**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 REACHED A LICENSE AGREEMENT WITH MERCK FOR PIMICOTINIB (ABSK021)

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 board of directors of the Company is pleased to announce that Abbisko Therapeutics Co., Ltd. ("**Abbisko Therapeutics**"), a subsidiary of the Company, entered into a license agreement (the "**License Agreement**") with MERCK HEALTHCARE KGAA ("**Merck**") on December 1, 2023. Under the terms of the License Agreement, Merck will be granted an exclusive license to commercialize products comprising or containing pimicotinib (ABSK021) for all indications in Chinese mainland, Hong Kong, Macau and Taiwan (the "**Licensed Territory**"), and Abbisko Therapeutics will retain the exclusive rights to develop pimicotinib within the Licensed Territory. Abbisko Therapeutics has also granted Merck an exclusive option for global commercial rights of pimicotinib, subject to the terms and conditions as agreed between the parties (the "**Global Commercialization Option**"). In addition, Merck has the option to co-develop pimicotinib in additional indications under certain conditions.

Pursuant to the terms of the License Agreement, Abbisko Therapeutics will receive a one-time, non-refundable upfront 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 amount of upfront payment, exercising payment, and payment for development and commercialization milestones will total US$605.5 million, plus a double-digit percentage (%) royalty on actual annual net sales.

The licensed pimicotinib, which was independently developed by Abbisko Therapeutics, is a novel, orally administered, highly selective and highly potent small-molecule inhibitor of CSF-1R, and has been granted the breakthrough therapy designation ("**BTD**") and priority medicine ("**PRIME**") designation by China National Medical Products Administration ("**NMPA**"), U.S. Food and Drug Administration ("**FDA**"), and European Medicines Agency ("**EMA**") for the treatment of patients with tenosynovial giant cell tumor ("**TGCT**") that are not amenable to surgery. The entering into the License Agreement is to expand the coverage of pimicotinib through the current commercial organizational structure of Merck, and to extend the availability of such medicines to patients in the Licensed Territory.

Merck, a leading science and technology company, operates across life science, healthcare and electronics. More than 64,000 employees work to make a positive difference to millions of people's lives every day by creating more joyful and sustainable ways to live. From providing products and services that accelerate drug development and manufacturing as well as discovering unique ways to treat the most challenging diseases to enabling the intelligence of devices – Merck is everywhere. In 2022, Merck generated sales of € 22.2 billion in 66 countries.

To the best knowledge and belief of the directors of the Company, as at the date of this announcement, Merck is independent of and not connected with the Company and its connected persons (as defined in the Listing Rules). The transactions contemplated under the License Agreement do not constitute notifiable transactions or connected transactions of the Company under the Listing Rules. The Group cannot guarantee that pimicotinib will be marketed successfully in the future. 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 4, 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.*

**About Pimicotinib (ABSK021)**

Pimicotinib (ABSK021), which was independently developed by Abbisko Therapeutics, is a novel, orally administered, highly selective and potent small-molecule inhibitor of CSF-1R, and has been granted the BTD and PRIME designation by China NMPA, U.S. FDA, and EMA for the treatment of patients with TGCT that are not amenable to surgery, followed by a global Phase III MRCT clinical trial initiated simultaneously in China, the U.S., Canada and Europe. TGCT is a locally invasive tumor, and according to epidemiological data, its incidence rate rose from 28/million people in 1998 to 49/million people in 2012, and the new cases in China and the U.S. are about 60,000 and 14,000 people each year, respectively. Thus, many existing patients are in desperate need for drug treatment. TGCT presents clinically with swelling, pain, stiffness, and limited mobility of the affected joints which seriously affect the patient's quality of life. There is currently no approved drug available in China for the disease, and only one drug has been approved in the U.S. However, it is only available through the Risk Evaluation and Mitigation Strategy (REMS) Program which is a restricted procedure due to the potential liver injuries it may cause. There are unmet medical needs of TGCT patients in China, the U.S., and Europe.

A Phase Ia dose escalation study for pimicotinib has been completed in the U.S. On November 3, 2023, Abbisko Therapeutics presented at the CTOS annual meeting a further update of the one-year long-term follow-up data of TGCT patients from the Phase Ib clinical trial data of pimicotinib. The ORR of pimicotinib in the 50 mg QD cohort achieved 87.5% (28/32, including 3 CR), which demonstrated excellent efficacy data. In addition to TGCT, Abbisko Therapeutics is actively exploring the potential of pimicotinib in treating other indications including many types of solid tumors in and has obtained approval from NMPA to conduct a Phase II clinical study in chronic graft-versus-host disease and advanced pancreatic cancer. As of the date of this announcement, no highly selective CSF-1R inhibitor has 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 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 15 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 herein relate only to the events or information as of the date on which the statements are made herein. 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 announcement completely and with the understanding that our actual future results or performance may be materially different from what we expect. In this announcement, 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 announcement. Any of these intentions may alter in light of future development.