CStone Pharmaceuticals

基石藥業

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 2616)

VOLUNTARY ANNOUNCEMENT
CSTONE RECEIVED CHINA NMPA IND ACCEPTANCE FOR LORLATINIB IN CHINESE PATIENTS WITH ROS1-POSITIVE ADVANCED NSCLC

CStone Pharmaceuticals (the "**Company**" or "**CStone**") is pleased to announce that the investigational new drug ("**IND**") application of lorlatinib for the treatment of Chinese patients with c-ros oncogene 1 ("**ROS1**")-positive advanced non-small cell lung cancer ("**NSCLC**") has been accepted by the National Medical Products Administration ("**NMPA**") of China. This clinical study is designed to evaluate the anti-tumor activity and safety of lorlatinib in patients with ROS1-postive advanced NSCLC. It will also be the world's first pivotal study of lorlatinib in ROS1-positive NSCLC.

Lorlatinib is a third-generation tyrosine kinase inhibitor ("**TKI**") which targets ROS1 and anaplastic lymphoma kinase ("**ALK**") receptor tyrosine kinase, and it has excellent central nervous system ("**CNS**") penetration. With its impressive clinical data from the CROWN study, a study of lorlatinib versus crizotinib in first line treatment of patients with ALK-positive NSCLC, lorlatinib has been approved by the U.S. Food and Drug Administration ("**FDA**") as a first-line treatment for adults with metastatic NSCLC whose tumors are ALK-positive as detected by an FDA-approved test. Pfizer conducted multiple clinical studies of lorlatinib in ALK-positive lung cancer in China and submitted a new drug application ("**NDA**") for the treatment of patients with ALK-positive advanced NSCLC in March 2021.

In June 2021, CStone announced that it will work with Pfizer to jointly develop lorlatinib for ROS1-positive advanced NSCLC in Greater China region, marking another milestone under the strategic partnership reached between the company and Pfizer last year.

Dr. Jason Yang, Chief Medical Officer of CStone, said, "Globally, patients with ROS1-positive NSCLC who are resistant to crizotinib lack of effective therapies. We are very glad that the IND of lorlatinib in China has been accepted by the NMPA of China, and we will quickly advance the clinical study of lorlatinib to cater to the huge unmet medical needs from this patient population as early as possible. We will continue to work closely with Pfizer to bring more treatment options to patients who suffer from cancers."

In clinical studies, lorlatinib demonstrated superior efficacy and well-tolerated safety in patients with ROS1-positive advanced NSCLC. In a Phase I/II study, lorlatinib demonstrated the improvements in both objective response rate ("**ORR**") and intracranial ORR in patients with ROS1-positive advanced NSCLC who were TKI-naïve or failed crizotinib treatment. In addition, lorlatinib also achieved a high response rate and durable responses in patients with brain metastases.

In September 2020, CStone and Pfizer reached a strategic partnership that encompassed a US$200 million equity investment by Pfizer in CStone, collaboration for the development and commercialization of CStone's sugemalimab in mainland China, and a framework to bring additional oncology assets to the Greater China market. CStone will work with Pfizer to select late-stage post proof-of-concept oncology assets in Pfizer's pipeline for co-development in Greater China, and the two companies will also work together to selectively introduce other oncology therapies into Greater China.

About lorlatinib

Lorlatinib is an oral macrocyclic adenosine triphosphate ("**ATP**") competitive small molecule inhibitor of ROS1 kinase and ALK. In preclinical studies, lorlatinib demonstrated potent and selective inhibitory activity against ROS1/ALK rearrangements, crizotinib-resistant ROS1 mutations, as well as acquired ALK mutations that are resistant to crizotinib, alectinib, ceritinib and brigatinib. Lorlatinib can also efficiently penetrate the blood-brain barrier. Lorlatinib was approved in the United States as a first line treatment for adults with metastatic NSCLC whose tumors are ALK-positive as detected by an FDA-approved test. In the European Union, lorlatinib is approved as a monotherapy for the treatment of adult patients with ALK-positive advanced NSCLC whose disease has progressed after alectinib or ceritinib as the first ALK TKI therapy, or crizotinib and at least one other ALK TKI. Previously, Pfizer conducted multiple clinical studies of lorlatinib in ALK-positive lung cancer in China and submitted an NDA for the treatment of patients with ALK-positive advanced NSCLC in March 2021. Lorlatinib has also demonstrated preliminary efficacy and well-tolerated safety in patients with ROS1-positive advanced NSCLC, showing great potential for further development.

About CStone

CStone is a biopharmaceutical company focused on researching, developing and commercializing innovative immuno-oncology and precision medicines to address the unmet medical needs of cancer patients in Mainland China and worldwide. Established in 2015, CStone has assembled a world-class management team with extensive experience in innovative drug development, clinical research, and commercialization. The Company has built an oncology-focused pipeline of 15 drug candidates with a strategic emphasis on immuno-oncology combination therapies. Currently, CStone has received three drug approvals in Greater China, including two in Mainland China and one in Taiwan, China. CStone's vision is to become globally recognized as a world-renowned biopharmaceutical company by bringing innovative oncology therapies to cancer patients worldwide.

For more information about CStone, please visit: www.cstonepharma.com.

By Order of the Board
CStone Pharmaceuticals
Dr. Frank Ningjun Jiang
Chairman

Suzhou, the People's Republic of China, October 20, 2021

As at the date of this announcement, the board of directors of the Company comprises Dr. Frank Ningjun Jiang as Chairman and executive director, Dr. Wei Li, Mr. Qun Zhao, Mr. Yanling Cao, Mr. Xianghong Lin and Mr. Edward Hu as non-executive directors, and Dr. Paul Herbert Chew, Mr. Ting Yuk Anthony Wu and Mr. Hongbin Sun as independent non-executive directors.