**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 PRIME BY THE 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., a subsidiary of the Company, announced that its novel CSF-1R inhibitor pimicotinib (ABSK021) has been granted the Priority Medicine designation by the European Medicines Agency for the treatment of tenosynovial giant cell tumor patients that are not amenable to surgery. The PRIME designation was granted based on clinical results from the ongoing Phase Ib clinical trial of TGCT cohort for pimicotinib. PRIME is similar to breakthrough therapy designation in the other countries with the goal to expedite the development and review of new medicines indicated for serious or life-threatening conditions.

This is a voluntary announcement made by the Company. The Group cannot guarantee that pimicotinib (ABSK021) 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, June 7, 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; Dr. Xia Gavin Guoyao and Ms. Tang Yanmin as non-executive directors; and Dr. Sun Piaoyang, Mr. Sun Hongbin and Mr. Wang Lei as independent non-executive directors.*

**Abbisko Therapeutics announces that Europe EMA has granted Priority Medicine designation for its CSF-1R inhibitor Pimicotinib (ABSK021)**

June 7, 2023, Shanghai – Abbisko Therapeutics Co., Ltd. ("**Abbisko Therapeutics**" hereafter) today announced that its novel CSF-1R inhibitor pimicotinib (ABSK021)has been granted the Priority Medicine ("**PRIME**") designation by the European Medicines Agency ("**EMA**") for the treatment of tenosynovial giant cell tumor ("**TGCT**") patients that are not amenable to surgery. The PRIME designation was granted based on clinical results from the ongoing Phase Ib clinical trial of TGCT cohort for pimicotinib. PRIME is similar to breakthrough therapy designation ("**BTD**") in the other countries with the goal to expedite the development and review of new medicines indicated for serious or life-threatening conditions.

Pimicotinib is a novel and potential best-in-class CSF-1R inhibitor. Previously, pimicotinib was granted BTD by the National Medical Products Administration of China ("**NMPA**") in July 2022, and by the U.S. Food and Drug Administration (FDA) in January 2023. With the PRIME designation by the EMA, it demonstrates that the clinical data of pimicotinib has been well recognized by regulatory agencies globally with support to accelerate its clinical development and advancement into commercialization.

The eligibility criteria for PRIME are identical to the EMA's accelerated assessment criteria. It is a scheme to reinforce scientific and regulatory support to enable accelerated development and assessment of new medicines. It targets medicines to solve major unmet medical needs and with therapeutic innovations. PRIME primarily requires meeting two requirements. Firstly, it focuses on target conditions with an unmet medical need, i.e. for which there exists no satisfactory method of diagnosis, prevention or treatment in the Community or, even if such a method exists, in relation to which the medicinal product concerned will be of major therapeutic advantage to those affected. Secondly, it aims to demonstrate the potential to address the unmet medical need for maintaining and improving the health of the Community, for example, by introducing new methods of therapy or improving existing ones.

Pimicotinib is a novel, orally available, highly selective, and highly potent small molecule inhibitor of CSF-1R independently discovered and developed by Abbisko Therapeutics. A number of studies have shown that blocking the CSF-1R signaling pathway could effectively modulate and change macrophage functions, and potentially treat many macrophage-dependent human diseases. Prior to these, pimicotinib demonstrated significant antitumor efficacy in a Phase Ib trial in patients with TGCT, achieving objective response rate (ORR) of 77.4% and favorable safety profile, which was presented in the 2023 American Society of Clinical Oncology (ASCO) annual meeting. Abbisko has advanced pimicotinib into a global Phase III Multiregional Clinical Trial (MRCT) for TGCT, and completed dosing of the first patient in April, 2023.

Abbisko Therapeutics has completed a Phase Ia dose escalation study for pimicotinib in the U.S. and is conducting an ongoing Phase Ib multi-cohort expansion trial in both the U.S. and China. In addition to TGCT and chronic graft-versus-host disease (cGvHD) that have been approved by NMPA for clinical studies, Abbisko Therapeutics is actively exploring the potential of pimicotinib in treating many other types of solid tumors and non-oncology indications including amyotrophic lateral sclerosis (ALS). As of today, no highly selective CSF-1R inhibitor has been approved in China.

**About TGCT**

TGCT, also known as pigmented villonodular synovitis, is a locally aggressive neoplasm which 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. According to the 2013 World Health Organization classification, TGCTs were classified as localized TGCT and diffuse TGCT. Compared with localized TGCT (80%-90%), the incidence rate of diffuse TGCT is lower (10-20%). Overexpression of colony-stimulating factor 1(CSF1) 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 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 will undergo recurrence after surgical resection. For those TGCT patients not amenable to surgery, there is currently no approved drug available in China.

**About Abbisko Therapeutics**

Founded in April 2016, Abbisko Therapeutics Co., Ltd., a subsidiary of Abbisko Cayman Limited (Stock Code: 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 seven clinical stage assets and eight pre-clinical stage assets. As of today, Abbisko Therapeutics has received 17 IND or clinical trial approvals in multiple countries and regions.

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.