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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 THERAPEUTICS ANNOUNCES THE INITIATION OF A CLINICAL STUDY EVALUATING ABSK043 IN COMBINATION WITH FURMONERTINIB MESYLATE TABLETS FOR THE TREATMENT OF ADVANCED NON-SMALL CELL LUNG CANCER

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 investigational oral small molecule PD-L1 inhibitor, ABSK043, will be evaluated in a clinical study in combination with Furmonertinib Mesilate Tablets (IVESA<sup>®</sup>, "Furmonertinib"), independently developed by Shanghai Allist Pharmaceuticals Co., Ltd. ("Allist", SSE code: 688578), for the treatment of patients with advanced Non-Small Cell Lung Cancer (NSCLC).

This is a voluntary announcement made by the Company. The Group cannot guarantee that ABSK043 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, May 9, 2024

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 Announces the Initiation of a Clinical Study Evaluating ABSK043 in Combination with Furmonertinib Mesylate Tablets for the Treatment of Advanced Non-Small Cell Lung Cancer

On May 9, 2024, Abbisko Therapeutics announced that its investigational oral small molecule PD-L1 inhibitor, ABSK043, will be evaluated in a clinical study in combination with Furmonertinib Mesilate Tablets (IVESA<sup>®</sup>, "**Furmonertinib**"), independently developed by Shanghai Allist Pharmaceuticals Co., Ltd. ("Allist", SSE code: 688578), for the treatment of patients with advanced Non-Small Cell Lung Cancer (NSCLC). Details of the research collaboration includes an IND/CTA filing pertaining to the exploration of ABSK043 in combination with Furmonertinib in a multicenter, open-label phase 2 dose-escalation or dose-expansion clinical trial.

Abbisko Therapeutics previously disclosed first-in-human clinical trial results for ABSK043 in patients with advanced solid tumors at the 2023 European Society for Medical Oncology (ESMO) Congress. Among 11 evaluable patients (BID dosing), ABSK043 demonstrated an Objective Response Rate (ORR) of 27.3%. No dose-limiting toxicities or peripheral neuropathy cases were observed across all dose levels. ABSK043 is the first oral small molecule PD-L1 inhibitor in China and the second globally to have disclosed efficacy data, and exhibits best-in-class potential. In comparison to antibodies, small molecule inhibitors typically possess a lower risk of immunogenicity, flexible dosing regimens, and a convenient oral administration profile that can reduce cost of medical service in hospital caused by intravenous infusions.

The clinical study of ABSK043 in combination with Furmonertinib is expected to bring potential better treatment regimen for advanced non-small cell lung cancer patients.

## About ABSK043

ABSK043 is a novel, orally administered small molecule PD-L1 inhibitor, displaying exceptional activity and high selectivity. Tumor cells can exploit immune checkpoints such as PD-1 and its ligand PD-L1 to evade immune detection and clearance, thereby suppressing or restricting T-cell responses. While several PD-1/PD-L1 antibodies have been approved worldwide, there are currently no approved PD-1/PD-L1 small molecule drugs. ABSK043 specifically binds to the PD-L1 receptor and induces its endocytosis from the cell surface, effectively inhibiting the interaction of PD-1/PD-L1 and alleviating PD-L1-mediated suppression of T-cell activation. In several preclinical models, ABSK043 has demonstrated anti-tumor efficacy comparable to approved PD-L1 antibody drugs. At present, ABSK043 is undergoing Phase I clinical trial targeting advanced solid tumors in Australia and China.

# About Furmonertinib

Furmonertinib is a self-developed 3rd generation of EGFR-TKI with independent IP from China. It is approved for the second-line and first-line indication treatment of adult patients with locally advanced or metastatic NSCLC with EGFR mutations in March 2021 and June 2022, respectively, both of which are included in the National Reimbursement Drug List. Allist has entered into a licensing agreement with ArriVent Biopharma, Inc. in June 2021 for the exclusive global rights (ex-China) of Furmonertinib. Thus far, the global multi-center (including China, the United States, the United Kingdom, France, Japan, South Korea, etc.), registrational Phase III clinical study of Furmonertinib is well advanced, which is used for the first-line indication treatment of NSCLC patients harboring EGFR Exon 20 insertion mutations. In addition, Furmonertinib has been granted as Breakthrough Therapy Designation in China and the United States for the indication treatment of NSCLC with EGFR Exon 20 insertion mutations. The phase III clinical studies for adjuvant treatment of NSCLC with EGFR-sensitive mutations and for the first-line treatment of NSCLC with uncommon EGFR mutations are also progressing smoothly.

## **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 the discovery and development of innovative medicines that 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 16 innovative small molecule programs focused on precision oncology and immuno-oncology.

For more information, please visit www.abbisko.com.

## **About Allist**

Shanghai Allist Pharmaceuticals Co., Ltd, founded in March 2004, is an innovative pharmaceutical company with a fully integrated system for research and development, manufacturing, and commercialization of novel oncology drugs with a purpose to meet with medical needs across the globe. In accordance with its development concept "Advancing Long Life with Innovation of Science and Technology", Allist is dedicated to self-develop First-in-class and Best-in-class drug candidates. After 20 years of endeavor, Allist has successfully developed and received approvals of two innovative drugs by its own. On December 2, 2020, Shanghai Allist Pharmaceuticals Co., Ltd. was officially listed on the Science and Technology Innovation Board of the Shanghai Stock Exchange (stock number: 688578). Based on the Best-in-class potential of Furmonertinib and professional commercial capability, Allist has achieved a leap-forward growth. In 2023, Allist achieved a total operating revenue of 2.018 billion yuan and a net profit attributable to shareholders of 306 million yuan.

For additional information, please visit www.allist.com.cn.

### **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.