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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
EGFR EXON20INS INHIBITOR ABSK112
RECEIVED CLINICAL TRIAL APPROVAL FROM 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., a subsidiary of the Company, announced that its self-developed next-generation EGFR Exon20ins inhibitor ABSK112, received the clinical trial approval by the U.S. Food and Drug Administration (“**FDA**”), and it will start the first-in-human Phase I clinical trial for the treatment of non-small cell lung cancer (“**NSCLC**”).

This is a voluntary announcement made by the Company. The Group cannot guarantee that ABSK112 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 4, 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 Therapeutic Announces the Clinical Trial Approval by FDA for its Next-generation EGFR Exon20ins Inhibitor ABSK112

July 4, 2023, Shanghai – Abbisko Therapeutics Co., Ltd. (“**Abbisko Therapeutics**”) announced that its self-developed next-generation EGFR Exon20ins inhibitor ABSK112, received the clinical trial approval by the FDA, and it will start the first-in-human Phase I clinical trial for the treatment of NSCLC.

ABSK112 is a next-generation oral EGFR Exon20ins inhibitor with excellent activity, selectivity and brain penetrating ability. In comparison to previously approved or clinically studied EGFR Exon20ins inhibitors, ABSK112 in preclinical studies demonstrated excellent brain penetrating ability, better selectivity over wild type EGFR, broader spectrum of Exon20ins mutation coverage, and superior in vivo efficacy in various EGFR Exon20ins mouse xenograft models. These findings highlight ABSK112’s potential to offer an improved therapeutic window and enhanced efficacy in clinical settings, positioning it as a next-generation and potentially best-in-class EGFR Exon20ins inhibitor.

About NSCLC

Lung cancer is the second most common cancer worldwide, with more than 2 million new cases in 2020, including 227,875 cases in U.S. and 815,563 cases in China, respectively. It ranks first in terms of mortality, with more than 1.7 million deaths per year, including 138,225 cases (7.7%) in U.S. and 714,699 cases (39.8%) in China¹. NSCLC comprises the vast majority (85%) of all lung cancers. Epidermal growth factor receptor (EGFR) mutations were reported in about 17% and 50% of lung adenocarcinoma in Caucasians and Asians, respectively².

About ABSK112-101

This is a first-in-human (FIH), multicenter, non-randomized, open-label Phase I study. The study will start with a dose escalation of ABSK112 in patients with NSCLC to evaluate the safety, tolerability, pharmacokinetic (PK), and preliminary antitumor efficacy.

References:

1. International Agency for Research on Cancer (IARC). Cancer Today (iarc.fr). Released December 14, 2022. Accessed May 6, 2023.
2. Fang W, Huang Y, Hong S, et al. EGFR exon 20 insertion mutations and response to osimertinib in non-small-cell lung cancer. *BMC Cancer*. 2019;19(1):595.

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.