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
FDA ACCEPTANCE OF THE 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 New Drug Application ("**NDA**") for its novel, orally administered, highly selective, and potent small-molecule colony-stimulating factor 1 receptor ("**CSF-1R**") inhibitor, pimicotinib (ABSK021), for the systemic treatment of patients with tenosynovial giant cell tumor ("**TGCT**"), has been formally accepted by the US Food and Drug Administration ("**FDA**").

This is a voluntary announcement made by the Company. The Group cannot guarantee that pimicotinib will ultimately be successfully commercialized. 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, 13 January 2026

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 FDA Acceptance of the NDA for Pimicotinib for the Treatment of Tenosynovial Giant Cell Tumor

On 13 January 2026, Abbisko Therapeutics Co., Ltd. ("**Abbisko Therapeutics**") announced that the New Drug Application ("**NDA**") for its novel, orally administered, highly selective, and potent small-molecule colony-stimulating factor 1 receptor ("**CSF-1R**") inhibitor, pimicotinib (ABSK021), for the systemic treatment of patients with tenosynovial giant cell tumor ("**TGCT**"), has been formally accepted by the US Food and Drug Administration ("**FDA**").

Pimicotinib was independently developed by Abbisko Therapeutics and has been licensed to Merck KGaA, Darmstadt, Germany, for worldwide commercialization. In December 2025, pimicotinib received approval from the China National Medical Products Administration ("**NMPA**") for the treatment of adult patients with symptomatic TGCT for which surgical resection will potentially cause functional limitation or relatively severe morbidity. Additional applications are under review by regulatory authorities in other markets.

The FDA's acceptance of the NDA for pimicotinib is supported by the robust efficacy and safety outcomes from the global, multicenter, randomized, double-blind, placebo-controlled Phase III MANEUVER trial.

In the trial, TGCT patients who received once-daily oral pimicotinib achieved a statistically significant improvement in the primary endpoint of objective response rate ("**ORR**") evaluated at Week 25 by blinded independent review committee ("**BIRC**") based on RECIST v1.1.

The trial 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.

Longer-term results with a median follow-up of 14.3 months further showed ORR continued to increase over time among patients treated with pimicotinib from the beginning of the study.

TGCT is a rare, locally aggressive tumor occurring in or around the joint leading to progressive swelling, stiffness and reduced mobility of the affected joint, significantly impacting daily activities and quality of life. If left untreated or in recurrent cases, TGCT may result in irreversible damage to the bone, joint and surrounding tissues. With regulatory submissions progressing across major markets worldwide, pimicotinib is expected to provide TGCT patients with a once-daily, oral, effective and well-tolerated therapeutic option, helping address unmet clinical needs in the management of TGCT.

About Pimicotinib

Pimicotinib is a novel, oral, highly selective, and potent small-molecule CSF-1R inhibitor independently developed by Abbisko Therapeutics. Positive results from the global Phase III MANEUVER study of pimicotinib for the treatment of TGCT were announced in November 2024. Currently, pimicotinib has been approved by NMPA for the treatment of adult patients with symptomatic TGCT for which surgical resection will potentially cause functional limitation or relatively severe morbidity. In December 2023, Abbisko entered into an agreement with Merck KGaA, Darmstadt, Germany, pertaining to the commercial rights to pimicotinib, pursuant to which Merck KGaA, Darmstadt, Germany, is responsible for the commercialization of pimicotinib globally.

Outside of China, pimicotinib has been granted Breakthrough Therapy Designation by the 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.