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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)

VOLUNTARY ANNOUNCEMENT
FGFR4 INHIBITOR IRPAGRATINIB GRANTED FDA FAST TRACK DESIGNATION FOR HCC PATIENTS

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 U.S. Food and Drug Administration ("**FDA**") has granted Fast Track Designation ("**FTD**") to irpagratinib (ABSK-011), a highly selective small-molecule FGFR4 inhibitor independently developed by Abbisko Therapeutics, for the treatment of patients with hepatocellular carcinoma ("**HCC**") with FGF19 overexpression who have been previously treated with immune checkpoint inhibitors ("**ICIs**") and multi-targeted kinase inhibitors ("**mTKIs**") therapies.

This is a voluntary announcement made by the Company. The Group cannot guarantee that irpagratinib 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, February 10, 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 Granted FDA Fast Track Designation for HCC Patients

On February 10, 2026, Abbisko Therapeutics Co., Ltd. ("**Abbisko Therapeutics**") announced that the U.S. Food and Drug Administration ("**FDA**") has granted Fast Track Designation ("**FTD**") to irpagratinib (ABSK-011), a highly selective small-molecule FGFR4 inhibitor independently developed by Abbisko Therapeutics, for the treatment of patients with hepatocellular carcinoma ("**HCC**") with FGF19 overexpression who have been previously treated with immune checkpoint inhibitors ("**ICIs**") and multi-targeted kinase inhibitors ("**mTKIs**") therapies.

Currently, patients with advanced or unresectable HCC have limited effective treatment options after failure of ICIs- and mTKIs-based therapies. Studies indicate that approximately 30% of HCC patients have FGF19 overexpression, a subgroup associated with relatively poor prognosis following first-line targeted-immunotherapy combinations. Precision therapies targeting the FGF19/FGFR4 pathway are expected to provide an effective treatment option for these patients.

Irpagratinib is a highly selective FGFR4 inhibitor developed by Abbisko Therapeutics for the treatment of advanced HCC with FGF19 overexpression. The FDA's FTD was primarily based on positive results from a Phase I clinical study presented at the 2024 European Society for Medical Oncology ("**ESMO**") Annual Congress. Data demonstrated that irpagratinib monotherapy showed meaningful antitumor activity with a favorable safety and tolerability profile in patients with advanced HCC who had failed prior ICIs and mTKIs therapies and had FGF19 overexpression, achieving an objective response rate ("**ORR**") of 46.7% and a median progression-free survival ("**mPFS**") of 5.5 months.

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

In addition, Abbisko Therapeutics presented the latest study results of irpagratinib in combination with atezolizumab for the treatment of HCC at the 2025 ESMO Gastrointestinal Cancers Congress ("**ESMO-GI**"). In both treatment-naïve patients and those previously treated with ICIs whose tumors exhibited FGF19 overexpression, the combination therapy achieved ORR exceeding 50% and mPFS of more than 7 months, with no new safety signals observed, demonstrating the potential to challenge current first-line treatment paradigms for HCC.

The FDA's FTD is expected to accelerate the global clinical development and regulatory review of irpagratinib. Abbisko Therapeutics will continue to advance the international clinical development of this program, with the goal of delivering more precise and effective innovative treatment 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 Ltd. and Roche (China) Holding Ltd. , 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.