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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

POSITIVE TOP-LINE RESULTS FROM PIVOTAL PHASE 3 MANEUVER STUDY OF PIMICOTINIB IN TGCT PATIENTS AND UPDATED RESULTS FROM PHASE 1 STUDY OF PIMICOTINIB IN TGCT PATIENTS

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 Company hereby informs the shareholders and potential investors of the Company of the attached press release that, on November 12, 2024, Abbisko Therapeutics Co., Ltd. ("**Abbisko Therapeutics**"), a subsidiary of the Company, announced positive topline results from the pivotal Phase 3 MANEUVER study of pimicotinib, a small molecule inhibitor of CSF-1R, in-house developed by Abbisko Therapeutics, in patients with Tenosynovial Giant Cell Tumor ("**TGCT**"), and updated results from the Phase 1 study of pimicotinib in TGCT.

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, November 12, 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.

Abbisko Therapeutics Announces Positive Top-line Results from Pivotal Phase 3 MANEUVER Study of Pimicotinib in Patients with Tenosynovial Giant Cell Tumor and Updated Results from Phase 1 Study of Pimicotinib in TGCT

On November 12, 2024, Abbisko Therapeutics Co., Ltd. ("**Abbisko Therapeutics**") announced positive topline results from the pivotal Phase 3 MANEUVER study of pimicotinib, a small molecule inhibitor of CSF-1R, in-house developed by Abbisko Therapeutics, in patients with Tenosynovial Giant Cell Tumor ("**TGCT**"), and updated results from the Phase 1 study of pimicotinib in TGCT.

– The MANEUVER study met the primary endpoint with an objective response rate ("**ORR**") at Week 25 of 54.0% for pimicotinib compared with 3.2% for placebo ($p<0.0001$).

– The study also achieved statistically significant and clinically meaningful improvements versus placebo in all key secondary endpoints at Week 25, including ORR per tumor volume score, active range of motion, stiffness, pain, and physical function.

– Treatment with oral, once-daily pimicotinib was well-tolerated, with very low rates of discontinuation due to treatment-related adverse events.

– Updated results from Phase 1b study of pimicotinib demonstrated best ORR of 85.0% with median treatment duration of 20 months.

About MANEUVER

The pivotal Phase 3 MANEUVER study is a three-part, randomized, double-blind, placebo-controlled study to assess the efficacy and safety of pimicotinib in patients with TGCT who are eligible for systemic therapy and have not received prior anti-CSF1/CSF1R therapy. The study is being conducted in China (n=45), Europe (n=28), and the US and Canada (n=21).

In the double-blind Part 1, 94 patients were randomized 2:1 to receive either 50 mg QD of pimicotinib (n=63) or placebo (n=31) for 24 weeks. The primary endpoint is ORR at Week 25 as measured by Response Evaluation Criteria in Solid Tumors ("**RECIST**") version 1.1 by Blinded Independent Review Committee ("**BIRC**") in the intent-to-treat ("**ITT**") population. Secondary endpoints include tumor volume score, active range of motion, stiffness by Numeric Rating Scale ("**NRS**"), pain by Brief Pain Inventory ("**BPI**"), and physical function measured by PROMIS. Further efficacy and safety data from Part 1 of the MANEUEVER study will be presented at an upcoming medical conference.

After the double-blind Part 1, eligible patients may continue to the open-label Part 2 for up to 24 weeks of dosing. Patients who complete Part 2 may then enter the open-label extension phase (Part 3) for extended treatment and safety follow-up.

The study met its primary endpoint in the ITT population, showing a statistically significant and clinically meaningful improvement in ORR at Week 25 versus placebo, based on BIRC per RECIST v1.1. In the ITT population, the ORR at Week 25 was 54.0% for the pimicotinib arm and 3.2% for placebo arm ($p<0.0001$).

In MANEUVER, pimicotinib was well-tolerated, and the safety profile was consistent with previously reported data, with no evidence of cholestatic hepatotoxicity. Treatment-emergent adverse events ("**TEAEs**") leading to treatment discontinuation occurred in 1.6% (n=1) of patients treated with pimicotinib; TEAEs leading to dose reduction occurred in 7.9% (n=5) of pimicotinib-treated patients.

Updated long-term follow-up results from the phase 1b study of pimicotinib in TGCT

Abbisko Therapeutics also announced the updated results from the Phase 1 open-label, multicenter study evaluating the safety and efficacy of pimicotinib in patients with TGCT. The poster, titled, "Long-term efficacy and safety profile of Pimicotinib (ABSK021) in tenosynovial giant cell tumor: Phase 1b update," will be presented at the Connective Tissue Oncology Society ("**CTOS**") 2024 Annual Meeting in San Diego, United States from November 13, 2024 to November 16, 2024.

As of the June 30, 2024, updated data from 42 patients who received the 50 mg dose of pimicotinib showed:

– The best ORR was 85.0% by RECIST v1.1 per Independent Review Committee ("**IRC**"). With a median treatment duration of 20.67 months (0.5, 30.1), 54.8% and 38.1% patients had an exposure of ≥ 18 months and ≥ 24 months, respectively. The median duration of response was not reached ("**NR**") by Kaplan-Meier estimates, and 69.0% patients remained on treatment. Continuous and gradual improvement in tumor regression, pain and stiffness relief, and joint mobility were observed during long-term treatment.

– The overall safety profile remains largely consistent, with no distinct adverse events emerging upon long-term follow-up.

– No evidence of cholestatic hepatotoxicity was observed.

Conference Call and Webcast

Abbisko Therapeutics will host a conference call and webcast to discuss this announcement today, November 12, 2024, at 9:00 AM Beijing Time.

The conference call may be accessed via this link:

https://us06web.zoom.us/meeting/register/tZMkc-2grjooHNRNdPMn_xO7mEgGzbiwlUlJ

A webcast of the conference call will be available on the website:

https://live.vhall.com/v3/lives/watch/362484882

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 the discovery and development of innovative medicines that 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.

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.