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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

FGFR4 INHIBITOR IRPAGRATINIB GRANTED ODD BY 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 its self-developed FGFR4 inhibitor, irpagratinib (ABSK011), a highly selective small molecule, has been granted Orphan Drug Designation (“**ODD**”) by the U.S. Food and Drug Administration (“**FDA**”) for the treatment of Hepatocellular Carcinoma (“**HCC**”).

This is a voluntary announcement made by the Company. The Group cannot guarantee that irpagratinib (ABSK011) 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, April 25, 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 Irapagatinib, an Innovative FGFR4 inhibitor, has been Granted ODD by FDA for the Treatment of HCC

On April 25, 2024, Abbisko Therapeutics announced that its innovative FGFR4 inhibitor, irapagatinib (ABSK011), has been granted ODD by FDA for the treatment of HCC.

FDA grants ODD to investigational drugs and biologics that are intended for the treatment of rare diseases that affect fewer than 200,000 people in the U.S.. Receiving ODD provides drug developers with various benefits designed to support the development of novel drugs and biologics, including marketing exclusivity for seven years upon FDA approval, tax credits for qualified clinical trial expenditures, and exemptions from FDA application and user fees.

Irapagatinib is a highly selective FGFR4 small molecule inhibitor intended for the treatment of advanced solid tumors that present with abnormalities in the FGFR4 signaling pathway (e.g., ligand FGF19 amplification/overexpression, FGFR4 mutation/amplification/fusion), including advanced HCC, cholangiocarcinoma, breast cancer, among others. The FGFR4 signaling pathway is a recognized and promising target for the treatment of HCC. Clinical data with irapagatinib have demonstrated improved potency and anti-tumor efficacy compared to competitors, among other favorable therapeutic properties. At the 2023 European Society of Medical Oncology (ESMO) conference, Abbisko Therapeutics presented updated clinical data for irapagatinib demonstrating excellent preliminary efficacy and safety in patients with previously treated hepatocellular carcinoma with aberrant FGF19 expression, with an ORR of 40.7% in patients enrollment of BID cohort, significantly exceeding the previous FGFR4 inhibitors that have entered clinical trials globally.

We believe irapagatinib is potentially a novel and leading FGFR4 inhibitor for the treatment of HCC patients with hyper-activation of FGF19/FGFR4 pathway based on competitive landscape of FGFR4 inhibitors globally, according to Frost & Sullivan.

Based on epidemiological records from the International Agency for Research on Cancer (IARC), a specialized cancer agency of the World Health Organization (WHO), there were 42,284 new cases of primary liver and 31,078 attributable deaths in the United States in 2020, with rates highest among American Indian or Alaska Native individuals ^[1]. HCC accounts for 85%-90% of primary liver cancers, with challenging treatment and poor prognosis. The ratio of incidence rate to fatality rate is high, which seriously threatens human life and health.

Reference:

1. World Health Organisation: Globocan 2020 – United States of America Factsheet. Available at: <https://gco.iarc.fr/today/data/factsheets/populations/840-united-states-of-america-fact-sheets.pdf>

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.

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.