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
FGFR4 INHIBITOR IRPAGRATINIB COMPLETED FIRST U.S. PATIENT DOSING IN THE EXPANSION PART OF A GLOBAL PHASE I STUDY

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 first patient in the United States has been successfully dosed in the global, multicenter Phase I clinical study (ABSK-011-101) of its independently developed, highly selective small-molecule FGFR4 inhibitor irpagratinib (ABSK-011) for patients with FGF19 overexpression advanced hepatocellular carcinoma ("**HCC**"). Previously, irpagratinib was granted Fast Track Designation ("**FTD**") by the U.S. Food and Drug Administration ("**FDA**"), which is expected to further accelerate its global clinical development.

This is a voluntary announcement made by the Company. The Group cannot guarantee that ABSK-011 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, 11 February 2026

As at the date of this announcement, the board of directors of the Company comprises Dr. Xu Yao-Chang, Dr. Yu Hongping and Dr. Ji Jing as executive directors; and Dr. Sun Piaoyang, Mr. Sun Hongbin and Ms. Chui Hoi Yam as independent non-executive directors.

Abbisko Therapeutics' FGFR4 Inhibitor Irpagratinib Completed First U.S. Patient Dosing in the Expansion Part of a Global Phase I Study

On 11 February 2026, Abbisko Therapeutics Co., Ltd. ("**Abbisko Therapeutics**") announced that the first patient in the United States has been successfully dosed in the global, multicenter Phase I clinical study (ABSK-011-101) of its independently developed, highly selective small-molecule FGFR4 inhibitor irpagratinib (ABSK-011) for patients with FGF19 overexpression advanced hepatocellular carcinoma ("**HCC**"). Previously, irpagratinib was granted Fast Track Designation ("**FTD**") by the U.S. Food and Drug Administration ("**FDA**"), which is expected to further accelerate its global clinical development.

Currently, the standard therapy for patients with advanced or unresectable HCC include immune checkpoint inhibitors ("**ICIs**") and multi-targeted kinase inhibitors ("**mTKIs**"), etc. Studies indicate that approximately 30% of HCC patients exhibit FGF19 overexpression, a subgroup associated with relatively poor outcomes following existing ICIs and mTKIs treatment, underscoring a substantial unmet medical need. Precision therapies targeting the FGF19/FGFR4 signaling pathway are therefore considered a promising strategy to deliver meaningful clinical benefit to this defined patient population.

Irpagratinib is a highly selective, oral small-molecule FGFR4 inhibitor developed by Abbisko Therapeutics for the treatment of advanced HCC with FGF19 overexpression. ABSK-011-101 is an open-label, global, multicenter Phase I study (NCT04906434) designed to assess the safety, tolerability, and pharmacokinetics of irpagratinib in patients with advanced solid tumors. The study consists of dose-escalation and dose-expansion parts. In the U.S., patients will be treated at the recommended dose determined from the completed dose-escalation part to further assess safety, tolerability, and preliminary efficacy in FGF19 overexpression advanced HCC.

Data from the China cohort of ABSK-011-101 demonstrated that irpagratinib monotherapy achieved durable antitumor activity with a favorable safety and tolerability profile in patients with FGF19 overexpression advanced HCC. Notably, in the subgroup of patients previously treated with ICIs and mTKIs, irpagratinib showed particularly encouraging efficacy, with an objective response rate ("**ORR**") of 46.7% and a median progression-free survival ("**mPFS**") of 5.5 months. These results were presented at the 2024 European Society for Medical Oncology ("**ESMO**") Congress.

In May 2025, irpagratinib received Breakthrough Therapy Designation ("**BTD**") from the Center for Drug Evaluation ("**CDE**") of China's National Medical Products Administration, and a pivotal registration clinical study was initiated across more than 50 research centers nationwide.

In addition, Abbisko presented the latest Phase II clinical data of irpagratinib in combination with atezolizumab for the treatment of HCC at the 2025 ESMO Gastrointestinal Cancers Congress ("**ESMO-GI**"). The combination demonstrated robust antitumor activity in both treatment-naïve and ICI-pretreated patients with FGF19 overexpression HCC, achieving an ORR exceeding 50% and an mPFS of more than 7 months. The overall safety profile was manageable, with no new safety signals observed, suggesting potential synergistic benefit with immunotherapy and supporting the regimen's promise as a candidate for first-line HCC treatment.

Looking ahead, Abbisko will accelerate the global clinical development and commercialization of irpagratinib, strengthen our international multi-center clinical network, and deliver transformative therapeutic options for patients with HCC worldwide.

About Irpagratinib (ABSK-011)

Irpagratinib is a highly-selective small molecule FGFR4 inhibitor designed to target overexpression of the FGF19 signaling pathway. Several epidemiological studies indicate that approximately 30% of HCC patients worldwide exhibit FGF19 overexpression. Development of targeted therapies against FGFR4 represent an innovative and novel approach to the treatment of HCC.

To date, no FGFR4 inhibitor has been granted regulatory approval globally. According to Frost & Sullivan, irpagratinib is expected to become the first breakthrough treatment for the treatment of HCC patients with FGF19 overexpression.

In addition to monotherapy, Abbisko Therapeutics is exploring irpagratinib in combination with atezolizumab, an anti-PD-L1 antibody manufactured by F. Hoffmann-La Roche and Roche (China), in a Phase II study.

About Abbisko Therapeutics

Founded in April 2016, Abbisko Therapeutics Co., Ltd. is an oncology-focused biopharmaceutical company based in Shanghai that is dedicated to the discovery and development of innovative medicines to treat unmet medical needs in China and globally. The Company was established by a group of seasoned drug hunters with rich research & development and managerial expertise from top multinational pharmaceutical companies. Since its founding, Abbisko Therapeutics has built an extensive pipeline of innovative 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.