CStone Pharmaceuticals
基石藥業

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 2616)

INSIDE INFORMATION
BUSINESS UPDATES

This announcement is issued pursuant to Rule 13.09 of the Rules Governing the Listing of the Securities on The Stock Exchange of Hong Kong Limited (the "**Listing Rules**") and the inside information provision (as defined in the Listing Rules) under Part XIVA of the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong).

CStone Pharmaceuticals (the "**Company**" or "**CStone**") is pleased to announce that the National Medical Products Administration ("**NMPA**") of China has approved GAVRETO® (pralsetinib) capsules for the treatment of adult patients with locally advanced or metastatic rearranged during transfection ("**RET**") fusion-positive non-small cell lung cancer ("**NSCLC**") after platinum-based chemotherapy. Discovered by CStone's partner Blueprint Medicines, GAVRETO is China's first approved selective RET inhibitor, as well as CStone's first approved precision therapy in China.

The ARROW study is a global phase I/II clinical study designed to evaluate the efficacy and safety of GAVRETO in patients with RET fusion-positive NSCLC, RET-mutant medullary thyroid cancer, and other advanced solid tumors with RET fusions. Data from the ARROW study showed that GAVRETO had robust and durable anti-tumor activity in Chinese patients with advanced or metastatic RET fusion-positive NSCLC after platinum-based chemotherapy. In these patients, the confirmed overall response rate was 56%, the median duration of response ("**DOR**") was not reached, and the six-month DOR rate was 83%. GAVRETO was well-tolerated, and there were no adverse events related to treatment with GAVRETO that led to treatment discontinuation or death.

Dr. Frank Ningjun Jiang, executive director, chairman and chief executive officer of CStone, noted: "This is a key milestone for CStone. The approval of GAVRETO reflects CStone's commitment to research and develop innovative therapies to meet patients' unmet medical needs as well as strong execution capabilities. We would like to thank all the patients and investigators involved in the clinical study and extend our gratitude to the NMPA and other government authorities for their support in the priority review leading to the fast approval of GAVRETO ®. We continue to advance the development of

GAVRETO ® in other indications such as first-line NSCLC, thyroid cancer and other solid tumors, aiming to bring the treatment to more patients soon."

Professor Yi-long Wu of Guangdong Provincial People's Hospital, a principal investigator on the ARROW study, said: "The development of a RET-targeted therapy is a huge breakthrough in precision medicine for lung cancer. The approval of GAVRETO ® in China, greatly supported by the strong trial results from the ARROW study, may change the standards of care for patients with RET fusion-positive NSCLC."

About RET fusion positive NSCLC

In recent years, China has had rising lung cancer incidence. In 2018, an estimated 770,000 new lung cancer cases and 690,000 new lung cancer deaths occurred in China. Among all Chinese cancer patients, lung cancer is the leading cause of cancer-related deaths. NSCLC is the most common type of lung cancer.

In lung cancer, there are a number of somatic mutations, including EGFR, ALK, and ROS1 that can be targeted with approved therapies. RET fusions account for 1-2% of NSCLC patients, the majority of whom are non-smokers.

About GAVRETO® (pralsetinib) Capsules

GAVRETO® (pralsetinib) is a once-daily oral targeted therapy approved by the NMPA of China, for the treatment of adults with locally advanced or metastatic RET fusion-positive NSCLC after platinum-based chemotherapy.

GAVRETO has been approved by the U.S. Food and Drug Administration ("**FDA**") for the treatment of 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 medullary thyroid cancer (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).

GAVRETO is not approved for the treatment of any other indication in China by the NMPA or in the U.S. by the FDA, or for any indication in any other jurisdiction by any other health authority.

GAVRETO is designed to selectively and potently target oncogenic RET alterations, including secondary RET mutations predicted to drive resistance to treatment. In preclinical studies, GAVRETO inhibited RET at lower concentrations than other pharmacologically relevant kinases, including VEGFR2, FGFR2, and JAK2.

About CStone

CStone is a biopharmaceutical company focused on the development and commercialization of innovative tumor immunotherapy and precision medicines to meet the ardent medical needs of cancer patients in China and worldwide. Established at the end of 2015, CStone Pharmaceuticals has assembled a world-class management team with extensive experience in innovative drug development, clinical research, and commercialization. With a strategic emphasis on immuno-oncology combination therapies, the Company has built an oncology-focused pipeline of 14 drug candidates. Currently, one product has been approved by China NMPA and multiple late-stage candidates are at pivotal clinical trials or registration stages. Cstone's vision is to become a world-renowned biopharmaceutical company leading the way to conquering cancer.

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

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

Suzhou, People's Republic of China, March 24, 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.