CStone Pharmaceuticals

基石藥業

(Incorporated in the Cayman Islands with limited liability)

(**Stock Code: 2616**)

VOLUNTARY ANNOUNCEMENT
CSTONE ANNOUNCED THE JOINT DEVELOPMENT OF LORLATINIB IN ROS1-POSITIVE ADVANCED LUNG CANCER WITH PFIZER TO FURTHER DEEPEN EXISTING STRATEGIC PARTNERSHIP

CStone Pharmaceuticals (the "**Company**" or "**CStone**") is pleased to announce that it will work with Pfizer to jointly develop lorlatinib for c-ros oncogene 1 ("**ROS1**")-positive advanced non-small cell lung cancer ("**NSCLC**") in Greater China. The upcoming pivotal clinical study in ROS1-positive lung cancer in China will be the world's first pivotal study of lorlatinib in ROS1-positive NSCLC, marking another milestone under the strategic partnership reached between the Company and Pfizer last year. CStone has chosen this asset, which has significant market potential among Pfizer's multiple compelling oncology medicines, to address the unmet medical needs in this patient population.

The incidence and mortality rates of lung cancer, the leading cause of cancer death in China, have significantly increased in recent years. In 2020, there are approximately 0.82 million new lung cancer cases and approximately 0.71 million new lung cancer deaths occurred in China. As a novel and unique molecular subset, ROS1 rearrangement has been identified as an important oncogenic driver in NSCLC, the most common type of lung cancer. In China, there is only one targeted therapy approved for the treatment of patients with ROS1-positive advanced lung cancer, and there remains a need for additional treatment options for patients who develop drug resistance.

Lorlatinib is a third-generation tyrosine kinase inhibitor ("**TKI**") which targets ROS1 and anaplastic lymphoma kinase ("**ALK**") receptor tyrosine kinase. With its positive clinical data from the CROWN study, a study of lorlatinib versus crizotinib in first line treatment of patients with ALK-positive NSCLC, lorlatinib's indication was recently expanded by the Food and Drug Administration ("**FDA**") in the United States following an approval 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 clinical studies, lorlatinib demonstrated potent and selective inhibitory activity against ROS1-positive advanced NSCLC. In a Phase 1/2 study, lorlatinib demonstrated the improvements in the co-primary endpoints of objective response rate ("**ORR**") and intracranial ORR in patients with ROS1-positive advanced NSCLC who were TKI-naïve or failed ROS1 inhibitor treatment. In addition, lorlatinib also achieved a high response rate and durable responses in patients with brain metastases.

Dr. Frank Jiang, Chairman and CEO of CStone, said, "We are excited to work with Pfizer to jointly develop lorlatinib. This drug candidate is a new generation of ALK/ROS1 targeted therapy in Pfizer's global pipeline. This co-development collaboration shows the deepening of our strategic partnership since last year, fully reflecting Pfizer's recognition of our robust clinical development capabilities, and further expanding CStone's pipeline. We will work with Pfizer to bring more innovative oncology therapies to the patients in an efficient way."

Pierre Gaudreault, China President of Pfizer Biopharmaceuticals Group, said, "Our company has an extensive and proud history of delivering breakthroughs that change patients' lives, and this deepened collaboration with CStone builds on that history. Globally, we offer a portfolio of precision medicines for the treatment of biomarker-driven lung cancers and have a deep understanding and insight into the market of ALK and ROS1 targeted therapy. CStone focuses on the development of innovative immuno-oncology therapies and precision medicines and contributes its strong clinical development expertise under our partnership. We hope our collaboration will demonstrate the safety and efficacy of lorlatinib in ROS1-positive advanced non-small cell lung cancer patients in China and help them potentially benefit from lorlatinib as early as possible."

In 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.

Moving forward, CStone and Pfizer will continue to advance diversified cooperation to bring more innovative oncology therapies to cancer patients in 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.

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 late 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 14 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. 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.

About Pfizer

Pfizer applies science and their global resources to bring therapies to people that extend and significantly improve their lives. Pfizer strives to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer's colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of their time. Consistent with Pfizer's responsibility as one of the world's premier innovative biopharmaceutical companies, Pfizer collaborates with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 170 years, Pfizer has worked to make a difference for all who rely on Pfizer.

For more information about Pfizer, please visit: www.pfizer.com.

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

Suzhou, People's Republic of China, June 15, 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 Dr. Lian Yong Chen as non-executive Directors, and Dr. Paul Herbert Chew, Mr. Ting Yuk Anthony Wu and Mr. Hongbin Sun as independent non-executive Directors.