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
Pimicotinib (ABSK021) Patient Enrollment Completed

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. ("**Abbisko Therapeutics**"), a subsidiary of the Company, announced the completion of patient enrollment for its pivotal Phase III trial, MANEUVER (ABSK021-301) STUDY, for evaluating the efficacy and safety of pimicotinib in patients with tenosynovial giant cell tumor ("**TGCT**"). A total of 94 patients were enrolled. The study was conducted across more than 30 investigational sites worldwide, with European and North American patients accounted for more than half of the total enrollment. This study is a Phase III, randomized, double-blind, placebo-controlled, multicenter trial, which is the first global Phase III trial of TGCT simultaneously conducted in China, the U.S., Canada and Europe.

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, April 9, 2024

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 Completed All Patient Enrollment for the Global Phase III TGCT Trial of Its CSF-1R Inhibitor Pimicotinib (ABSK021)

On April 9, 2024, Abbisko Therapeutics announced the completion of patient enrollment for its pivotal Phase III trial, MANEUVER (ABSK021-301) STUDY, for evaluating the efficacy and safety of pimicotinib in patients with TGCT. A total of 94 patients were enrolled and exceeded the original target of 90 patients. The study was conducted across more than 30 investigational sites worldwide, with European and North American patients accounted for more than half of the total enrollment. This study is a Phase III, randomized, double-blind, placebo-controlled, multicenter trial, which is the first global Phase III trial of TGCT simultaneously conducted in China, the U.S., Canada and Europe. The approval to conduct this Phase III trial was received by China NMPA in October 2022, the U.S. FDA in March 2023, and the EMA in September 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. It has obtained the Breakthrough Therapy Designation ("**BTD**") from China NMPA and the U.S. FDA, as well as the PRIME Designation from EMA. Furthermore, the U.S. FDA granted Fast Track Designation ("**FTD**"), and Orphan Drug Designation ("**ODD**") granted by EMA in January 2024, for the treatment of TGCT patients who are not amenable to surgery. The designations are poised to accelerate the global development and commercialization of pimicotinib.

In December 2023, Abbisko Therapeutics entered into a license agreement with MERCK HEALTHCARE KGAA ("**Merck**"). Under the terms of the agreement, Abbisko Therapeutics has granted Merck an exclusive license to commercialize products comprising or containing pimicotinib in the Chinese mainland, Hong Kong, Macau and Taiwan, and an exclusive option for global commercial rights of pimicotinib.

TGCT, a locally aggressive neoplasm which affects synovial joints, mucous sacs, and tendon membranes, resulting in swelling, pain, stiffness, and decreased activity of the affected joints which seriously affect – patient's quality of life. Currently, there is no systemic therapy approved in China and Europe, and there are unmet medical needs of TGCT patients in the regions of China, U.S. and Europe. In addition to TGCT, Abbisko Therapeutics is actively exploring the potential of pimicotinib in treating other indications. The company has obtained approval from China NMPA to conduct Phase II clinical studies in chronic graft-versus-host disease (cGvHD) and advanced pancreatic cancer.

PHASE III MANEUVER (ABSK021-301) STUDY

The Phase III MANEUVER (ABSK021-301) STUDY is a randomized, double-blind, placebo-controlled, multi-centered clinical trial designed to evaluate the safety and efficacy of pimicotinib in patients with TGCT. This study consists of two parts. Part 1 is a double-blinded phase, in which eligible patients were randomized to the pimicotinib treatment group or matching placebo group and received 50mg QD of pimicotinib or matching placebo (28 days/cycle) until completion of 24 weeks of dosing (Part 1). Patients who complete Part 1 were eligible to continue in Part 2 of the study. Part 2 is an open-label treatment phase, and all patients entering this phase received 50mg QD of open-label pimicotinib until 24 weeks of dosing or withdrawal from the study. Approximately 90 patients were planned to be enrolled, and the primary endpoint is 25-Week ORR by the Blinded Independent Review Committee (BIRC).

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 16 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.