**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

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 the updated results of Phase Ib study of CSF-1R inhibitor pimicotinib (ABSK021) in treating patients with advanced tenosynovial giant cell tumor, will be presented at the 2023 American Society of Clinical Oncology annual meeting held in Chicago, USA from June 2 to June 6, 2023.

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, May 28, 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 to present updated Phase Ib clinical results of Pimicotinib (ABSK021) in patients with advanced TGCT at the 2023 ASCO annual meeting**

May 28, 2023, Shanghai – Abbisko Therapeutics Co., Ltd. ("**Abbisko Therapeutics**") announced that the updated results of Phase Ib study of CSF-1R inhibitor pimicotinib (ABSK021) in treating patients with advanced tenosynovial giant cell tumor ("**TGCT**"), will be presented at the 2023 American Society of Clinical Oncology ("**ASCO**") annual meeting held in Chicago, USA from June 2 to June 6, 2023.

The data demonstrates the excellent antitumor efficacy and safety profile of pimicotinib in the treatment of patients with advanced TGCT and will be presented with the title of "EFFICACY AND SAFETY PROFILE OF PIMICOTINIB (ABSK021) IN TENOSYNOVIAL GIANT CELL TUMOR (TGCT): PHASE 1B UPDATE" in a poster presentation with the poster Bd# of "493".

As of December 2022, the enrollment of TGCT indication amounted to 49 patients, including 37 patients in 50 mg QD cohort and 12 patients in 25 mg QD cohort. At the ASCO annual meeting, Abbisko Therapeutics will further release the updated data of 50mg QD cohort as well as the preliminary data of 25mg QD cohort in TGCT patients for the first time, including safety, efficacy, pharmacokinetic ("**PK**") and pharmacodynamic ("**PD**") data.

**Efficacy**

- A total of 31 patients who were treated with 50mg QD Pimicotinib had at least one post-treatment tumor response assessment. Tumor regression was observed across all patients, and median Duration of Response ("**DOR**") was not reached.

- The best objective response rate ("**ORR**") was 77.4% (24/31), including two complete response ("**CR**") and 22 Partial response ("**PR**"), and 87.5% (21/24) of objective responses were observed within the first 25 weeks.

- Proportion of responders based on BPI-30 at week 25 was 66.7% (16/24) in 50 mg QD cohort. Durable improvements in stiffness and Range of Motion ("**ROM**") between baseline and week 25 were observed in patients.

- Significant PD changes were observed, such as increase in plasma CSF-1 levels, decrease in non-classical monocytes and C-terminal telopeptide ("**CTx**"). Changes from baselines in both CSF-1 and CTx showed a correlation with pimicotinib plasma concentrations.

**Safety Profile**

- Pimicotinib has a favorable safety profile, 89.8% of patients remained on treatment. Median treatment duration were 9.3 months, and the longest treatment duration was 12.5 months in 50mg QD cohort.

- Most Treatment Emerged Adverse Events ("**TEAEs**") were Grade 1 or 2. CPK and transaminase elevations were asymptomatic, on-target and quickly recovered after drug interruptions.

- Hair color change, which is one of common TEAEs in other competitor, was not observed in this study. No serious liver injuries were reported.

- For more data on pimicotinib, welcome to visit the official website of the 2023 ASCO annual meeting.

**Conclusion**

- Pimicotinib demonstrated significant antitumor activity with the objective response rate ("**ORR**") of 77.4% in 50 mg QD cohort by Independent Review Committee ("**IRC**") based on RECIST1.1, and a favorable safety profile with no apparent hepatotoxicity. 89.8% of patients remained on treatment.

- Range of motion, stiffness and pain indicated a trend of alleviation after the treatment of pimicotinib, and the changes in PD biomarkers indicated significant CSF-1R inhibition in TGCT patients.

- Updated data from 50 mg QD cohort showed higher ORR, continuous improvement over a longer treatment time and sufficient PK exposure, together with PD data observed supports the further evaluation of pimicotinib in a Phase III study (NCT05804045).

**About Pimicotinib**

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. Pimicotinib was granted the breakthrough therapy designation from both CDE on July 20, 2022 and FDA on January 30, 2023 for the treatment of TGCT patients who are not amenable to surgery.

Pimicotinib is the first highly selective CSF-1R inhibitor discovered by a Chinese company that entered into a global Phase III clinical trial. April 27, 2023, the first patient dosing of "A Phase III, Randomized, Double-blind, Placebo-Controlled, Multicenter Study of ABSK021 to Assess the Efficacy and Safety in Patients with TGCT" was completed in Beijing Jishuitan Hospital. This study is the first global Phase III study of TGCT to be conducted simultaneously in China and the U.S.. Approximately 100 participants are scheduled to be enrolled in approximately 50 centers worldwide, including 30 centers in China.

**About Phase I Study of Pimicotinib (NCT04192344)**

NCT04192344 is an open-label, first-in-human Phase I study currently ongoing in China and the U.S. for pimicotinib. The trial includes the following two parts, (i) a Phase Ia dose escalation study on patients with advanced solid tumor; and (ii) a Phase Ib dose expansion study to further evaluate the preliminary antitumor efficacy among selected tumor types, including TGCT. For TGCT cohort, the primary endpoint is the ORR under RECIST 1.1, and the secondary endpoints include overall tolerability, improvement of motion range and patient report outcome of pain and stiffness. Abbisko Therapeutics published the preliminary Phase Ib results of pimicotinib for advanced TGCT in November 15, 2022 at the 2022 Connective Tissue Oncology Society ("**CTOS**") annual meeting with a poster presentation (poster number: P164).

## About TGCT

TGCT is a locally aggressive neoplasm which 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 will undergo recurrence after surgical resection[2]. For TGCT patients 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: 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.