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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 ABBISKO THERAPEUTICS COMPLETES FIRST PATIENT DOSING IN REGISTRATIONAL STUDY OF IRPAGRATINIB FOR HCC

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 has completed first patient dosing in a registrational study of irpagratinib, a self-developed and highly-selective small molecule FGFR4 inhibitor, for the treatment of Hepatocellular Carcinoma ("HCC").

In May 2025, irpagratinib received Breakthrough Therapy Designation from the Center for Drug Evaluation of China's National Medical Products Administration. It is the first therapeutic agent to utilize molecularly defined biomarkers for precision-targeted treatment of HCC.

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, June 16, 2025

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 Completes First Patient Dosing in Registrational Study of Irpagratinib for HCC

On June 16, 2025, Abbisko Therapeutics Co., Ltd. ("Abbisko Therapeutics") announced that it has completed first patient dosing in a registrational study of irpagratinib, a self-developed and highly-selective small molecule FGFR4 inhibitor, for the treatment of Hepatocellular Carcinoma ("HCC").

In May 2025, irpagratinib received Breakthrough Therapy Designation from the Center for Drug Evaluation ("CDE") of China's National Medical Products Administration ("NMPA"). It is the first therapeutic agent to utilize molecularly defined biomarkers for precision-targeted treatment of HCC.

The vast majority of patients with advanced HCC treated with current standard-of-care therapies – including immune checkpoint inhibitors ("ICIs") and multi-targeted kinase inhibitors ("mTKIs") – experience disease progression within one year. Additionally, approximately 30% of HCC patients exhibit FGF19 overexpression, a biomarker associated with more aggressive tumor biology and poorer prognosis. The registrational study of irpagratinib (ABSK-011-205) is a multi-center, randomized, double-blind, placebo-controlled clinical trial designed to evaluate the efficacy and safety of irpagratinib in combination with Best Supportive Care ("BSC") versus placebo in combination with BSC, in patients with advanced or unresectable HCC who exhibit FGF19 overexpression and have previously been treated with ICIs and mTKIs. Eligible patients will be randomized in a 2:1 ratio to receive irpagratinib or placebo.

About Irpagratinib (ABSK-011)

Irpagratinib is a highly-selective FGFR4 small molecule 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. At the previous 2024 ESMO GI Congress, Abbisko Therapeutics presented clinical data demonstrating 220mg irpagratinib BID in combination with atezolizumab achieved a 50% objective response rate ("ORR") in FGF19 + HCC patients who had previously received ICI therapy.

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.