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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**

## ABSK011 AND ABSK043 CLINICAL RESULTS WILL BE PRESENTED AT ESMO

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., a subsidiary of the Company, announced that the important clinical trial results of two self-developed innovative small molecule drug candidates, namely the clinical results of first-in-human study of FGFR4 inhibitor Irpagratinib (ABSK011) with advanced hepatocellular carcinoma and the clinical results of first-in-human dose-escalating of PD-L1 inhibitor ABSK043 with advanced solid tumors will be presented at the 2023 European Society for Medical Oncology (ESMO) annual meeting.

This is a voluntary announcement made by the Company. The Group cannot guarantee that Irpagratinib (ABSK011) and 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, July 31, 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 will present clinical results of two First-in-Human Studies at the 2023 European Society for Medical Oncology (ESMO)

31 July 2023, Shanghai – Abbisko Therapeutics Co., Ltd. ("Abbisko Therapeutics") announced that the important clinical trial results of two self-developed innovative small molecule drug candidates, namely the clinical results of first-in-human study of FGFR4 inhibitor Irpagratinib (ABSK011) with advanced hepatocellular carcinoma and the clinical results of first-in-human dose-escalating of PD-L1 inhibitor ABSK043 with advanced solid tumors will be presented at the 2023 European Society for Medical Oncology (ESMO) annual meeting. The Irpagratinib Phase 1b data, since the first announcement at the end of 2022, includes further updates after enrolling more patients. Both research results will be the first of such release by a Chinese company for the respective target, which will be presented at the ESMO in Spain from October 20 to 24, 2023.

Abstract number: 1012P

Title: First-in-human study of ABSK011, a novel, highly selective fibroblast growth factor receptor (FGFR) 4 inhibitor for treating advanced hepatocellular carcinoma (HCC) with FGF19 overexpression.

Time: 20-24 October 2023

Abstract number: 700P

Title: First-in-human dose-escalating study of ABSK043, a novel and oral small-molecule inhibitor of PD-L1, in patients with advanced solid tumors

Time: 20-24 October 2023

### **About Irpagratinib (ABSK011)**

Irpagratinib (ABSK011) is a potent and highly selective small molecule inhibitor of FGFR4. Irpagratinib is being developed for the treatment of advanced HCC with hyperactivation of FGF19 signaling. The research studies have shown that about 30% of global HCC patients have FGF19/FGFR4 signaling, thus, the FGFR4 signaling pathway is a promising direction for the development of molecular targeted therapies in HCC. Irpagratinib demonstrated improved potency and antitumor efficacy compared to competitors as well as favorable physical-chemical properties in preclinical studies. According to Frost & Sullivan and the global competitive landscape of FGFR4 inhibitors, we believe that Irpagratinib is potentially a novel and leading FGFR4 inhibitor for the treatment of HCC patients with hyper-activation of FGF19 pathway. As of today, no FGFR4 inhibitors have been approved in the world.

Abbisko Therapeutics is also conducting a Phase II trial of Irpagratinib in combination with the anti-PD-L1 antibody Atezolizumab produced by F. Hoffmann-La Roche Ltd. and Roche China Holding Ltd. in late-stage HCC patients with FGF19 overexpression in China's mainland. Patient enrollment is ongoing.

In November 2022, ABSK-011 was given the generic name "Irpagratinib" by the World Health Organization under the International Nonproprietary Name system.

#### **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 monoclonal antibodies have been approved worldwide, there are currently no approved PD-1/PD-L1 small molecule drugs. ABSK043 selectively binds to the PD-L1 receptor and induces its internalization 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 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 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 seven clinical stage assets and eight pre-clinical stage assets. As of today, Abbisko Therapeutics has received 18 IND or clinical trial approvals in multiple 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.