Abbisko Cayman Limited
和譽開曼有限责任公司
(Incorporated in the Cayman Islands with limited liability)
(Stock Code: 2256)

VOLUNTARY ANNOUNCEMENT
IMPORTANT CLINICAL RESEARCH RESULTS OF ABSK011 AND ABSK043 WILL PRESENT AT THE ESMO CONFERENCE

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 the important clinical trial results of two self-developed innovative small molecule drug candidates, namely the clinical results of first-in-human study of FGFR4 inhibitor Irpagratinib (ABSK011) with advanced hepatocellular carcinoma and the clinical results of first-in-human dose-escalating of PD-L1 inhibitor ABSK043 with advanced solid tumors will be presented at the 2023 European Society for Medical Oncology (“ESMO”) annual meeting. The Irpagratinib BID cohorts demonstrated a promising efficacy with an ORR of 40.7% in FGF19+ HCC patients with prior therapies. Both research results will be the first of such release developed by a Chinese company for the respective target.

This is a voluntary announcement made by the Company. The Group cannot guarantee that Irpagratinib and ABSK043 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, October 16, 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.
Important Clinical Research Results of Irpagratinib and ABSK043 Will Debut at the 2023 ESMO Conference

On October 16, 2023, Abbisko Therapeutics announced that the important clinical trial results of two self-developed innovative small molecule drug candidates, namely the clinical results of first-in-human study of FGFR4 inhibitor Irpagratinib with advanced hepatocellular carcinoma and the clinical results of first-in-human dose-escalating of PD-L1 inhibitor ABSK043 with advanced solid tumors will be presented at the 2023 ESMO annual meeting. The Irpagratinib BID cohorts demonstrated a promising efficacy with an ORR of 40.7% in FGF19+ HCC patients with prior therapies. Both research results will be the first of such release developed by a Chinese company for the respective target.

Abbisko will present the following posters at the ESMO conference:

First-in-human study of ABSK-011, a novel, highly selective fibroblast growth factor receptor (FGFR) 4 inhibitor for treating advanced hepatocellular carcinoma (HCC) with FGF19 overexpression

Background:

• FGF19 overexpression (+) is in approximately 30% of HCC with poor prognosis;
• FGF19/FGFR4 signaling pathway could be a possible target for HCC;
• ABSK-011 is a highly selective and small molecule FGFR4 inhibitor.

Conclusion:

• ABSK-011 was generally safe and tolerated in HCC patients;
• The ABSK-011 BID cohorts demonstrated a promising efficacy with an ORR of 40.7% in FGF19+ HCC patients with prior therapies.
• The preliminary efficacy data of BID cohorts of ABSK-011 is promising, and such study is still ongoing, the efficacy of which is highly expected.
First-in-human dose-escalating study of ABSK043, a novel and oral small-molecule inhibitor of PD-L1, in patients with advanced solid tumors

Background:

- Immunotherapies targeting the PD-1/PD-L1 pathway with therapeutic antibodies have shown remarkable anti-tumor effects.


- At the ESMO, we report the preliminary results from the dose escalation part of first-in-human (FIH) study of ABSK043 in patients with advanced solid tumors (NCT04964375).

Conclusion:

- ABSK043 was well tolerated up to 1000 mg BID with no DLT reported and has a safety profile consistent with monoclonal antibody immune checkpoint inhibitors.

- On-target PD effects were consistent with PD-L1 inhibition and data reported by anti-PD-(L)1 mAbs.

- Preliminary anti-tumor activity was observed, and further investigation is warranted to explore the efficacy in a larger number of patients.

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 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.