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 II efficacy and safety data of Fexagratinib (ABSK091) in patients with urothelial carcinoma.

This is a voluntary announcement made by the Company. The Group cannot guarantee that Fexagratinib (ABSK091) 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 8, 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 II safety and efficacy results of Fexagratinib (ABSK091) in patients with urothelial carcinoma

8 December 2022, Shanghai – Abbisko Therapeutics Co., Ltd. ("**Abbisko Therapeutics**" hereafter) announced today the preliminary Phase II efficacy and safety results of its investigational pan-FGFR inhibitor Fexagratinib (ABSK091) in patients with urothelial carcinoma harboring FGFR2 or FGFR3 alterations in mainland China.

About Phase Ib/II trial of Fexagratinib (ASBK091) (NCT05086666)

NCT05086666 is an open-label Phase Ib/II clinical study. In the Phase Ib study, the safety, tolerability and PK of Fexagratinib (ASBK091) in Chinese patients with advanced solid tumors was evaluated and recommended Phase II dose ("**RP2D**") was determined. In the Phase II study, the primary endpoint is to evaluate the objective response rate ("**ORR**") (based on RECIST 1.1) of Fexagratinib (ABSK091) on treating patients diagnosed with locally advanced or metastatic urothelial carcinoma ("**mUC**") harboring FGFR2 or FGFR3 genetic alterations. Preliminary efficacy and safety data has been analyzed for the first 13 response-evaluable patients as of October 2022. It is expected that a total of approximately 88 patients will be enrolled for the Phase II clinical trial.

Results

1) Conclusion

- The preliminary efficacy results showed an ORR confirmed by Independent Review Committee ("**IRC**") of 30.7% (4/13) in mUC patients with FGFR3 alteration (including mutations and/or fusions) and an IRC confirmed ORR of 44% (4/9) in patients with FGFR3 mutations, which is consistent with results from the prior BISCAY trial of Fexagratinib (ABSK091) in similar patient groups outside of China. The preliminary safety results showed that 80mg BID of Fexagratinib (ABSK091) was well-tolerated in Chinese patients, and no drug related grade 4 or above adverse effects were reported. These results support further development of Fexagratinib (ABSK091) in the ongoing Phase II trial.

2) Efficacy

- Most of the mUC patients with FGFR3 alterations had tumor shrinkage and approximately 30.7% (4/13) of the patients achieved partial response confirmed by IRC per RECIST 1.1.

- Better efficacy was observed in mUC Patients with FGFR3 mutations with an IRC confirmed ORR of 44% (4/9) per RECIST 1.1.

3) Safety

- 80mg BID of Fexagratinib (ABSK091) was well-tolerated in Chinese patients with solid tumors, with no DLT events reported, and was determined as RP2D.

- No drug related grade 4 or above adverse effects were reported in mUC patients.

- FGFR-specific adverse effects, such as retinal disorder, nail disorder, dry mouth, hyperphosphatemia etc., were mild to moderate, reversible and manageable.

About Fexagratinib (ABSK091)

Fexagratinib (ABSK091) is a highly potent and selective inhibitor of FGFR1-3. Results from multiple prior clinical trials outside of China have demonstrated preliminary efficacy of Fexagratinib (ABSK091) in treating urothelial carcinoma and other types of solid tumors. In November 2021, Abbisko Therapeutics initiated a Phase II trial Fexagratinib (ABSK091) in patients with urothelial carcinoma harboring FGFR2 or FGFR3 alterations in mainland China. In February 2022, the Company also entered into partnership with BeiGene, Ltd. ("**BeiGene**") on the combination therapy of Fexagratinib (ABSK091) and Tislelizumab, an anti-PD-1 antibody developed by BeiGene, for the treatment of urothelial carcinoma with FGFR2/3 genetic alterations.

In addition to urothelial carcinoma, the Company also plans to conduct clinical trials for Fexagratinib (ABSK091) in other solid tumors. In March 2022, the Company received Orphan Drug Designation granted by the U.S. Food and Drug Administration to Fexagratinib (ABSK091) in gastric cancer.

In November 2022, ABSK091 was given the generic name "Fexagratinib" by World Health Organization under the International Nonproprietary Name system.

About urothelial carcinoma

According to research reports, there are about 80,000 new cases of urothelia carcinoma diagnosed in China every year. The FGFR aberration rate in urothelial carcinoma is approximately 30%. Surgery or radical cystectomy are the recommended first-line treatment for non-muscle invasive or early-stage urothelial carcinoma. For advanced or metastatic urothelial carcinoma, systemic therapies including but not limited to gemcitabine combined with cisplatin/carboplatin, gemcitabine combined with cisplatin/carboplatin and paclitaxel, and immune checkpoint inhibitors are recommended as first-line treatment options. So far there is no FGFR inhibitor approved in China for urothelial carcinoma.

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.