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 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 which states that Abbisko Therapeutics Co., Ltd., a subsidiary of the Company, announces the preliminary Phase I efficacy and safety data of Irpagratinib (ABSK011) in patients in second-line hepatocellular carcinoma with FGF19 overexpression.

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, December 15, 2022

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; Dr. Xia Gavin Guoyao and Ms. Tang Yanmin as non-executive directors; and Dr. Sun Piaoyang, Mr. Sun Hongbin and Mr. Wang Lei as independent non-executive directors.

Abbisko Therapeutics announces preliminary Phase I safety and efficacy results of Irpagratinib (ABSK011) in patients in second-line hepatocellular carcinoma with FGF19 overexpression

15 December 2022, Shanghai – Abbisko Therapeutics Co., Ltd. ("**Abbisko Therapeutics**" hereafter) announced today the preliminary Phase I efficacy and safety results of its potent and highly selective small molecule inhibitor of fibroblast growth factor receptor 4 ("**FGFR4**") Irpagratinib (ABSK011), in the treatment of second-line hepatocellular carcinoma ("**HCC**") with fibroblast growth factor 19 ("**FGF19**") overexpression.

About Phase I trial of Irpagratinib (ABSK011) (NCT04906434)

NCT04906434 is an open-label, multi-center Phase I trial of Irpagratinib (ABSK011) with an escalation part (Phase Ia) and an expansion part (Phase Ib). In the Phase Ia trial, the Company assessed multiple dosages and, based on safety, tolerability, PK and PD data obtained from the Phase Ia trial, 180mg QD was identified as the first recommended dose for expansion ("**RDE**") in 2021. We have extended to higher doses including but not limited to 320mg QD, 400mg QD and 160mg BID for dose escalation.

The primary objective of Phase Ib trial is to evaluate the preliminary anti-tumor activity of Irpagratinib (ABSK011) in advanced HCC patients with FGF19 overexpression. We are currently conducting the Phase Ib monotherapy trial at 180mg QD in second-line treatment of HCC patients with FGF19 overexpression and will explore higher dose or dosing schedule for expansion in addition to 180mg QD in mainland China.

Preliminary efficacy and safety data for 42 HCC patients, out of which 27 patients are FGF19 IHC+, has been analyzed as of September 2022.

Results

1) Conclusion

- The preliminary proof-of-concept data of Irpagratinib (ABSK011) Phase I has shown promising efficacy in FGF19+ HCC patients, with 22% objective response rate ("**ORR**") (4/18) in patients with high FGF19 expression and 33.3% ORR (2/6) in the 160mg BID cohort. Irpagratinib (ABSK011) is well tolerated across all cohorts.

2) Efficacy

- Patient group with high expression of FGF19, which was observed in 67% of the FGF19 IHC+ HCC patients, experienced 22% ORR (4/18)

- Patients in the 160mg BID cohort in dose escalation were all FGF19+ and experienced 33% ORR (2/6).

3) Safety

- No drug related adverse effect of grade 4 or above was reported.
- Diarrhea was reported in 72.9% of patients, which is an expected on-target toxicity related to enhanced bile-acid secretion through inhibition of FGFR4. Most patients experienced low-grade diarrhea and only one patient (2.1%) experienced grade 3 diarrhea.
- Most ALT and AST elevations were transient and manageable with supportive care, and only a small number of patients needed dose interruption or reduction.
- No ocular or nail toxicity was reported.

About Irpagratinib (ABSK011)

Irpagratinib (ABSK011) is a potent and highly selective small molecule inhibitor of FGFR4. Irpagratinib (ABSK011) is being developed for the treatment of advanced HCC with hyper-activation of FGF19/FGFR4 signaling. The FGFR4 signaling pathway is a promising direction for the development of molecularly targeted therapies in HCC. Irpagratinib (ABSK011) demonstrated improved potency and anti-tumor efficacy compared to competitors as well as favorable physical-chemical properties in preclinical studies. We believe Irpagratinib (ABSK011) 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.

Abbisko Therapeutics is also conducting a Phase II trial of Irpagratinib (ABSK011) 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 mainland China. Patient enrollment is ongoing.

In November 2022, ABSK011 was given the generic name "Irpagratinib" by World Health Organization under the International Nonproprietary Name system.

About hepatocellular carcinoma

HCC is the most common type of liver cancer, one of the most lethal cancers and the third-most-common cause of cancer-related deaths worldwide. In 2020, the number of new HCC cases reached 0.8 million worldwide, and is expected to reach 1.0 million by 2030, according to Frost & Sullivan. Despite advances in the treatment of HCC, there remains a significant unmet needs for treatments of FGFR4-driven HCC. Patients with an overexpression of FGF19/FGFR4 account for approximately 30% of total HCC patients worldwide, according to Frost & Sullivan. Currently, no FGFR4 inhibitor has been approved to the market yet as far as we are aware.

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 Zhangjiang, Shanghai, dedicated to discovering and developing innovative medicines to treat unmet medical needs in China and around the world. 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 up an extensive pipeline of 15 innovative small molecule programs primarily 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 15 IND or clinical trial approvals in four 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.