Ascletis Pharma Inc.
歌禮製藥有限公司
(incorporated in the Cayman Islands with limited liability)
(Stock Code: 1672)

ANNOUNCEMENT
INSIDE INFORMATION

CHINA NMPA APPROVES PHASE III CLINICAL TRIAL OF ASC40 COMBINED WITH BEVACIZUMAB FOR TREATMENT OF PATIENTS WITH RECURRENT GLIOBLASTOMA

- *Phase III trial will evaluate progression-free survival and overall survival of patients with recurrent glioblastoma*

- *Glioblastoma has an incidence rate of approximately 2.85 to 4.56 per 100,000 population per year in China, suggesting approximately 40,000 to 64,000 new cases of glioblastoma per year. More than 90% glioblastoma patients will relapse after surgery, radiation and chemotherapies*

- *This is the first Phase III trial of ASC40 as a first-in-class drug candidate targeting tumor lipid metabolism*

- *Phase II data of patients with recurrent glioblastoma have shown that the overall response rate for ASC40 plus Bevacizumab treatment was 65% including a complete response of 20% and a partial response of 45%*

- *Phase I data of ASC40 alone and with a taxane have demonstrated promising responses in patients with advanced breast cancer and non-small cell lung cancer containing KRAS mutations*

This announcement is made by Ascletis Pharma Inc. (the "**Company**") pursuant to Rule 13.09 of the Rules Governing the Listing of Securities (the "**Listing Rules**") on The Stock Exchange of Hong Kong Limited and the Inside Information Provisions under Part XIVA of the Securities and Futures Ordinance (Chapter 571 of the Laws of Hong Kong).

The board of directors (the "**Board**") of the Company is pleased to announce that China National Medical Products Administration (NMPA) has approved the Phase III clinical trial application of ASC40 combined with Bevacizumab for treatment of patients with recurrent glioblastoma (rGBM).

The Phase III registrational study 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 1:1 randomized to Cohort 1 (oral ASC40 tablet QD + Bevacizumab) and Cohort 2 (matching placebo tablet QD + Bevacizumab).

On May 25, 2021, the Company announced that the clinical trial application for rGBM was accepted for review by China NMPA.

Based on published data, in China, glioblastoma (GBM) represents 46.1% of gliomas and has an incidence rate of approximately 2.85 to 4.56 per 100,000 population per year, suggesting approximately 40,000 to 64,000 new cases of GBM per year. More than 90% GBM patients will relapse after surgery, radiation and chemotherapies. In the United States, GBM represents 56.6% of gliomas and has an incidence rate of approximately 3.21 per 100,000 population per year.

Bevacizumab is the only drug which has been approved for rGMB indication in China as of September, 2020. The data of BELOB Trial indicated that median PFS was three months for patients with rGBM after Bevacizumab treatment.

Lipid metabolism has been reported to play a critical role in various cancers. Fatty acid synthase (FASN) is one of the most important proteins which regulate lipid metabolism. Many solid and hematopoietic tumors overexpress FASN, including rGBM, non-small cell lung, breast, ovarian, prostate, colon, pancreatic cancers, and non-Hodgkin lymphoma.

ASC40 (known as TVB-2640 outside China) is a potent, selective and safe oral small molecule inhibitor of FASN. The data from the Phase II trial have shown that the overall response rate (ORR) for ASC40 (TVB-2640) plus Bevacizumab was 65% including a complete response (CR) of 20% and a partial response (PR) of 45%. Furthermore, the Phase II data indicate that the progression-free survival at six months (PFS6) observed for ASC40 (TVB-2640) plus Bevacizumab was 47%, representing a statistically significant improvement in PFS6 over the historical Bevacizumab monotherapy PFS6 of 16% (BELOB Trial) (P=0.01). ASC40 (TVB-2640) in combination with Bevacizumab was safe and well tolerated in such patient population (ClinicalTrials.gov Identifier: NCT03032484).

A Phase I clinical trial was completed on 136 patients with advanced tumors from the United States and United Kingdom. The patients were treated with ASC40 (TVB-2640) alone and with a taxane. The data from this Phase I trial have demonstrated FASN target engagement, good safety, pharmacokinetics as well as promising responses of ASC40 (TVB-2640) in patients with advanced solid tumors, particularly in lung cancer with KRAS mutations, ovarian cancer, and breast cancer (ClinicalTrials.gov Identifier: NCT02223247).

There are additional clinical trials of ASC40 (TVB-2640) ongoing in the United States in patients with KRAS mutation non-small cell lung cancer (ClinicalTrials.gov Identifier: NCT03808558) and breast cancer (ClinicalTrials.gov Identifier: NCT03179904).

Cautionary Statement required by Rule 18A.05 of the Listing Rules: We cannot guarantee that we will be able to ultimately commercialize ASC40 successfully.

Shareholders and potential investors are advised to exercise caution when dealing in the shares of the Company.

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
July 22, 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.