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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 RECEIVES FDA IND CLEARANCE FOR ACHONDROPLASIA IN CHILDREN

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 cleared the Investigational New Drug ("**IND**") application for ABSK061, a highly selective small-molecule FGFR2/3 inhibitor, for the treatment of children with achondroplasia ("**ACH**"). Coupled with the recent Rare Pediatric Disease Designation ("**RPDD**") and Orphan Drug Designation ("**ODD**") granted by the FDA, this will help Abbisko Therapeutics accelerate the overseas clinical development process for ABSK061.

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, 30 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 Receives FDA IND Clearance for Achondroplasia in Children

On 30 March, 2026, Abbisko Therapeutics Co., Ltd. ("**Abbisko Therapeutics**") announced that the U.S. Food and Drug Administration ("**FDA**") has cleared the Investigational New Drug ("**IND**") application for ABSK061, a highly selective small-molecule FGFR2/3 inhibitor, for the treatment of children with achondroplasia ("**ACH**"). Coupled with the recent Rare Pediatric Disease Designation ("**RPDD**") and Orphan Drug Designation ("**ODD**") granted by the FDA, this will help Abbisko Therapeutics accelerate the overseas clinical development process for ABSK061.

ABSK061 is currently being evaluated in a Phase II clinical trial for ACH, and in December 2025, the study dosed its first patient in China. Preliminary data are expected to be reported in the second half of 2026. As an important part in the global development strategy for ABSK061, Abbisko Therapeutics plans to enroll US patients into the Phase II study to further evaluate safety, tolerability, and efficacy of ABSK061 for the treatment of ACH.

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.

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 RPDD 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.

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.