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 THERAPEUTICS PRESENTS UPDATED CLINICAL PROGRESS ON IRPAGRATINIB AND PIMICOTINIB AT ESMO CONGRESS

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 it presents updated clinical safety and efficacy results for its self-discovered small molecule FGFR4 inhibitor irpagratinib (ABSK011), from a phase I clinical trial in patients with advanced hepatocellular carcinoma ("**aHCC**") harboring FGF19 overexpression at the European Society for Medical Oncology ("**ESMO**") Congress 2024. Irpagratinib 220mg BID cohort demonstrated excellent efficacy in immune checkpoint inhibitors ("**ICIs**") and multi-target small molecule tyrosine kinase inhibitors ("**mTKIs**") pre-treated aHCC patients harboring FGF19 overexpression, achieving an overall response rate ("**ORR**") of 44.8% with a median duration of response ("**mDoR**") of 7.4 months, and median progressionfree survival ("**mPFS**") of 5.5 months. In addition, the design of the phase II study of small molecule CSF-1R inhibitor pimicotinib (ABSK021) in combination with chemotherapy and with/without toripalimab as first-line treatment for advanced pancreatic ductal adenocarcinoma ("**PDAC**") will be presented at this conference.

This is a voluntary announcement made by the Company. The Group cannot guarantee that irpagratinib (ABSK011) and pimicotinib (ABSK021) will ultimately be successfully approved to the market. 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, September 15, 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 Presents Updated Clinical Progress on Irpagratinib and Pimicotinib at European Society for Medical Oncology (ESMO) 2024

On September 15, 2024, Abbisko Therapeutics presents updated clinical safety and efficacy results for its self-discovered small molecule FGFR4 inhibitor irpagratinib (ABSK011), from a phase I clinical trial in patients with advanced hepatocellular carcinoma ("**aHCC**") harboring FGF19 overexpression at the European Society for Medical Oncology ("**ESMO**") Congress 2024. **Irpagratinib 220mg BID cohort demonstrated excellent efficacy in immune checkpoint inhibitors ("ICIs") and multi-target small molecule tyrosine kinase inhibitors ("mTKIs") pre-treated aHCC patients harboring FGF19 overexpression, achieving an overall response rate ("ORR") of 44.8% with a median duration of response ("mDoR") of 7.4 months, and median progression-free survival ("mPFS") of 5.5 months.** In addition, the design of the phase II study of small molecule CSF-1R inhibitor pimicotinib (ABSK021) in combination with chemotherapy and with/without toripalimab as first-line treatment for advanced pancreatic ductal adenocarcinoma ("**PDAC**") will be presented at this conference.

Abbisko Therapeutics presentations at 2024 ESMO Congress:

Poster number: 983P

Title:

Updated Safety and Efficacy Results of Irpagratinib (ABSK011) in Advanced Hepatocellular Carcinoma (aHCC) with FGF19 Overexpression from a Phase I Study

Study background:

Patients were treated QD or BID in this study. Here, we mainly report the updated safety and efficacy results from the BID cohorts to further evaluate the efficacy and safety of irpagratinib (ABSK011).

Study population:

As of September 5, 2024, 122 patients have been enrolled, including 74 in the BID cohorts with doses consisting of 160mg BID, 220mg BID, and 300mg BID. 5.4% of the patients were BCLC Stage B, and 89.2% of the patients were BCLC Stage C. 64.9% of the patients had a Child-Pugh ("**CP**") Score of 5, 27% of the patients had a CP Score of 6, and 6.8% of the patients had a CP Score of 7. 64.9% of the patients received multiple lines of treatment. 85.1% of the patients had previously been treated with ICIs, and 75.7% of the patients had previously been treated with both ICIs and mTKIs.

Efficacy:

Forty pre-treated aHCC patients with FGF19 overexpression were treated with irpagratinib 220mg BID. Among the 38 evaluable patients, the response rate was 36.8% (14/38), and the disease control rate ("**DCR**") was 78.9% (30/38). The response rate from the subset of patients who had received ICIs and mTKIs was 44.8% (13/29), the longest DoR was 16.4 months, mDoR was 7.4 months, DCR was 79.3% (23/29), and mPFS was 5.5 months.

Safety:

One dose-limiting toxicity ("**DLT**") event was observed in the 300mg BID cohort. The most common treatment-related adverse effects (TRAEs, >20%) were ALT elevation, diarrhea, AST elevation, hyperphosphatemia, bilirubin elevation, alkaline phosphatase elevation, platelet decrease, and total bile acid elevation. Grade 3-4 treatment-related adverse events (>5%) included AST elevation, ALT elevation, and diarrhea. No grade 5 adverse events occurred.

Conclusion:

Currently there is no approved standard of care for aHCC patients who have progressed from first-line ICIs based therapies. The FGF19/FGFR4 signaling axis could be a novel therapeutic target for aHCC patients. **Irpagratinib demonstrated a tolerable safety profile and promising anti-tumor activity as a single agent.** Notably, the irpagratinib 220mg BID of regimen exhibited a 44.8% ORR, 7.4 months mDoR and 5.5 months mPFS in heavily pre-treated aHCC patients who had received both ICIs and mTKIs therapy, supporting further late-stage development of irpagratinib in such populations with substantial unmet medical need.

Poster number: 1533TiP

Title:

A Multicenter, Open-Label Phase II Study to Evaluate the Efficacy and Safety of Pimicotinib (ABSK021) in Combination with Chemotherapy with or without Toripalimab in Patients with Advanced Pancreatic Ductal Adenocarcinoma.

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 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.