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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' IRPAGRATINIB COMBINED WITH TARGETED-IMMUNOTHERAPY COMPLETES FIRST PATIENT DOSING IN PHASE II TRIAL FOR FIRST-LINE TREATMENT OF ADVANCED 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 the first patient has been dosed in a Phase II study evaluating its independently developed, highly selective, oral small-molecule FGFR4 inhibitor irpagratinib (ABSK-011), in combination with standard of care (toripalimab plus bevacizumab biosimilar) as first-line treatment for patients with advanced or unresectable hepatocellular carcinoma ("**HCC**").

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, 16 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' Irpagratinib Combined with Targeted-Immunotherapy Completes First Patient Dosing in Phase II Trial for First-Line Treatment of Advanced HCC

On 16 March 2026, Abbisko Therapeutics Co., Ltd. ("**Abbisko Therapeutics**") announced that the first patient has been dosed in a Phase II study evaluating its independently developed, highly selective, oral small-molecule FGFR4 inhibitor irpagratinib (ABSK-011), in combination with standard of care (toripalimab plus bevacizumab biosimilar) as first-line treatment for patients with advanced or unresectable hepatocellular carcinoma ("**HCC**").

Primary liver cancer ranks as the third leading cause of cancer-related mortality worldwide, with HCC accounting for approximately 75%-85% of cases. Currently, targeted-immunotherapy (immune checkpoint inhibitors combined with anti-angiogenic therapy) have become the standard first-line treatment for advanced HCC. However, clinical practice has shown that treatment outcomes vary among patients with different molecular subtypes.

Retrospective analyses have demonstrated that, compared with patients with low FGF19 expression, those with FGF19 overexpression experienced a significantly shorter median progression-free survival ("**mPFS**") when receiving first-line targeted immunotherapy combinations (6.1 vs. 11.4 months)[1]. A downward trend in objective response rate ("**ORR**") was also observed (33.3% vs. 45.2%)[1]. This difference may be associated with aberrant activation of the FGFR4/FGF19 signaling pathway. Persistent activation of this pathway can upregulate PD-L1 expression in tumor cells, thereby promoting immune evasion and metastasis, and potentially attenuating the efficacy of immunotherapy-based combinations[2,3].

Therefore, adding an FGFR4 inhibitor to the existing standard immunotherapy-anti-angiogenic combination regimen may enhance antitumor activity through a complementary mechanism and potentially deliver additional clinical benefit to these patients. However, despite FGF19 overexpression occurring in up to 30% of HCC patients, there are currently no approved therapies targeting this pathway, leaving this population with unmet medical needs under the existing standard of care treatment paradigm.

Irpagratinib is a highly selective, orally administered small-molecule FGFR4 inhibitor independently developed by Abbisko Therapeutics that precisely targets the FGFR4/FGF19 signaling pathway. At the 2025 European Society for Medical Oncology Gastrointestinal Cancers Congress ("**ESMO GI**"), Abbisko Therapeutics presented Phase II study results of irpagratinib in combination with atezolizumab for the treatment of HCC. In both treatment-naïve patients and those previously treated with immune checkpoint inhibitors whose tumors exhibited FGF19 overexpression, the combination achieved an ORR exceeding 50% and mPFS of more than 7 months, with a manageable safety profile with no new safety signals observed[1]. These findings highlight the potential synergistic activity of irpagratinib with immunotherapy and provide a strong foundation for further studies combining irpagratinib with first-line standard therapy.

Based on these encouraging findings, Abbisko Therapeutics has initiated the clinical study evaluating irpagratinib in combination with toripalimab and bevacizumab biosimilar, aiming to systematically assess the safety, tolerability, and preliminary efficacy of this triplet regimen as a first-line treatment for patients with FGF19-overexpressing advanced or unresectable HCC.

In addition to this study, researchers worldwide are actively exploring new strategies combining irpagratinib with additional standard of care therapies. As more high-quality clinical studies progress and additional data accumulate, irpagratinib has the potential to offer new hope for patients with FGF19-overexpressing HCC and help advance the management of HCC toward more precise and personalized treatment.

References

[1] Cheng, Q., et al. (2025). 149MO Irpagratinib (ABSK-011) plus atezolizumab in first-line (1L) and immune checkpoint inhibitors (ICIs) treated advanced hepatocellular carcinoma (HCC) with FGF19 overexpression (+): Updated results of the phase II ABSK-011-201 study. Annals of Oncology.

[2] Guo C, et al. FGF19/FGFR4 signaling contributes to hepatocellular carcinoma survival and immune escape by regulating IGF2BP1-mediated expression of PD-L1. Biomed Pharmacother. 2024 Jan;170:115955.

[3] Xie M, et al. FGF19/FGFR4-mediated elevation of ETV4 facilitates hepatocellular carcinoma metastasis by upregulating PD-L1 and CCL2. J Hepatol. 2023 Jul;79(1):109-125.

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.

In addition to monotherapy, Abbisko Therapeutics is exploring irpagratinib in combination with anti-PD-L1 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 ORR exceeding 50% and a 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.