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Abbisko Cayman Limited

和譽開曼有限責任公司

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 2256)

INSIDE INFORMATION

ABBISKO THERAPEUTICS' CSF-1R INHIBITOR PIMICOTINIB APPROVED BY THE CHINA NMPA

This announcement is made by Abbisko Cayman Limited (the “**Company**”, together with its subsidiaries, the “**Group**”) pursuant to Rule 13.09(2)(a) of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the “**Listing Rules**”) as well as the Inside Information Provisions (as defined under the Listing Rules) under Part XIVA of the Securities and Futures Ordinance (Chapter 571 of the Laws of Hong Kong).

The Company hereby informs the shareholders and potential investors of the Company of the attached press release that, on December 22, 2025, Abbisko Therapeutics Co., Ltd. (“**Abbisko Therapeutics**”), a subsidiary of the Company, announced that, the China National Medical Products Administration (“**NMPA**”) has approved pimicotinib for the treatment of adult patients with symptomatic Tenosynovial Giant Cell Tumor (“**TGCT**”) for which surgical resection will potentially cause functional limitation or relatively severe morbidity. Following this approval, Merck KGaA, Darmstadt, Germany is working to ensure timely TGCT patient access in China.

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, December 22, 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' CSF-1R Inhibitor Pimicotinib Approved by the China NMPA, Addressing the Treatment Gap for Tenosynovial Giant Cell Tumor in China

- Based on the positive global Phase III MANEUVER study, the China National Medical Products Administration (“NMPA”) has granted the world’s first regulatory approval for pimicotinib, the first domestically developed systemic therapy for the treatment of Tenosynovial Giant Cell Tumor (“TGCT”), to our partner Merck KGaA, Darmstadt, Germany, which holds worldwide commercialization rights.
- Pimicotinib, a Class 1 innovative drug discovered and developed by Abbisko Therapeutics Co., Ltd. (“**Abbisko Therapeutics**”), received zero-deficiency approval in just over six months following NDA acceptance. During the review, the Center for Food and Drug Inspection (“**CFDI**”) conducted its first-ever overseas clinical site inspection for pimicotinib, with the inspection being successfully passed. This outcome reflects Abbisko’s rigorous R&D standards and regulators’ strong recognition of the therapy’s clinical value and data quality.
- Pimicotinib’s approval for the treatment of TGCT marks a key milestone in the company’s advancement from pioneering innovative research to first product commercialization.

On 22 December 2025, Abbisko Therapeutics announced that the China NMPA has approved pimicotinib for the treatment of adult patients with symptomatic TGCT for which surgical resection will potentially cause functional limitation or relatively severe morbidity. Following this approval, Merck KGaA, Darmstadt, Germany, is working to ensure timely TGCT patient access in China.

TGCT is a rare and locally aggressive tumor primarily affecting joints, tendon sheaths, and bursae with considerable morbidity and functional impairment. TGCT is driven by overexpression of colony-stimulating factor-1 (“**CSF-1**”) in neoplastic synovial cells which leads to accumulation of colony-stimulating factor-1 receptor (“**CSF-1R**”)–expressing inflammatory cells in the tumor. The *Chinese expert consensus on clinical diagnosis and treatment of TGCT* recommends CSF-1/CSF-1R pathway inhibitors as the preferred systemic treatment for patients with unresectable TGCT (Recommendation Level 1; Evidence Level A).

Pimicotinib is a novel, oral, highly selective, and potent small-molecule CSF-1R inhibitor independently developed by Abbisko Therapeutics. The approval by the China NMPA is based on the positive results from the global Phase III MANEUVER study, in which pimicotinib demonstrated the highest objective response rate (“**ORR**”) based on RECIST v1.1 seen in a Phase III clinical trial for the treatment TGCT.

At week 25, pimicotinib demonstrated a statistically significant improvement in the primary endpoint of ORR compared with placebo (54.0% vs. 3.2%; $p < 0.0001$) as assessed by Blinded Independent Review Committee (“**BIRC**”) based on RECIST v1.1. Pimicotinib also demonstrated clinically meaningful and statistically significant improvements across secondary endpoints relevant to patient daily life, improving relative Range of Motion ($p = 0.0003$) and physical function as measured by the PROMIS-PF scale ($p = 0.0074$), as well as reducing Worst Stiffness NRS ($p < 0.0001$) and BPI Worst Pain NRS ($p < 0.0001$). Longer-term follow-up data presented at the 2025 European Society for Medical Oncology (“**ESMO**”) Congress further demonstrated that pimicotinib provides robust and durable tumor responses for patients with TGCT. With a median follow-up of 14.3 months, ORR per RECIST v1.1 increased from 54% at week 25 to 76.2% (95% CI: 63.8, 86.0), including four patients achieving a Complete Response (“**CR**”).

In the MANEUVER study, pimicotinib also demonstrated a generally well-tolerated safety profile. The median dose intensity remained high at 88.2% during treatment. Most treatment-emergent adverse events (“TEAEs”) were Grade 1-2. No new safety signals were observed with longer-term follow-up, and there was no evidence of cholestatic hepatotoxicity, drug-induced liver injury, or hair/skin hypopigmentation.

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 the China NMPA in China 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 Therapeutics 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 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.