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 FIRST PATIENT DOSED IN PHASE II TRIAL OF CSF-1R INHIBITOR PIMICOTINIB FOR CGVHD

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 the first patient has been dosed in the Phase II trial evaluating its CSF-1R inhibitor, pimicotinib (ABSK021), in patients with chronic graft-versus-host disease ("**cGvHD**").

This is a voluntary announcement made by the Company. The Group cannot guarantee that pimicotinib (ABSK021) 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, June 12, 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; 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 First Patient Dosed in Phase II Trial of CSF-1R Inhibitor Pimicotinib (ABSK021) for cGvHD

June 12, 2023, Shanghai – Abbisko Therapeutics Co., Ltd. ("**Abbisko Therapeutics**") announced that the first patient has been dosed in the Phase II trial evaluating its CSF-1R inhibitor, pimicotinib (ABSK021), in patients with cGvHD.

The primary underlying mechanism of cGvHD is immune inflammation, which leads to frequent pathological changes in chronic tissue repair and fibrosis. During this process, CSF-1-activated macrophages induce inflammatory response and tissue damage, accelerate abnormal tissue repair and fibrosis, and lead to cGvHD. Recent studies have shown that inhibition of CSF1-R can reduce the expansion and infiltration of donor-derived myeloid macrophages in recipient tissues, which may alleviate cGvHD.

Pimicotinib is a novel, orally available, highly selective, and highly potent small molecule inhibitor of CSF-1R discovered and developed by Abbisko Therapeutics independently. A number of studies have shown that blocking the CSF1/CSF-1R signaling pathway could effectively modulate and change macrophage functions, and potentially treat many macrophage-dependent human diseases. Pimicotinib demonstrated significant antitumor efficacy in a Phase Ib trial in patients with tenosynovial giant cell tumor ("**TGCT**"), achieving ORR of 77.4% and favorable safety profile and PK/PD data which was presented in the 2023 American Society of Clinical Oncology (ASCO) annual meeting. Abbisko has advanced pimicotinib into a global Phase III Multiregional Clinical Trial (MRCT) for TGCT, and completed dosing of the first patient in April, 2023.

In addition to the ongoing TGCT and cGvHD clinical trials, Abbisko Therapeutics is actively exploring the clinical application of pimicotinib in treating many other types of solid tumors and non-oncology indications including amyotrophic lateral sclerosis (ALS). As of today, no highly selective CSF-1R inhibitor has been approved in China.

About cGvHD

Chronic graft-versus-host disease (cGvHD) is the clinicopathological syndrome (including classical cGvHD and overlap syndrome) caused by donor lymphocytes attacking the recipient organs during the process of rebuilding recipient immunity after allogeneic hematopoietic stem cell transplantation, which is one of the major complications after transplantation. The incidence ranges from 30% to 70%[1] [2].

The clinical manifestations of cGvHD are diverse with great individual differences, and the course of cGvHD is long-lasting. Multiple vital organs can become involved, thereby seriously affecting the quality of life and long-term survival of patients. Glucocorticoids are still the standard first-line treatment for cGvHD but more than half of treated patients will develop tolerance and require second-line therapy[2]. There are currently no approved therapeutic agents for patients with cGvHD who have failed to respond to glucocorticoid therapy in China.

References

1. Xu L, Chen H, Chen J, et al. The consensus on indications, conditioning regimen, and donor selection of allogeneic hematopoietic cell transplantation for hematological diseases in Chinarecommendations from the Chinese Society of Hematology[J]. J Hematol Oncol, 2018, 11(1): 33. DOI: 10.1186/s13045 – 018 – 0564-x

2. Wang Y, Chen H, Chen J, et al. The consensus on the monitoring, treatment, and prevention of leukemia relapse after allogeneic hematopoietic stem cell transplantation in China. Cancer Lett. [J]. Cancer Lett, 2018, 438: 63 – 75. DOI: 10.1016/j.canlet.2018.08.030.

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 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 17 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.