Abbisko Cayman Limited
和譽開曼有限責任公司
(Incorporated in the Cayman Islands with limited liability)
(Stock Code: 2256)

VOLUNTARY ANNOUNCEMENT
ABSK021 PHASE III TGCT CLINICAL TRIAL APPROVED BY EMA

Abbisko Cayman Limited (the "**Company**", together with its subsidiaries, the "**Group**") hereby informs the shareholders and potential investors of the Company of the attached press release that Abbisko Therapeutics Co., Ltd., a subsidiary of the Company, announced that the European Medicines Agency (EMA) had approved its innovative CSF-1R inhibitor Pimicotinib（ABSK021）for a randomized, double-blind, placebo-controlled, multi-centered Phase III clinical study for the safety and efficacy in patients with tenosynovial giant cell tumor（TGCT）. This is another important milestone after Pimicotinib was approved by the Center for Drug Evaluation, National Medical Products Administration of China (NMPA) in October last year and approved by the U.S. Food and Drug Administration (FDA) in March this year to enter Phase III clinical research.

This is a voluntary announcement made by the Company. The Group cannot guarantee that Pimicotinib (ABSK021) will ultimately be successfully marketed. Shareholders and potential investors of the Company are advised to exercise caution when dealing in the shares of the Company.

By order of the Board
Abbisko Cayman Limited
Dr. Xu Yao-Chang
Chairman

Shanghai, September 11, 2023

As at the date of this announcement, the board of directors of the Company comprises Dr. Xu Yao-Chang, Dr. Yu Hongping and Dr. Chen Zhui as executive directors; Ms. Tang Yanmin as a non-executive director; and Dr. Sun Piaoyang, Mr. Sun Hongbin and Mr. Wang Lei as independent non-executive directors.

Abbisko Therapeutics Obtained Approval from EMA for Pivotal Global Multi-centered Phase III Clinical Trial of CSF-1R Inhibitor Pimicotinib (ABSK021)

September 11, 2023, Abbisko Therapeutics Co., Ltd. ("**Abbisko Therapeutics**") announced that the European Medicines Agency ("**EMA**") had approved its innovative CSF-1R inhibitor Pimicotinib (ABSK021) for a randomized, double-blind, placebo-controlled, multi-centered Phase III clinical study for the safety and efficacy in patients with tenosynovial giant cell tumor ("**TGCT**"). This is another important milestone after Pimicotinib was approved by the Center for Drug Evaluation, National Medical Products Administration ("**NMPA**") of China in October last year and approved by the U.S. Food and Drug Administration ("**FDA**") in March this year to enter Phase III clinical research. Pimicotinib is the first small-molecule inhibitor in Abbisko's pipeline that has been approved for international multi-centered Phase III clinical trial in China, the U.S., and Europe. It is the first highly selective CSF-1R inhibitor developed in China entering global Phase III clinical trial. Pimicotinib demonstrated significant anti-tumor efficacy with a preliminary objective response rate ("**ORR**") of 77.4% in the clinical Phase Ib trial for the treatment of advanced TGCT patients and has good safety and PK/PD characteristics.

The Phase III ABSK021-301 trial

The Phase III ABSK021-301 study is a randomized, double-blind, placebo-controlled, multi-centered clinical trial designed to evaluate the safety and efficacy of ABSK021 in patients with TGCT. This study consists of two parts. Part 1 is a double-blind phase, eligible patients will be randomized to ABSK021 treatment group or matching placebo group and will receive 50mg QD of ABSK021 or matching placebo (28 days/cycle) until completion of Part 1. Patients who complete Part 1 will be eligible to continue in Part 2 of the study. Part 2 is an open-label treatment phase, and all patients entering this phase will receive 50mg QD of open-label ABSK021 until 24 weeks of dosing or withdrawal from the study. Approximately 100 patients are planned to be enrolled, and the primary endpoint is 25-Week ORR by Blinded Independent Review Committee (BIRC). The global multi-centered Phase III study has been conducted simultaneously in the U.S. and China. Recently, patients will be enrolled simultaneously in Europe. The European part will be included in the global multi-centered clinical Phase III of ABSK021-301, and the results will be used for NDA applications in China, U.S., and Europe.

Pimicotinib is a novel, orally available, highly selective and potent small molecule CSF-1R inhibitor, independently developed by Abbisko Therapeutics. It has been granted the breakthrough therapy designation (BTD) and Priority Medicine (PRIME) designation by China NMPA, U.S. FDA, and EMA for the treatment of TGCT patients that are not amenable to surgery. TGCT is a locally invasive tumor, and according to epidemiological data, its incidence rate rose from 28/million people in 1998 to 49/million people in 2012, and the new cases in China and the U.S. are about 60,000 and 14,000 people each year, respectively. Thus, many existing patients are in desperate need for drug treatment. TCGT presents clinically with swelling, pain, stiffness, and limited mobility of the affected joints which seriously affect the patient's quality of life. There is currently no approved drug available in China for the disease, and only one drug has been approved in the U.S.. However, it is only available through the Risk Evaluation and Mitigation Strategy (REMS) Program which is a restricted procedure due to the potential liver injuries it may cause. There are unmet medical needs of TGCT patients in China, the U.S., and Europe.

We has completed a Phase Ia dose escalation study for Pimicotinib in the U.S., with Phase Ib expansion ongoing in both China and the U.S.. In addition to TGCT indication, Abbisko Therapeutics is actively exploring the clinical potential of Pimicotinib in many types of solid tumors, and has obtained approval from NMPA to conduct a Phase II clinical study in chronic graft-versus-host disease and a Phase II clinical study in advanced pancreatic cancer. We are also exploring its application for treating Amyotrophic lateral sclerosis(ALS) and other CNS diseases. As of the date of this announcement, no highly selective CSF-1R inhibitor has been approved in China.

About Abbisko Therapeutics

Founded in April 2016, Abbisko Therapeutics Co., Ltd., a subsidiary of Abbisko Cayman Limited (Stock Code on the Hong Kong Stock Exchange: 2256.HK), is an oncology-focused biopharmaceutical company founded in Shanghai, dedicated to discovering and developing innovative medicines to treat unmet medical needs in China and globally. The Company was established by a group of seasoned drug hunters with rich R&D and managerial expertise from top multinational pharmaceutical companies. Since its founding, Abbisko Therapeutics has built an extensive pipeline of 15 innovative small molecule programs focused on precision oncology and immuno-oncology, including eight clinical stage assets.

Please visit www.abbisko.com for more information.

Forward-Looking Statements

The forward-looking statements made in this article relate only to the events or information as of the date on which the statements are made in this article. Except as required by law, we undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise, after the date on which the statements are made or to reflect the occurrence of unanticipated events. You should read this article completely and with the understanding that our actual future results or performance may be materially different from what we expect. In this article, statements of, or references to, our intentions or those of any of our Directors or our Company are made as of the date of this article. Any of these intentions may alter in light of future development.