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
CSF-1R INHIBITOR PIMICOTINIB GRANTED ODD BY EMA

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 its investigational innovative CSF-1R inhibitor pimicotinib (ABSK021) has been granted orphan drug designation ("**ODD**") by the European Medicines Agency ("**EMA**") for the treatment of inoperable tenosynovial giant cell tumor ("**TGCT**").

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, January 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.

EMA Has Granted ODD for Abbisko Therapeutics Self-developed Innovative CSF-1R Inhibitor Pimicotinib for the Treatment of TGCT

On January 9, 2024, Abbisko Therapeutics announced that its investigational innovative CSF-1R inhibitor pimicotinib has been granted ODD by the EMA for the treatment of inoperable TGCT patients.

Following the successful ODD granted by the EMA, the product will benefit from incentives, including protocol assistance, fee reductions, procedural advantages for market authorization, and market exclusivity and so on. In addition to the above-mentioned benefits within the European Union, member states may also offer specific stimuli for orphan drugs.

Previously, in June 2023, pimicotinib was granted the Priority Medicines (PRIME) designation by the EMA, which aims to expedite the review process for promising medicines in areas of unmet medical needs.

In early December 2023, Abbisko Therapeutics entered into an agreement with Merck KGaA, Darmstadt, Germany ("**Merck**"), that granted it an exclusive license to commercialize Pimicotinib for all indications in the Chinese mainland, Taiwan, Hong Kong, Macau. Merck also obtained an exclusive option for global commercial rights of pimicotinib, subject to the terms and conditions as agreed between the parties. Pursuant to the terms of the license agreement, Abbisko Therapeutics will receive a one-time, non-refundable down payment of US$70 million. In the event that Merck exercises the global commercialization option, Merck will pay Abbisko Therapeutics an additional option exercising fee. The aggregate amounts of upfront payment, option exercising payment, and payment for development and commercialization milestones will total US$605.5 million. Abbisko Therapeutics will also receive double-digit percentage (%) royalties on annual net sales from Merck.

Pimicotinib is a novel, orally available, highly selective, and potent small molecule CSF-1R inhibitor, independently developed by Abbisko Therapeutics. It has been granted the Break Through Designation (BTD) and PRIME designation by China NMPA, U.S. FDA, and EMA for the treatment of TGCT patients who are not amenable to surgery. The study is the first global Phase III clinical trial of TGCT conducted simultaneously in China, the U.S., Canada and Europe.

Upon 1-year follow-up in a Phase 1b trial for TGCT, pimicotinib demonstrated an ORR of 87.5% (28/32, including 3 CR) in the 50 mg QD cohort，which was presented at the 2023 CTOS.

Abbisko Therapeutics has completed a Phase I dose-escalation trial for pimicotinib in the U.S. In December 2023. Pimicotinib was granted Fast Track Designation (FTD) by the U.S. FDA for the treatment of unresectable TGCT patients.

In addition to TGCT, Abbisko Therapeutics is actively exploring the potential of pimicotinib in treating other indications including many types of solid tumors in clinic, and it has obtained approval from China NMPA to conduct Phase II clinical studies in chronic graft-versus-host disease（cGVHD) and advanced pancreatic cancer. Up until today, no highly selective CSF-1R inhibitors have been approved in China.

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 for 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 in top multinational pharmaceutical companies. Since its founding, Abbisko Therapeutics has built up 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.