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
ABBISKO THERAPEUTICS ANNOUNCES CHINA NMPA ACCEPTANCE OF NDA FOR PIMICOTINIB FOR THE TREATMENT OF TGCT

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 that the China National Medical Products Administration ("**NMPA**") has accepted the New Drug Application ("**NDA**") for pimicotinib, a highly selective, small-molecule CSF-1R inhibitor, as a Class 1 innovative drug for adult patients with Tenosynovial Giant Cell Tumor ("**TGCT**"). Pimicotinib is the first internally discovered and self-developed program from Abbisko Therapeutics to enter the NDA approval process, and has the potential to provide patients with a best-in-class therapy to treat TGCT given its exceptional clinical efficacy, safety, and tolerability as demonstrated in multiple clinical trials.

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, June 10, 2025

As at the date of this announcement, the board of directors of the Company comprises Dr. Xu Yao-Chang, Dr. Yu Hongping and Dr. Ji Jing as executive directors; and Dr. Sun Piaoyang, Mr. Sun Hongbin and Ms. Chui Hoi Yam as independent non-executive directors.

Abbisko Therapeutics Announces China NMPA Acceptance of NDA for Pimicotinib for the Treatment of TGCT

On June 10, 2025, Abbisko Therapeutics Co., Ltd. ("**Abbisko Therapeutics**") announced that the China National Medical Products Administration ("**NMPA**") has accepted the New Drug Application ("**NDA**") for pimicotinib, a highly selective, small-molecule CSF-1R inhibitor, as a Class 1 innovative drug for adult patients with Tenosynovial Giant Cell Tumor ("**TGCT**"). Pimicotinib is the first internally discovered and self-developed program from Abbisko Therapeutics to enter the NDA approval process, and has the potential to provide patients with a best-in-class therapy to treat TGCT given its exceptional clinical efficacy, safety, and tolerability as demonstrated in multiple clinical trials.

The submission follows the granting of Priority Review to pimicotinib by the Center for Drug Evaluation ("**CDE**") of the China NMPA in May for the treatment of patients with TGCT who require systemic therapy, which is expected to expedite the review process. Pimicotinib also has been granted breakthrough therapy designation ("**BTD**") by the China NMPA. In December 2023, Abbisko Therapeutics entered into an agreement with Merck pertaining to the commercial rights to pimicotinib, pursuant to which Merck is responsible for the commercialization of pimicotinib globally.

The submission is based on results from Part 1 of the global Phase 3 MANEUVER study, in which once-daily pimicotinib demonstrated a statistically significant improvement in the primary endpoint of objective response rate ("**ORR**") assessed by blinded independent review committee ("**BIRC**") compared with placebo at week 25 (54.0% vs. 3.2% for placebo; $p<0.0001$). The study also demonstrated statistically significant and clinically meaningful improvements in all secondary endpoints related to key patient-reported outcomes in TGCT, including improvements in active range of motion and physical function and reductions in stiffness and pain. The data were presented earlier this month at the 2025 ASCO Annual Meeting.

Outside of China, pimicotinib has been granted BTD by the US Food and Drug Administration ("**FDA**") and PRIME Designation by the European Medicines Agency ("**EMA**").

About Abbisko Therapeutics

Founded in April 2016, Abbisko Therapeutics Co., Ltd. is an oncology-focused biopharmaceutical company based in Shanghai that is dedicated to the discovery and development of innovative medicines to treat unmet medical needs in China and globally. The Company was established by a group of seasoned drug hunters with rich research & development and managerial expertise from top multinational pharmaceutical companies. Since its founding, Abbisko Therapeutics has built an extensive pipeline of innovative programs focused on precision oncology and immuno-oncology.

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.