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 COMPLETION OF ENROLLMENT OF 120 PATIENTS IN THE PHASE III CLINICAL TRIAL OF FASN INHIBITOR ASC40 COMBINED WITH BEVACIZUMAB FOR TREATMENT OF RECURRENT GLIOBLASTOMA

– *Based on prespecified interim analysis condition, 120 patients are likely to lead sufficient events for interim analysis of progression-free survival (PFS)*

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 the completion of enrollment of 120 patients in the Phase III registration clinical trial of ASC40 combined with bevacizumab for treatment of recurrent glioblastoma (rGBM). ASC40 is an oral, selective small molecule inhibitor of fatty acid synthase (FASN), a key enzyme which regulates de novo lipogenesis (DNL). ASC40 inhibits energy supply and disturbs membrane phospholipid composition of tumor cells by blocking de novo lipogenesis [1].

The Phase III registration clinical trial (ClinicalTrials.gov Identifier: **NCT05118776**) is a randomized, double-blind, placebo-controlled, multi-center clinical trial in China to evaluate progression-free survival (PFS), overall survival (OS) and safety of patients with rGBM. Approximately 180 patients will be randomized at the ratio of 1:1 to Cohort 1 (oral ASC40 tablet, once daily + Bevacizumab) and Cohort 2 (matching placebo tablet, once daily + Bevacizumab). Based on prespecified interim analysis condition, 120 patients are likely to lead sufficient events for interim analysis of PFS. The interim analysis will be conducted after 93 PFS events are observed.

Glioblastoma (GBM) is the most aggressive diffuse glioma of astrocytic lineage and is considered a grade IV glioma based on the World Health Organization (WHO) classification [2]. Research shows that glioblastoma (GBM) accounts for 57% of gliomas and has an incidence rate of approximately 2.85 to 4.56 per 100,000 population in China per year, suggesting approximately 40,000 to 64,000 new cases of GBM per year [3]. In the U.S., GBM represents 56.6% of gliomas and has an incidence rate of approximately 3.21 per 100,000 population per year [4]. Over 90% GBM patients will relapse after surgery, radiation and chemotherapies. Effective treatments are extremely limited for patients with rGBM.

[1] Fhu CW, Ali A. Fatty Acid Synthase: An Emerging Target in Cancer. Molecules. 2020;25(17):3935. doi:10.3390/molecules25173935.

[2] Louis N, Perry A, Reifenberge RG, von Deimling A, Figarella-Branger D, Cavenee WK, et al. The 2016 World Health Organization classification of tumors of the central nervous system: A summary. Acta Neuropathol. 2016;131:803-20.

[3] 2017 China Cancer Registry Annual Report.

[4] Ostrom Q T, Gittleman H, Truitt G, et al. CBTRUS Statistical Report: Primary Brain and Other Central Nervous System Tumors Diagnosed in the United States in 2011-2015 [J]. Neuro Oncol 2018, 20(suppl_4): iv1-iv86. DOI: 10.1093/neuonc/noy131.

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 ASC40 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 26, 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.