The forward-looking statements made in this announcement relate only to the events or information as of the date on which the statements are made in this announcement. 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 announcement completely and with the understanding that our actual future results or performance may be materially different from what we expect. In this announcement, statements of, or references to, our intentions or those of any of our directors and/or our Company are made as of the date of this announcement. Any of these intentions may alter in light of future development.

CStone Pharmaceuticals
基石藥業
(Incorporated in the Cayman Islands with limited liability)
(Stock Code: 2616)

VOLUNTARY ANNOUNCEMENT
CSTONE PRESENTS UPDATED DATA FOR GAVRETO® (PRALSETINIB) IN CHINESE PATIENTS WITH RET-FUSION POSITIVE NON-SMALL CELL LUNG CANCER AT ESMO ASIA CONGRESS 2022

CStone Pharmaceuticals (the "**Company**" or "**CStone**") is pleased to announce that it has presented updated efficacy and safety data for GAVRETO® (pralsetinib) in Chinese patients with rearranged during transfection (RET) fusion-positive non-small cell lung cancer ("**NSCLC**") enrolled in the global ARROW study at the ESMO Asia Congress 2022. The data showed that GAVRETO® had robust and durable anti-tumor activity and a generally well-tolerated safety profile in Chinese patients with locally advanced or metastatic RET fusion-positive NSCLC.

Key Highlights

- The results from the ARROW study showed GAVRETO® had robust and durable anti-tumor activity and a generally well-tolerated safety profile in Chinese patients with locally advanced or metastatic RET fusion-positive NSCLC.

- As the first selective RET inhibitor approved in China, GAVRETO® is currently indicated for the treatment of locally advanced or metastatic RET fusion-positive NSCLC after platinum-based chemotherapy, and for the treatment of advanced or metastatic RET-mutant medullary thyroid cancer and RET fusion-positive thyroid cancer.

- The supplemental new drug application for GAVRETO® as a first-line treatment of patients with locally advanced or metastatic RET fusion-positive NSCLC is under review by National Medical Products Administration ("**NMPA**") of China.

GAVRETO® is a potent and selective RET inhibitor discovered by CStone's partner Blueprint Medicines Corporation (NASDAQ: BPMC) ("**Blueprint Medicines**"). CStone has an exclusive collaboration and license agreement with Blueprint Medicines for the development and commercialization of GAVRETO® in Greater China, which encompasses Mainland China, Hong Kong, Macau and Taiwan.

This ARROW study (ClinicalTrials.gov identifier: NCT03037385) is a global phase 1/2 clinical study designed to evaluate the safety, tolerability and efficacy of GAVRETO® in patients with RET fusion-positive NSCLC, RET-mutant medullary thyroid cancer ("**MTC**") and other advanced solid tumors with RET alterations.

As of the data cut-off date (March 4, 2022), a total of 68 patients with advanced RET fusion-positive NSCLC were enrolled in 10 China sites and received a starting GAVRETO® dose of 400 mg once daily. Among these patients, 37 received prior platinum-based chemotherapy and 31 received no prior systemic treatment. The response of the tumor to treatment was assessed by the Blinded Independent Central Review (BICR) according to the Response Evaluation Criteria in Solid Tumors (RECIST) v1.1.

Efficacy: Durable and long-term clinical benefit of GAVRETO® was observed in both treatment-naïve and previously treated Chinese patients with advanced RET fusion-positive NSCLC. Response rate in the treatment naïve patients was higher.

- For patients who have previously received platinum-based chemotherapy (patients with measurable disease at baseline, n=33), the confirmed overall response rate ("**ORR**") was 66.7%, including 1 complete response ("**CR**") and 21 partial responses ("**PR**"). The disease control rate ("**DCR**") reached 93.9%.

- For patients who have not received prior systemic treatment (patients with measurable disease at baseline, n=30), the confirmed ORR was 83.3%, including 2 CRs and 23 PRs. The DCR was 86.7%.

- Long-term survival benefit was observed. The median overall survival (OS) was not reached.

Safety: GAVRETO® had a generally well-tolerated safety profile in Chinese patients, with no new safety signals observed.

Professor Yi-Long Wu of Guangdong Provincial People's Hospital, the Principal Investigator of the ARROW study in China, said, "GAVRETO®, as the first RET inhibitor approved in China, is a highly promising precision medicine. The updated data from the ARROW study were consistent with previously reported results, demonstrating that GAVRETO® had robust and durable anti-tumor activity in Chinese patients with RET fusion-positive NSCLC, regardless of whether they received prior treatment or not. No new safety signals were observed. GAVRETO® may provide an effective treatment option for Chinese patients with RET fusion-positive NSCLC."

Dr. Jason Yang, CEO and executive director of CStone, said, "We are delighted to present the updated data of GAVRETO® for the treatment of Chinese patients with RET fusion-positive NSCLC at the ESMO Asia Congress. So far, GAVRETO® has been approved for second-line treatment of RET-fusion positive NSCLC and for first-line treatment of RET-altered thyroid cancer. GAVRETO® has benefited thousands of patients since its commercial launch more than a year ago, and it is under China regulatory review for the first-line treatment of patients with RET fusion-positive NSCLC. CStone is committed to addressing unmet medical needs, and we will accelerate drug discovery and development to bring forward more innovative therapies to patients."

As the first selective RET inhibitor in China, GAVRETO® has been approved by the NMPA for the treatment of locally advanced or metastatic RET fusion-positive NSCLC after platinum-based chemotherapy, and for the treatment of RET-mutant MTC and RET fusion-positive thyroid cancer (TC). In addition, GAVRETO® has been approved in Hong Kong, China for the treatment of adult patients with RET fusion-positive metastatic NSCLC. A new drug application for GAVRETO® is under review in Taiwan, China.

With its established clinical profile, GAVRETO® has been included in a number of authoritative clinical guidelines and consensus in the field of lung cancer, including China Expert Consensus on Clinical Detection of RET Gene Fusion in NSCLC, Clinical Practice Guidelines for Molecular and Pathological Detection of NSCLC (2021), the Chinese Society of Clinical Oncology (CSCO): Clinical Guidelines for Diagnosis and Treatment of NSCLC (2022), the Clinical Guidelines for Diagnosis and Treatment of Primary Lung Cancer (2022), and NCCN Clinical Practice Guidelines in Oncology for NSCLC (2022) in the United States. GAVRETO® has also been included in the CACA Guidelines – Thyroid Cancer, CSCO: Clinical Guidelines for Diagnosis and Treatment of Differentiated Thyroid Cancer (2021), China Expert Consensus on Diagnosis and Treatment of Medullary Thyroid Cancer (2020), Expert Consensus on RET Gene Detection and Clinical Application in Thyroid Cancer (2021), Guidelines of Chinese Society of Clinical Oncology (CSCO): Medullary Thyroid Carcinoma – 2022 and other authoritative clinical guidelines and consensus in the field of thyroid cancer.

As CStone's first approved product, GAVRETO® has been included in more than 100 major commercial insurance and government-led insurance programs in Greater China, and GAVRETO® is one of three precision medicines from CStone that have been listed in approximately 150 hospitals and DTP pharmacies in Greater China.

About GAVRETO® (pralsetinib)

GAVRETO® is a once-daily oral targeted therapy approved by the NMPA for the treatment of adults with locally advanced or metastatic RET fusion-positive NSCLC after platinum-based chemotherapy, and for the treatment of adult and pediatric patients 12 years of age and older with advanced or metastatic RET-mutant MTC who require systemic therapy, and adult and pediatric patients 12 years of age and older with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and radioactive iodine-refractory (if radioactive iodine treatment is appropriate). GAVRETO® has been approved in Hong Kong, China for the treatment of adult patients with RET fusion-positive metastatic NSCLC.

GAVRETO® is approved by the U.S. Food and Drug Administration ("**FDA**") for the treatment of three indications: adult patients with metastatic RET fusion-positive NSCLC as detected by an FDA approved test, adult and pediatric patients 12 years of age and older with advanced or metastatic RET-mutant MTC, and adult and pediatric patients 12 years of age and older with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate). These indications are approved under accelerated approval based on ORR and duration of response (DOR). Continued approval for these indications may be contingent upon verification and description of clinical benefit in confirmatory trials.

The European Commission (EC) has granted conditional marketing authorization for GAVRETO® as a monotherapy for the treatment of adult patients with RET fusion-positive advanced NSCLC not previously treated with a RET inhibitor.

GAVRETO® is not approved for the treatment of any other indication in China, the U.S. or Europe.

Blueprint Medicines and Roche are co-developing GAVRETO® globally (excluding Greater China) for the treatment of patients with RET-altered NSCLC, thyroid cancer, and other solid tumors. Blueprint Medicines and Genentech, a member of the Roche Group, are co-commercializing GAVRETO® in the U.S., and Roche has exclusive commercialization rights for GAVRETO® outside of the U.S. (excluding Greater China).

About CStone

CStone is a biopharmaceutical company focused on research, development, and commercialization of 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 nine NDA approvals for its four drugs. Multiple late-stage drug candidates are now under pivotal clinical trials or registration. 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.

Trademarks

Blueprint Medicines, GAVRETO and associated logos are trademarks of Blueprint Medicines.

Forward Looking Statement

There is no assurance that any forward-looking statements regarding the business development of the Group in this announcement or any of the matters set out herein are attainable, will actually occur or will be realised or are complete or accurate. The financial and other data relating to the Group as disclosed in this announcement has also not been audited or reviewed by its auditors. Shareholders and/or potential investors of the Company are advised to exercise caution when dealing in the securities of the Company and not to place any excessive reliance on the information disclosed herein. Any shareholder or potential investor who is in doubt is advised to seek advice from professional advisors.

By Order of the Board
CStone Pharmaceuticals
Dr. Wei Li
Chairman

Suzhou, the People's Republic of China, December 5, 2022

As at the date of this announcement, the board of directors of the Company comprises Dr. Wei Li as Chairman and non-executive director, Dr. Jianxin Yang as executive director, 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.