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 (ABSK021) GRANTED FAST TRACK DESIGNATION BY U.S. FDA

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 CSF-1R inhibitor pimicotinib (ABSK021) has been granted the fast track designation ("**FTD**") by the U.S. Food and Drug Administration ("**U.S. FDA**") for the treatment of tenosynovial giant cell tumor ("**TGCT**") patients that are not amenable to surgery. Previously, pimicotinib was granted the breakthrough therapy designation ("**BTD**") by the U.S. FDA for TGCT in January of this year. The grant of FTD and BTD will accelerate the global development and commercialization of pimicotinib.

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, December 14, 2023

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.

Abbisko Therapeutics Announces that U.S. FDA Has Granted Fast Track Designation for Its CSF-1R Inhibitor Pimicotinib (ABSK021)

On December 14, 2023, Abbisko Therapeutics announced that its CSF-1R inhibitor pimicotinib has been granted the FTD by the U.S. FDA for the treatment of TGCT patients that are not amenable to surgery. Previously, pimicotinib was granted the BTD by the U.S. FDA for TGCT in January of this year. The grant of FTD and BTD will accelerate the global development and commercialization of pimicotinib.

Fast Track is a policy designed to facilitate the development and expedite the review of drugs in order to treat serious conditions and fulfill unmet medical needs. Its purpose is to get important new drugs to patients earlier. Moreover, the FTD enables companies to maintain more frequent communications and meetings with the U.S. FDA. The drug also becomes eligible for accelerated approval and priority review by the U.S. FDA.

In early December, the Company entered into an agreement with Merck KGaA, Darmstadt, Germany ("**Merck**") that grants Merck the exclusive license to commercialize pimicotinib for all indications in China mainland, Hong Kong, Macau, and Taiwan. Merck also obtained an exclusive option for global commercial rights of pimicotinib, subject to the terms and conditions as agreed between the parties and payment of an additional option exercising fee. Pursuant to the terms of the license agreement, the Company 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 the Company 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. The Company will also obtain from Merck double-digit percentage (%) royalties based on actual annual net sales.

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 BTD and Priority Medicine (PRIME) designation by China National Medical Products Administration ("**NMPA**"), U.S. FDA, and European Medicines Agency (EMA) for the treatment of TGCT patients that 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 one-year follow-up in a Phase Ib trial for TGCT, pimicotinib demonstrated an ORR of 87.5% (28/32, including 3 CR) in the 50mg QD cohort, which was presented at the 2023 CTOS. A Phase Ia dose-escalation trial for pimicotinib has been completed in the U.S. previously.

In addition to TGCT, the Company 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 NMPA to conduct Phase II clinical studies in chronic graft-versus-host disease and advanced pancreatic cancer. Up until today, no highly selective CSF-1R inhibitors have been approved in China.

About TGCT

TGCT is a locally aggressive neoplasm that usually affects synovial joints, mucous sacs, and tendon membranes, resulting in swelling, pain, stiffness, and decreased activity of the affected joints which seriously affect the patient's quality of life[1]. According to the 2013 World Health Organization classification, TGCTs were classified as localized TGCT and diffuse TGCT. Diffuse TGCT encompasses formerly known nodular tenosynovitis and pigmented villonodular synovitis (PVNS). Overexpression of CSF-1 occurs in most TGCTs. Surgical resection is the standard treatment for TGCT. However, not all patients are suitable for surgical treatment. It is difficult to remove tumors of diffuse TGCT patients by surgery, which may possibly lead to severe joint damage, total synovectomy, joint replacement, or even amputation, and the risk of surgical complications can be high. It has been reported that more than 50% of patients with diffuse TGCT would undergo recurrence after surgical resection[2]. For TGCT patients who are not amenable to surgery, there is currently no approved drug available in China.

[1] Stacchiotti S, Dürr HR, Schaefer IM, et al. Best clinical management of tenosynovial giant cell tumour (TGCT): A consensus paper from the community of experts. Cancer Treat Rev. 2023;112:102491.

[2] Verspoor FG, van der Geest IC, Vegt E, Veth RP, van der Graaf WT, Schreuder HW. Pigmented villonodular synovitis: current concepts about diagnosis and management. FutureOncol. 2013;9(10):1515-1531.

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 to treat 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 from top multinational pharmaceutical companies. Since its founding, Abbisko Therapeutics has built an extensive pipeline of 16 innovative small molecule programs focused on precision oncology and immuno-oncology, including 8 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 the Company are made as of the date of this article. Any of these intentions may alter in light of future development.