**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 HCC CLINICAL TRIAL APPROVED BY U.S. 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 Irpagratinib (ABSK011), a highly selective small molecule inhibitor of fibroblast growth factor receptor 4 ("**FGFR4**"), has obtained an investigational new drug ("**IND**") approval from the U.S. Food and Drug Administration ("**U.S. FDA**") for Phase I study in patients with advanced hepatocellular carcinoma ("**HCC**").

This is a voluntary announcement made by the Company. The Group cannot guarantee that Irpagratinib 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, September 25, 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 Therapeutics Obtained an IND Approval from U.S. FDA for FGFR4 Inhibitor Irpagratinib (ABSK011)**

On September 25, 2023, Abbisko Therapeutics Co., Ltd. ("**Abbisko Therapeutics**") announced that Irpagratinib (ABSK011), a highly selective small molecule inhibitor of FGFR4, has obtained an IND approval from U.S. FDA for Phase I study in patients with advanced HCC.

The approved study is "A Phase 1, Open-Label Study of ABSK011 to Assess Safety, Tolerability, and Pharmacokinetics in Patients with Advanced Solid Tumors". The study population was mainly FGF19-overexpressing HCC patients. This is the first clinical trial of Irpagratinib conducted by Abbisko Therapeutics outside of China.

In December 2022, Abbisko Therapeutics announced preliminary results of Phase I trial of Irpagratinib as second-line treatment for HCC patients with FGF19 overexpression in China, which showed excellent safety and efficacy.

Abbisko Therapeutics will present updates on Irpagratinib's Phase I clinical trial at the European Society for Medical Oncology (ESMO) Annual Meeting in October 2023.

Meanwhile, Abbisko Therapeutics is also conducting a Phase II trial of Irpagratinib in combination with the anti-PD-L1 antibody Atezolizumab produced by Roche in advanced HCC patients with FGF19 overexpression in mainland China, and first patient enrollment was completed in February 2022.

According to statistics from the International Agency for Research on Cancer ("**IARC**") of the World Health Organization (WHO), primary liver cancer ranks sixth in terms of the malignant tumor incidence rate worldwide in 2020, with 906,000 new cases and 830,000 deaths per year[1]. In the U.S., there are more than 42,000 new cases and 31,000 deaths[2]. Liver cancer is particularly prevalent in our country, with 410,000 new cases and 391,000 deaths per year[3], accounting for approximately 50% of global liver cancer cases. IARC predicts that new cases and deaths of liver cancer will continue to increase by 2040. In general, liver cancer presents a formidable challenge in terms of treatment, often yielding a grim prognosis. The morbidity-to-mortality ratio can be as high as 1:0.9, posing a significant threat to both life and overall health. HCC , as the most common type of liver cancer, accounts for 85% to 90% of primary liver cancers[4]. Due to high malignancy, approximately 30% of HCC patients has abnormal FGFR4 overexpression and poor prognosis, and the existing treatment methods fall short in providing long-term survival benefits. There remains a significant unmet clinical need in addressing HCC treatment.

**About Irpagratinib**

Irpagratinib, a highly selective small molecule inhibitor of FGFR4, is developed for the treatment of advanced solid tumors, especially for advanced HCC, cholangiocarcinoma, breast cancer, etc. with abnormal FGFR4 signaling pathway (such as ligand FGF19 amplification/overexpression, FGFR4 mutation/amplification/fusion). The FGFR4 signaling pathway is a promising direction for the development of molecularly targeted therapies in HCC. Irpagratinib demonstrated improved potency and anti-tumor efficacy as well as favorable physical-chemical properties in preclinical studies. Based on the data from Frost Sullivan, within the competitive landscape of global FGFR4 inhibitors, **we believe that Irpagratinib has the potential to emerge as a novel leading FGFR4 inhibitor for the treatment of HCC patients with highly activated FGF19/FGFR4 pathways.**

**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 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 8 clinical stage assets.

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.

Reference:


1. World Health Organisation: Globocan 2020 – Liver Factsheet. Available at: https://gco.iarc.fr/today/data/factsheets/cancers/11-Liver-fact-sheet.pdf

2. 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

3. World Health Organisation: Globocan 2020 – China Factsheet. Available at: http://gco.iarc.fr/today/data/factsheets/populations/160-china-fact-sheets.pdf

4. El-Serag HB, Rudolph KL. Hepatocellular carcinoma: epidemiology and molecular carcinogenesis. Gastroenterology. 2007;132(7):2557-2576. doi:10.1053/j.gastro.2007.04.061