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 IND CLEARANCE FROM THE CDE FOR ABSK061, A HIGHLY SELECTIVE FGFR2/3 INHIBITOR, FOR THE TREATMENT OF 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, today announced that the Center for Drug Evaluation of the China National Medical Products Administration has cleared the IND application for ABSK061, a selfdeveloped and highly-selective small molecule inhibitor of FGFR2/3, for the treatment of children with achondroplasia.

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, March 26, 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 Announces IND Clearance from the CDE for ABSK061, a Highly Selective FGFR2/3 Inhibitor, for the Treatment of Achondroplasia

On March 26, 2025, Abbisko Therapeutics Co., Ltd. ("**Abbisko Therapeutics**") today announced that the Center for Drug Evaluation ("**CDE**") of the China National Medical Products Administration ("**NMPA**") has cleared the IND application for ABSK061, a self-developed and highly-selective small molecule inhibitor of FGFR2/3, for the treatment of children with achondroplasia ("**ACH**").

A clinical study of ACH will be conducted under the title "A Phase I/II, Multicenter, non-randomized, Open-Label Study of ABSK061 to Evaluate Safety, Tolerability, Pharmacokinetics, and Efficacy in Children with ACH".

ACH is a rare disorder that leads to disproportionate short stature and is the most common form of dwarfism in humans. According to literature, ACH has an estimated incidence rate of approximately 4.6/100,000 live births, affecting over 250,000 to 385,000 individuals worldwide[1][2]. Patients with ACH are frequently noted to have shorter life expectancy compared to that of the general population[3], in addition to negative impacts on quality of life. Currently, there are no specific medications or methods for the etiological treatment of ACH in China.

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. It is the first FGFR2/3 inhibitor to enter clinical trials globally. 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.

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.

References:

1. Stender M, et al. Comprehensive literature review on the prevalence of comorbid conditions in patients with achondroplasia. Bone. 2022;162:116472.

2. Savarirayan R, et al. International consensus statement on the diagnosis, multidisciplinary management and lifelong care of individuals with achondroplasia[J]. Nat Rev Endocrinol, 2022, 18(3): 173-189.

3. Wynn J, King TM, Gambello MJ, Waller DK, Hecht JT. Mortality in achondroplasia study: a 42-year follow-up. Am J Med Genet A. 2007;143A(21):2502-2511.

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.