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 ORPHAN DRUG DESIGNATION BY EMA FOR HEPATOCELLULAR CARCINOMA

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 its independently developed, highly selective, oral small-molecule FGFR4 inhibitor irpagratinib (ABSK-011), has been granted Orphan Drug Designation ("**ODD**") by the European Medicines Agency ("**EMA**") for the treatment of hepatocellular carcinoma ("**HCC**"). Irpagratinib is currently being evaluated in multiple clinical studies across different regions globally. The ODD granted by the EMA is expected to strongly support the product's clinical development, regulatory filings, and commercialization in Europe.

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, 31 March 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 Orphan Drug Designation by EMA for Hepatocellular Carcinoma

On 31 March 2026, Abbisko Therapeutics Co., Ltd. ("**Abbisko Therapeutics**") announced that its independently developed, highly selective, oral small-molecule FGFR4 inhibitor irpagratinib (ABSK-011), has been granted Orphan Drug Designation ("**ODD**") by the European Medicines Agency ("**EMA**") for the treatment of hepatocellular carcinoma ("**HCC**"). Irpagratinib is currently being evaluated in multiple clinical studies across different regions globally. The ODD granted by the EMA is expected to strongly support the product's clinical development, regulatory filings, and commercialization in Europe.

Orphan Drug Designation is a key incentive established by the EMA to facilitate the development and authorisation of medicines for rare diseases. The ODD granted to irpagratinib not only reflects regulatory recognition of its potential clinical value and need, but also provides access to a range of incentives, including eligibility for protocol assistance ("**PA**"), regulatory fee reductions, and 10 years of market exclusivity after marketing authorisation.

Primary liver cancer ranks as the third leading cause of cancer-related mortality worldwide, with HCC accounting for approximately 75%-85% of cases. Currently, immune checkpoint inhibitors combined with anti-angiogenic therapy have become the standard first-line treatment for advanced HCC. However, effective second-line and later-line options remain limited. Additionally, approximately 30% of HCC patients exhibit FGF19 overexpression, and this subgroup tends to derive limited benefit from first-line targeted immunotherapy combinations. As there are no approved therapies targeting the FGFR4/FGF19 signaling pathway, significant unmet medical needs remain for patients with FGF19 overexpression under the current standard of care.

Irpagratinib is a highly selective, orally administered small-molecule FGFR4 inhibitor independently developed by Abbisko Therapeutics. In prior clinical studies, irpagratinib has demonstrated favorable safety and tolerability along with antitumor activity both as a monotherapy and in combination regimens in patients with FGF19-overexpressing advanced HCC. Currently, multiple clinical trials of irpagratinib are underway globally in patients with FGF19-overexpressing advanced HCC, including studies evaluating irpagratinib in combination with different targeted-immunotherapies in the first-line setting, as well as monotherapy in the second-line and later-line settings. Among these, first patient dosing in the pivotal registrational study of irpagratinib monotherapy was completed in June 2025, the study covers more than 50 clinical research centers across China, and is progressing smoothly.

In addition to the EMA ODD, irpagratinib has previously been granted ODD and Fast Track Designation ("**FTD**") by the U.S. Food and Drug Administration ("**FDA**"), as well as Breakthrough Therapy Designation ("**BTD**") by China's National Medical Products Administration ("**NMPA**"). Leveraging the expedited review advantages provided by these regulatory designations, Abbisko Therapeutics will continue to advance the global clinical development and regulatory filings of irpagratinib, with the goal of bringing this innovative therapy to HCC patients worldwide as early as possible and providing a new safe and effective precision treatment option for this challenging disease.

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. 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 anti-PD-L1 antibodies and anti-angiogenic therapies, in a Phase II study. At the the 2025 ESMO GI Congress, Abbisko Therapeutics presented clinical data showing that the combination of irpagratinib and atezolizumab achieved an objective response rate ("**ORR**") exceeding 50% and a median progression-free survival ("**mPFS**") of more than 7 months in FGF19-overexpressing HCC patients previously treated with immune checkpoint inhibitors.

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.