ASC22 (Envafolimab), a subcutaneously administered PD-L1 antibody (ClinicalTrials.gov Identifier: NCT04465890), demonstrated sustained HBsAg loss in CHB patients with baseline HBsAg ≤ 500 IU/mL. The result abstract has been selected for oral presentation in Late Breaking Session at The Liver Meeting® 2021 by the American Association for the Study of Liver Diseases (AASLD), which has to be of sufficient scientific importance and high impact to meet the criteria of Late-Breaking Abstract of The Liver Meeting®.

The Phase IIb study is a randomized, single-blind, placebo-controlled, multi-center clinical trial in China which evaluates the efficacy and safety of treating CHB patients for 24-week treatment of 1 mg/kg or 2.5 mg/kg ASC22 or matching placebo given once every two weeks (Q2W) in combination with NAs.

Abstract to be presented is as follow:

HBsAg LOSS IN CHRONIC HEPATITIS B PATIENTS WITH SUBCUTANEOUS PD-L1 ANTIBODY ASC22 (ENVAFOLIMAB) PLUS NUCLEOS(T)IDE ANALOGS TREATMENT: INTERIM RESULTS FROM A PHASE IIb CLINICAL TRIAL

• **Presentation Type:** Oral, Parallel Session

Publication Number: LO12

• **Session Title:** Late Breaking Session 2

• **Presenting Author:** Dr. Jinzi J. Wu, Ascletis BioScience Co., Ltd.

• Session Broadcast Date and Time: Monday, November 15, 2021, 12:30-02:00 PM EST

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 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 November 09, 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.