CStone Pharmaceuticals

基石藥業

(Incorporated in the Cayman Islands with limited liability)

(**Stock Code: 2616**)

VOLUNTARY ANNOUNCEMENT
CSTONE ANNOUNCED IND APPROVAL FOR THE PIVOTAL STUDY IN CHINA OF LORLATINIB FOR THE TREATMENT OF ROS1-POSITIVE ADVANCED NON-SMALL CELL LUNG CANCER

CStone Pharmaceuticals (the "**Company**" or "**CStone**") is pleased to announce that the investigational new drug ("**IND**") application of lorlatinib for the treatment of c-ros oncogene 1 ("**ROS1**")-positive advanced non-small cell lung cancer ("**NSCLC**") has been approved by the National Medical Products Administration ("**NMPA**") of China. This is the first pivotal study of lorlatinib for the treatment of ROS1-positive NSCLC in the world.

Key Highlights

- It is the first pivotal study of lorlatinib for the treatment of ROS1-positive NSCLC in the world.
- Lorlatinib is approved globally in over 50 countries for metastatic anaplastic lymphoma kinase ("**ALK**")-positive NSCLC in audults.

Lorlatinib is a third-generation tyrosine kinase inhibitor ("**TKI**") which targets ROS1 and ALK. With its clinical data from the CROWN study, lorlatinib has been approved by the U.S. Food and Drug Administration ("**FDA**"), expanded to include the first-line treatment for adults with metastatic NSCLC whose tumors are ALK-positive as detected by an FDA-approved test.

This pivotal study is to evaluate the anti-tumor activity and safety of lorlatinib in patients with ROS1-postive advanced NSCLC. In a previous Phase I/II study, lorlatinib demonstrated deep and durable objective responses in patients with ROS1-positive advanced NSCLC who were TKI-naïve or failed initial treatment.

Dr. Jason Yang, Chief Medical Officer of CStone, said, "Patients with ROS1-positive NSCLC who are resistant to initial treatment lack effective standard of care. We are very glad that lorlatinib has been granted IND approval for a pivotal study in patients with ROS1-positive NSCLC in China. This

study will enroll patients with ROS1-positive advanced NSCLC whose diseases have progressed after chemotherapy and precision treatment. The primary study endpoint is objective response rate ("**ORR**"), assessed by an independent review committee. We will quickly advance the clinical study of lorlatinib and hope to bring a new treatment option to patients as early as possible."

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 both first line and second 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 new drug application 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.

In June 2021, CStone announced that it will work with Pfizer to jointly develop lorlatinib for ROS1-positive advanced NSCLC in Greater China region.

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 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 five drug approvals in Greater China, including three in Mainland China, one in Hong Kong, and one in Taiwan. 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, January 4, 2022

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. Kenneth Walton Hitchner III, 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.