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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
FGFR2/3 INHIBITOR ABSK061 GRANTED ORPHAN DRUG DESIGNATION BY FDA FOR ACHONDROPLASIA

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 FGFR2/3 inhibitor ABSK061, has been granted Orphan Drug Designation ("**ODD**") by the U.S. Food and Drug Administration ("**FDA**") for the treatment of achondroplasia ("**ACH**"). This marks another significant milestone in the global development of ABSK061, following its recent Rare Pediatric Disease ("**RPD**") designation from the FDA. The ODD is expected to strongly support the product's clinical development, regulatory filings, and commercialization in the United States.

This is a voluntary announcement made by the Company. The Group cannot guarantee that ABSK061 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, 19 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' FGFR2/3 Inhibitor ABSK061 Granted Orphan Drug Designation by FDA for Achondroplasia

On 19 March 2026, Abbisko Therapeutics Co., Ltd. ("**Abbisko Therapeutics**") announced that its independently developed, highly selective, oral small-molecule FGFR2/3 inhibitor ABSK061, has been granted Orphan Drug Designation ("**ODD**") by the U.S. Food and Drug Administration ("**FDA**") for the treatment of achondroplasia ("**ACH**"). This marks another significant milestone in the global development of ABSK061, following its recent Rare Pediatric Disease ("**RPD**") designation from the FDA. The ODD is expected to strongly support the product's clinical development, regulatory filings, and commercialization in the United States.

Orphan Drug Designation is a key incentive established by the FDA to support the development and evaluation of innovative therapies for rare diseases. The ODD granted to ABSK061 not only underscores the FDA's recognition of its potential clinical value and need, but also provides several potential benefits, including tax credits for qualified clinical trials, waiver of NDA/BLA user fees, and potential seven years of market exclusivity after approval.

ACH is a rare autosomal genetic disorder that causes severe growth and developmental impairments. Research has shown that the pathogenesis of ACH is driven by aberrant activation of the FGFR3 caused by FGFR3 gene mutations, which suppress normal endochondral ossification[1]. Targeted inhibitors offer the potential to deliver more precise and effective treatment options for ACH patients.

ABSK061, independently developed by Abbisko Therapeutics, is a highly potent and selective small-molecule FGFR2/3 inhibitor. It has demonstrated robust target inhibitory activity, favorable pharmacokinetic properties, and a promising safety profile in preclinical studies. Its oral administration is expected to significantly improve treatment convenience and compliance, particularly in pediatric populations, highlighting its potential as a therapeutic option for children and adolescents with ACH.

ABSK061 is currently being evaluated in a Phase II clinical trial in children aged 3-12 years with ACH. The study dosed its first patient in China in December 2025, and preliminary data are expected to be reported in the second half of 2026.

With both RPD and ODD granted by the FDA, Abbisko Therapeutics will continue to accelerate the global clinical development and regulatory advancement of ABSK061, with the goal of bringing a safe and effective innovative treatment option to patients with ACH worldwide.

Reference:

[1] Savarirayan R, et al. International Consensus Statement on the diagnosis, multidisciplinary management and lifelong care of individuals with achondroplasia. Nat Rev Endocrinol. 2022 Mar;18(3):173-189.

About ABSK061

ABSK061 is a novel, orally bioavailable, highly potent and selective small molecule inhibitor of FGFR2 and FGFR3 independently discovered and wholly-owned by Abbisko Therapeutics. First-generation pan-FGFR inhibitors demonstrated clinical efficacy in multiple tumors carrying FGFR2/3 variants and have steadily gained regulatory approval globally. However, the therapeutic window of pan-FGFRs and their clinical efficacy have been limited by side effects associated with FGFR1 inhibition. By reducing FGFR1 activity while maintaining potency against FGFR2 and FGFR3, ABSK061 is expected to achieve a wider therapeutic window with improved clinical efficacy as a new-generation of FGFR inhibitors. ABSK061 for the treatment of achondroplasia has received both RPD and ODD from the FDA, and its Phase II clinical trial is currently ongoing.

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.