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Abbisko Medicine Co., Ltd.
和譽醫藥有限責任公司
(Incorporated in the Cayman Islands with limited liability)
(Stock Code: 2256)

INSIDE INFORMATION

PIMJETMI® (pimicotinib) Receive U.S. FDA Approval for TGCT

This announcement is made by Abbisko Medicine Co., Ltd. (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 11 November, 2026, Abbisko Therapeutics Co., Ltd. ("**Abbisko Therapeutics**"), a subsidiary of the Company, announced that, U.S. Food and Drug Administration ("**FDA**") has approved PIMJETMI® (pimicotinib), a small-molecule CSF-1R inhibitor, as a systemic treatment for adults with symptomatic tenosynovial giant cell tumor ("**TGCT**") for which surgical resection may cause worsening functional limitation or severe morbidity.

The Group cannot guarantee that PIMJETMI® (pimicotinib) will ultimately be successfully commercialized outside of the regions in which it has already been 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 Medicine Co., Ltd.
Dr. Xu Yao-Chang
Chairman

Shanghai, 11 November, 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.

PIMJETMI® (pimicotinib) Developed by Abbisko Therapeutics and Licensed to Merck KGaA, Darmstadt, Germany Receive U.S. FDA Approval for TGCT

- PIMJETMI® (pimicotinib) is a new systemic treatment option for certain U.S. adult patients with symptomatic tenosynovial giant cell tumor ("**TGCT**"), demonstrating durable* tumor response with clinically meaningful improvements in certain clinical outcome assessments, including physical function and pain

- U.S. FDA approval marks the fourth marketing approval for PIMJETMI® following China NMPA, Health Canada and Swissmedic, accelerating worldwide commercialization

- Abbisko Therapeutics to receive US$20 million milestone payment upon the first commercial sale of PIMJETMI® in the U.S. in addition to double-digit royalties on net sales

On 11 November, 2026, Abbisko Therapeutics Co., Ltd. ("**Abbisko Therapeutics**") announced that the U.S. Food and Drug Administration ("**FDA**") has approved PIMJETMI® (pimicotinib), a small-molecule CSF-1R inhibitor, as a systemic treatment for adults with symptomatic tenosynovial giant cell tumor ("**TGCT**") for which surgical resection may cause worsening functional limitation or severe morbidity.

PIMJETMI® is an orally available and potent small-molecule CSF-1R inhibitor independently developed by Abbisko Therapeutics, with global commercialization rights granted to Merck KGaA, Darmstadt, Germany. The U.S. FDA approval marks the fourth NDA approval for PIMJETMI®, following approvals in China by the China National Medical Products Administration ("**NMPA**") in December 2025, in Canada by Health Canada in June 2026, and in Switzerland by the Swiss Agency for Therapeutic Products (Swissmedic) in October 2026, further accelerating the global commercialization plan. Upon the first commercial sale in the United States, Abbisko will receive an additional U.S. $20 million milestone payment. Abbisko is also eligible to receive double-digit royalties on global net sales of PIMJETMI®, as well as potential payments relating to other regulatory, development, and commercial sales milestones.

TGCT is a rare, locally aggressive tumor that primarily affects the joints, tendon sheaths, and bursae. It can cause pain, swelling, stiffness, and limited joint mobility, significantly affecting patients' daily activities and quality of life. TGCT is driven by overexpression of CSF-1 in neoplastic synovial cells which leads to accumulation of CSF-1R expressing inflammatory cells in the tumor.

The FDA approval of PIMJETMI® is based on primary and longer-term results from the global Phase III MANEUVER study and the Open-Label Extension. PIMJETMI® demonstrated a statistically significant improvement in objective response rate ("**ORR**") at week 25 as assessed by blinded independent review committee ("**BIRC**") based on RECIST v1.1 compared with placebo (56% vs. 3% for placebo; $p<0.0001$). PIMJETMI® also demonstrated clinically meaningful and statistically significant improvements as compared to placebo across secondary endpoints relevant to patients' daily lives, improving relative range of motion ($p=0.0003$), physical functioning ($p=0.0074$), and pain ($p<0.0001$). Results from the MANEUVER study were presented at the 2025 American Society of Clinical Oncology ("**ASCO**") Annual Meeting. In longer-term follow-up (median 14.3 months for patients initially randomized to pimicotinib), presented at the European Society for Medical Oncology ("**ESMO**") Congress in 2025, the median duration of response was not reached. The majority of patients (77%) with response at week 25 maintained clinical benefit after an additional 12 months of follow-up, demonstrating the durability* of response with PIMJETMI®.

The applications for PIMJETMI® in the United States and Canada were reviewed under Project Orbis, an international collaboration framework initiated by the FDA Oncology Center of Excellence to facilitate collaboration among participating regulatory authorities and accelerate the review of oncology products. Project Orbis currently brings together regulatory authorities from multiple countries and regions, providing an important platform for international regulatory collaboration and the coordinated global development of innovative medicines.

* The majority (77%) of patients with response at 25 weeks maintained this clinical benefit after an additional 12 months of treatment.

About PIMJETMI® (Pimicotinib)

PIMJETMI®, developed by Abbisko Therapeutics, is an orally administered and potent small-molecule inhibitor of CSF-1R. PIMJETMI® has been approved for the treatment of adult patients with symptomatic TGCT for which surgical resection will potentially cause functional limitation or relatively severe morbidity by China NMPA and Health Canada. 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 PIMJETMI® globally.

About Abbisko Therapeutics

Founded in 2016, Abbisko Therapeutics is a pharmaceutical company committed to the research, discovery, and development of innovative and differentiated medicines designed to address unmet medical needs in China and globally.

Adhering to international concepts and standards for drug development, Abbisko primarily centers on small molecules, emphasizing precision oncology and immuno-oncology, with a growing expansion into both non-oncology therapeutic areas and other modalities. Its self-developed Class 1 innovative drug, pimicotinib, has received approval from the China NMPA, while dozens of other candidates are currently in clinical development stages.

Abbisko is committed to creating first-in-class and best-in-class innovative drugs. Through an unwavering pursuit of scientific innovation, the company strives to provide transformative therapies with breakthrough efficacy for patients worldwide.

For more information, please visit www.abbisko.com.

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.