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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 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 a subsidiary of the Company, Abbisko Therapeutics Co., Ltd., has completed the dosing of the first patient in the Phase II clinical study for pan-FGFR inhibitor ABSK091 (AZD4547) in Urothelial Cancer.

This is a voluntary announcement made by the Company. The Group cannot guarantee that ABSK091 (AZD4547) 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, 2 December 2021

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

## Abbisko Therapeutics Completes Dosing of the First Patient in the Phase II Clinical Study for FGFR Inhibitor ABSK091 (AZD4547) in Urothelial Cancer

2 December, 2021, Shanghai – Abbisko Therapeutics Co., Ltd. ("Abbisko Therapeutics" hereafter) today announced dosing of the first patient in the phase II clinical study for ABSK091 (AZD4547), a pan-FGFR inhibitor, in urothelial cancer.

This clinical study (ABSK091-201, NCT05086666), which completed the enrollment of the first patient, is a phase II, multicenter, single-arm, open-label clinical trial conducted in China, to assess the efficacy of ABSK091 (AZD4547) in patients with locally advanced or metastatic urothelial carcinoma with FGFR2/3 genetic alterations, including mutations and/or fusions.

"Urothelial cancer is a common malignancy of the urinary system, with 20-30% of patients harboring FGFR aberrations, and currently there is no effective treatment for this group of patients in China," said Professor Dingwei Ye at Fudan University Shanghai Cancer Center, the principal investigator of the study. "There is still a large unmet clinical need. Therefore, I look forward to the clinical trial of this new therapy, which may provide a better treatment option for patients."

"ABSK091 (AZD4547) is one of the most advanced pan-FGFR inhibitors developed worldwide. The enrollment of the first patient in the Phase II clinical trial is another important milestone we have achieved for this program," said Dr. Jing Ji, Chief Medical Officer of Abbisko Therapeutics. "Together with the investigators, we are committed to quickly advance the clinical development of ABSK091 (AZD4547) and strive to provide more and better treatment options for patients."

#### About ABSK091 (AZD4547)

ABSK091, previously known as AZD4547, is a highly potent and selective inhibitor of FGFR subtypes 1, 2 and 3. Prior to the in-licensing of ABSK091 (AZD4547) by Abbisko Therapeutics, AstraZeneca has completed multiple clinical trials for AZD4547, including two Phase I trials and two Phase II trials. Among the clinical trials conducted by AstraZeneca, the BISCAY trial, a study in patients with advanced urothelial cancer who have progressed on prior treatments, achieved 31.3% response rate in the ABSK091 (AZD4547) monotherapy arm. In November 2019, Abbisko Therapeutics entered into an exclusive license agreement with AstraZeneca and obtained the global rights for the development, manufacturing and commercialization of ABSK091 (AZD4547). Abbisko Therapeutics has since completed a Phase I trial in Taiwan and a Phase Ib trial in Mainland China.

Further therapeutic areas like gastric cancers are also within the plan.

#### **About Urothelial Cancer**

According to research reports, the prevalence of urothelial cancer patients in China was about 200,000 in 2020. The FGFR aberration rate in urothelial cancer is approximately 30%. Surgery or radical cystectomy are the recommended first-line treatment for non-muscle invasive or early-stage urothelial cancer. For advanced or metastatic urothelial cancer, systemic therapies including but not limited to gemcitabine combined with cisplatin/carboplatin, gemcitabine combined with cisplatin/carboplatin and paclitaxel, and immune checkpoint inhibitors are recommended as first-line treatment options. So far there is no FGFR inhibitor approved in China for urothelial cancer.

### **About Abbisko Therapeutics**

Founded in April 2016, Abbisko Therapeutics Co., Ltd., a subsidiary of Abbisko Cayman Limited (Stock Code: 2256.HK), is an oncology focused biopharmaceutical company founded in Zhangjiang, Shanghai, dedicated to discovering and developing innovative medicines to treat unmet medical needs in China and around the world. 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 up an extensive pipeline of 14 innovative small molecule programs focused on precision oncology and immuno-oncology, including six clinical stage assets and eight pre-clinical stage assets. As of today, Abbisko Therapeutics has received ten IND or clinical trial approvals in four countries and regions.

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.