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 POSTER PRESENTATIONS AT AASLD ANNUAL MEETING 2023 INCLUDING A LATE-BREAKING ABSTRACT OF INTERIM RESULTS FROM PHASE IIB EXPANSION COHORT OF ASC22 FOR FUNCTIONAL CURE OF CHB

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 late-breaking abstract poster presentation of interim results from Phase IIb expansion cohort of ASC22 (Envafolimab) for functional cure of chronic hepatitis B (CHB), and abstract poster presentation of Phase I study results of ASC41 for treatment of non-alcoholic steatohepatitis (NASH) at The Liver Meeting® 2023 of the American Association for the Study of Liver Diseases (AASLD).

Late-Breaking Abstract Poster Presentation:

Poster ID: 5052-C

Title:

HBsAg Loss in Chronic Hepatitis B Patients After 24-Week Treatment with Subcutaneously Administered PD-L1 Antibody ASC22 (Envafolimab): Interim Results from a Phase IIb Expansion Cohort

Background:

An expansion cohort of 49 patients with baseline hepatitis B surface antigen (HBsAg)≤100 IU/mL has been initiated to explore sustained HBsAg loss in this specific population.

Methods:

ASC22 expansion cohort enrolled 49 patients with baseline HBsAg≤100 IU/mL. At a ratio of approximately 4:1, patients are subcutaneously administered with 1.0 mg/kg ASC22 once every two weeks (Q2W) (ASC22 cohort, n=40) or placebo (n=9) for 24-week treatment in background Nucleot(s)ide Analogues (NAs). After treatment, the follow-up period is 24 weeks. Patients who achieve HBsAg loss at completion of 24-week treatment of ASC22 are expected to discontinue background NAs for the follow-up. The primary efficacy endpoint is HBsAg reduction. Interim analysis was conducted when approximately 50% of enrolled patients completed 24-week treatment of ASC22 or placebo.

Conclusion:

ASC22 monotherapy with background NAs showed statistically significant HBsAg reduction and 21.1% (4/19) HBsAg loss after 24-week treatment. Together with the acceptable safety profile and convenient subcutaneous injections, ASC22 demonstrated potential as a promising immune-therapy for CHB.

Poster Presentation:

Poster ID: 2401-C

Title:

ASC41, a Thyroid Hormone Receptor β Agonist, Showed Little Drug Interaction, Significant Lipid Reduction and Comparable Pharmacokinetic Profiles among Chinese and US Healthy Subjects and Patients with Non-alcoholic Fatty Liver Disease (NAFLD): Results from Two Phase 1 Studies

Background:

Results of ASC41 drug-drug interaction (DDI) study in US healthy subjects and pharmacokinetic (PK), safety and pharmacodynamic (PD) in Chinese healthy subjects or US subjects with non-alcoholic fatty liver disease (NAFLD) have been reported.

Methods:

NCT04527250 was a randomized, double-blind, placebo-controlled study to evaluate safety, tolerability, PK and PD of single and multiple ascending oral doses of ASC41. NCT04845646 was an open label, DDI study to evaluate effect of itraconazole (CYP3A strong inhibitor) and phenytoin (CYP3A strong inducer) on PK of ASC41 following a single dose of 5 mg ASC41 tablet and PK in NAFLD patients.

Conclusion:

PK of ASC41-A, the active metabolite of ASC41, was comparable among US and Chinese healthy subjects and NAFLD patients. ASC41 demonstrated significant reductions of lipids. ASC41 exhibited satisfactory safety and tolerability. Drug-drug interactions of ASC41/ASC41-A with strong CYP3A4 inhibitor or inducer were low, showing competitiveness to other thyroid hormone receptor β (THR-β) agonists in the late stage clinical development. It is unlikely that there will be clinically significant drug-drug interactions between ASC41/ASC41-A and the most frequently used antidepressants and statins, indicating broad application in patients with NASH. ASC41 is currently in a 52-week Phase 2 trial to treat biopsy-confirmed NASH patients.

About AASLD

American Association for the Study of Liver Diseases (AASLD) is the leading organization of scientists and health care professionals committed to preventing and curing liver disease. AASLD fosters research that leads to improved treatment options for millions of liver disease patients. AASLD advances the science and practice of hepatology through educational conferences, training programs, professional publications, and partnerships with government agencies and sister societies.

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 and/or ASC41 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 13, 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.