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 MUTANT INHIBITOR
ABSK012 OBTAINED CLINICAL STUDY APPROVAL FROM U.S. FDA

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 ABSK012, its self-developed small molecule inhibitor overcoming resistant mutations of fibroblast growth factor receptor 4 ("**FGFR4**"), has obtained an approval from the U.S. Food and Drug Administration ("**FDA**") to be used as a single medicine for first-in-human ("**FIH**") Phase I clinical study in patients with advanced solid tumors.

This is a voluntary announcement made by the Company. The Group cannot guarantee that ABSK012 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, November 8, 2023

As at the date of this announcement, the board of directors of the Company comprises Dr. Xu Yao-Chang, Dr. Yu Hongping and Dr. Chen Zhui as executive directors; Ms. Tang Yanmin as a non-executive director; and Dr. Sun Piaoyang, Mr. Sun Hongbin and Mr. Wang Lei as independent non-executive directors.

Abbisko Therapeutics Obtained Approval from U.S. FDA to Conduct FIH Clinical Study of A Next-Generation FGFR4 Mutant Inhibitor ABSK012

November 8, 2023, Abbisko Therapeutics announced that ABSK012, its self-developed small molecule inhibitor overcoming resistant mutations of FGFR4, has obtained an approval from the U.S. FDA to be used as a single medicine for FIH Phase I clinical study in patients with advanced solid tumors.

The approved study is "A Phase I, Open-Label Study of ABSK012 to Assess Safety, Tolerability, and Pharmacokinetics in Patients with Advanced Solid Tumors". The study population are patients with advanced solid tumors harboring specific molecular alterations, hepatocellular carcinoma ("**HCC**") patients with FGF19 overexpression, and rhabdomyosarcoma ("**RMS**") patients with FGFR4 mutations, etc.

Cancer is a leading cause of death worldwide, accounting for nearly 10 million deaths in 2020[1]. Solid tumors represent more than 90% of all cancers. Primary liver cancer is the sixth most common cancer globally, with nearly 906,000 new cases and 830,000 deaths in 2020[2]. In the U.S., there are more than 42,000 new cases and 31,000 deaths from liver cancer[3]. Notably, China accounts for approximately 50% of the incidence and mortality of liver cancer worldwide (more than 410,000 new cases and 391,000 deaths per year)[4]. IARC predicts that by 2040, new cases and deaths from liver cancer will further increase. Generally speaking, the treatment of liver cancer is difficult, the prognosis is poor, and the ratio of morbidity v.s. mortality is as high as 1:0.9, which seriously threatens human life and health. HCC is the main type of liver cancer, accounting for 85% to 90% of primary liver cancers[5]. HCC is highly malignant, about 30% of HCC has abnormal overexpression of FGF19 and poor prognosis, and the existing treatment methods still cannot meet the long-term survival benefits. For the treatment of HCC, there is still a huge unmet clinical need. Sarcomas are a rare and heterogeneous group of solid tumors of mesenchymal origin accounting for only 1% of all adult malignancies[6], and they can be divided broadly into soft tissue sarcomas ("**STS**") and osteosarcoma. In 2022, an estimate of 13,190 people were diagnosed with STS in the U.S., with approximately 5,130 deaths[6]. RMS is a subtype of STS, which is exceedingly rare in adults and accounts for 3% of all STS[7].

About ABSK012

ABSK012 is a highly selective and next-generation small molecule FGFR4 inhibitor overcoming FGFR4 mutations resistant to first-generation inhibitors. The FGFR4 signaling pathway is a promising direction for the development of molecular targeted therapies in solid tumor (e.g., HCC, RMS). ABSK012 also showed anti-tumor activity and had favorable drug metabolism and pharmacokinetics properties in the preclinical study. In April 2023, ABSK012 was granted the orphan drug designation (ODD) by the U.S. FDA for the treatment of STS.

Reference:

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2. World Health Organisation: Globocan 2020 – Liver Factsheet. Available at: https://gco.iarc.fr/today/data/factsheets/cancers/11-Liver-fact-sheet.pdf
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6. National Comprehensive Cancer Network.(2023)Soft Tissue Sarcoma (version 2. 2023).
7. Ferrari, A., Dileo, P., Casanova, M., Bertulli, R., Meazza, C., Gandola, L., Navarria, P., Collini, P., Gronchi, A., Olmi, P., Fossati-Bellani, F., & Casali, P. G. (2003). Rhabdomyosarcoma in adults. A retrospective analysis of 171 patients treated at a single institution. Cancer, 98(3), 571-580. https://doi.org/10.1002/cncr.11550

About Abbisko Therapeutics

Founded in April 2016, Abbisko Therapeutics Co., Ltd., a subsidiary of Abbisko Cayman Limited (Stock Code on the Hong Kong Stock Exchange: 2256.HK), is an oncology-focused biopharmaceutical company founded in Shanghai, dedicated to discovering and developing innovative medicines to treat unmet medical needs in China and globally. The Company was established by a group of seasoned drug hunters with rich R&D and managerial expertise from top multinational pharmaceutical companies. Since its founding, Abbisko Therapeutics has built an extensive pipeline of 15 innovative small molecule programs focused on precision oncology and immuno-oncology, including eight clinical stage assets.

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.