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 POSITIVE INTERIM DATA FROM THE PHASE IIB EXPANSION COHORT OF ASC22 (ENVAFOLIMAB) FOR CHRONIC HEPATITIS B FUNCTIONAL CURE

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 positive interim data from the Phase IIb expansion cohort (the "**Expansion Cohort**") of subcutaneously administered PD-L1 antibody ASC22 (Envafolimab) for functional cure of chronic hepatitis B (CHB).

The Expansion Cohort is a randomized, single-blind, placebo-controlled and multi-center clinical trial (ClinicalTrials.gov: **NCT04465890**) and planned to enroll approximately 50 CHB patients with baseline hepatitis B surface antigen (HBsAg) ≤100 IU/mL who would be treated with 1.0 mg/kg ASC22 or placebo (at a ratio of approximately 4:1) once every two weeks(Q2W) for 24-week treatment plus 24-week follow-up. All patients in both ASC22 and placebo cohorts received nucleot(s)ide analogues (NAs) as a background therapy. In the second quarter of 2023, Ascletis successfully completed the enrollment of 49 CHB patients, including 40 patients in ASC22 cohort and 9 patients in placebo cohort.

Interim analysis was conducted when approximately 50% of the enrolled patients completed 24-week treatment of ASC22 or placebo. The interim analysis included 25 patients who completed 24-week treatment (19 patients in ASC22 cohort and 6 patients in placebo cohort). Topline results indicated that in ASC22 cohort, 4 patients (4/19, 21.1%) achieved HBsAg loss at the end of 24-week treatment. In contrast, there were no patients (0/6, 0%) achieving HBsAg loss at the end of 24-week treatment in the placebo cohort. ASC22 was generally safe and well tolerated. Most of ASC22 drug related adverse effects were Grade 1 or 2.

CHB remains to be a significantly unmet medical need globally, with approximately 86 million people in China and 1.59 million people in the U.S. infected with hepatitis B virus (HBV)[1].

[1] Lim J K, Nguyen M H, Kim W R, et al. Prevalence of Chronic Hepatitis B Virus Infection in the United States [J]. The American journal of gastroenterology 2020, 115(9): 1429-38.

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
September 29, 2023

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.