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 TRIAL FIRST PATIENT DOSED IN US

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 first patient has been dosed in "A Phase III, Randomized, Double-blind, Placebo-Controlled, Multicenter Study of ABSK021 to Assess the Efficacy and Safety in Patients with Tenosynovial Giant Cell Tumor (Protocol No.: ABSK021-301)" in US. Prior to this, Abbisko Therapeutics completed the first patient dose of Pimicotinib (ABSK021) in China in April, 2023.

This is a voluntary announcement made by the Company. The Group cannot guarantee that Pimicotinib 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, August 2, 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 Completes the First Patient Dose in US Phase III TGCT Trial of in CSF-1R Inhibitor – Pimicotinib(ABSK021)

August 2, 2023, Shanghai – Abbisko Therapeutics Co., Ltd. ("**Abbisko Therapeutics**" hereafter) announced that the first patient has been dosed in "A Phase III, Randomized, Double-blind, Placebo-Controlled, Multicenter Study of ABSK021 to Assess the Efficacy and Safety in Patients with Tenosynovial Giant Cell Tumor (Protocol No.: ABSK021-301)" in US. Prior to this, Abbisko Therapeutics completed the first patient dose of Pimicotinib in China in April, 2023.

Pimicotinib is a novel, orally available, highly selective, and highly potent small molecule inhibitor of CSF-1R independently discovered and developed by Abbisko Therapeutics. A number of studies have shown that blocking the CSF1/CSF1R signaling pathway could effectively modulate and change macrophage functions, and potentially treat many macrophage-dependent human diseases. Based on the excellent research results such as 77.4% objective response rate (ORR) in a Phase Ib clinical trail, Pimicotinib has been granted the breakthrough therapy designation and PRIME designation from Center for Drug Evaluation, National Medical Products Administration (CDE) on July 20, 2022, U.S. Food and Drug Administration (FDA) on January 30, 2023, and European Medicines Agency (EMA) on June 7, 2023 for the treatment of tenosynovial giant cell tumor ("**TGCT**") patients who are not amenable to surgery.

TGCT, a locally aggressive neoplasm which affects synovial joints, mucous sacs, and tendon membranes, resulting in pain, stiffness, swelling, hemorrhagic hydrops articuli, erosive arthritis, cartilage degradation and secondary osteoarthritis of the affected joints which seriously affect the quality of patient's life. Currently there is no approved drug available in China and Europe, and there's only one systemic therapy agent approved in the US. However, due to the potential liver injury it may cause, the drug is only available subject to procedures of the Risk Evaluation and Mitigation Strategy (REMS) Program. There are unmet medical needs of TGCT patients in the regions of China, US and Europe.

Pimicotinib is the first highly selective CSF-1R inhibitor independently discovered and developed by a Chinese company that entered into a global Phase III clinical trial. The study is also the first global Phase III study of TGCT to be conducted simultaneously in China, US and Europe. Approximately 100 patients are planned to be enrolled, with the participation of approximately 50 centers worldwide, including 30 centers in China.

PHASE III ABSK021-301 STUDY

The Phase III ABSK021-301 study is a randomized, double-blind, placebo-controlled, global multi-centered clinical trial designed to evaluate the safety and efficacy of ABSK021 in patients with TGCTs. 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 the completion of Part 1. Patients who complete Part 1 will be eligible to continue 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 the completion of dosing for 24 weeks 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).

About Abbisko Therapeutics

Founded in April 2016, Abbisko Therapeutics Co., Ltd., a subsidiary of Abbisko Cayman Limited (Stock Code: 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 seven clinical stage assets and eight pre-clinical stage assets. As of today, Abbisko Therapeutics has received 18 IND or clinical trial approvals in four countries and regions around the world.

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.