

Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.

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

REGISTRATIONAL STUDY OF PRALSETINIB IN CHINESE RET-FUSION NSCLC PATIENTS ACHIEVED THE EXPECTED RESULTS, CSTONE PLANS TO SUBMIT AN NDA TO THE NMPA FOR PRALSETINIB IN THE NEAR FUTURE

CStone Pharmaceuticals (the “**Company**” or “**CStone**”) announced that pralsetinib was well-tolerated, and showed deep and durable clinical activity among Chinese patients with RET-fusion non-small cell lung cancer (“**NSCLC**”) who were enrolled in the global, registrational phase I/II ARROW trial. Developed by CStone’s partner, Blueprint Medicines Corporation (NASDAQ: BPMC) (“**Blueprint Medicines**”), pralsetinib is an investigational, highly potent and selective drug that targets oncogenic RET alterations including predicted resistance mutations. Overall, the data showed that efficacy and safety outcomes in Chinese patients with RET-fusion NSCLC were consistent with previously reported data from the global patient population in the ARROW trial.

Dr. Jason Yang, the chief medical officer of CStone, commented, “It is gratifying to see that pralsetinib showed a promising, durable anti-tumor activity and a well-tolerated safety profile among Chinese patients with RET-fusion NSCLC previously treated with platinum-based chemotherapy. CStone plans to submit a new drug application (“**NDA**”) for pralsetinib in this indication to the Chinese National Medical Products Administration (“**NMPA**”) in the near future. At present, there is no selective RET inhibitor approved in China. At the same time, we will continue to make every effort to advance the development of pralsetinib in China and more extensively evaluate the potential therapeutic benefits of this drug candidate in patients with RET-altered NSCLC who are naïve to platinum-based chemotherapy, medullary thyroid cancer, and other solid tumors, with the goal of rapidly addressing the urgent clinical needs of this group of Chinese cancer patients.”

CStone plans to share the registrational study data at a future academic conference.

The key updates include:

- Primary efficacy data showed deep and durable anti-tumor activity of pralsetinib in RET-fusion NSCLC treated with platinum-based chemotherapy;
- pralsetinib was well-tolerated in the Chinese patient population;
- CStone plans to submit a NDA for pralsetinib in RET- fusion NSCLC previously treated with platinum-based chemotherapy to China’s Center for Drug Evaluation (“CDE”) of the NMPA in the near future.

About ARROW

The global ARROW study was designed to assess the safety, tolerability and efficacy of pralsetinib in patients with RET fusion-positive NSCLC, RET-mutant medullary thyroid cancer, RET-fusion thyroid cancer, and other advanced solid tumors with RET alterations. For Chinese patients with RET-fusion positive NSCLC previously treated with platinum-based chemotherapy, CStone previously announced that the first patient was dosed in August 2019 and the last patient was enrolled in December 2019. CStone plans to present ARROW trial data in Chinese patients with RET-fusion NSCLC at a future academic conference.

About pralsetinib

pralsetinib is an investigational, once-daily oral precision therapy specifically designed for highly potent and selective targeting of oncogenic RET alterations. Blueprint Medicines is developing pralsetinib for the treatment of patients with RET-altered NSCLC, thyroid cancer and other solid tumors. The United States (“U.S.”) Food and Drug Administration (“USFDA”) has granted a “Breakthrough Therapy Designation” recognition to pralsetinib for the treatment of RET-fusion positive NSCLC that has progressed following platinum-based chemotherapy, and RET-mutant medullary thyroid cancer that requires systemic treatment and for which there are no acceptable alternative treatments. In May 2020, Blueprint Medicines announced that the U.S. and European Union marketing applications for pralsetinib for the treatment of locally advanced or metastatic RET fusion-positive NSCLC were accepted by the USFDA and validated by the European Medicines Agency, respectively.

pralsetinib was designed by Blueprint Medicines' research team, leveraging its proprietary compound library. In preclinical studies, pralsetinib consistently demonstrated sub-nanomolar potency against the most common RET fusions, activating mutations and predicted resistance mutations. In these studies, pralsetinib demonstrated markedly improved selectivity for RET compared to pharmacologically relevant kinases, including approximately 80-fold improved potency for RET compared with VEGFR2. By suppressing primary and secondary mutants, pralsetinib has the potential to overcome and prevent the emergence of clinical resistance. This approach may enable durable clinical responses across a diverse range of RET alterations, with a favorable safety profile.

Blueprint Medicines and CStone have an exclusive collaboration and license agreement for the development and commercialization of pralsetinib and certain other drug candidates in regions including the mainland of the People’s Republic of China, Hong Kong Special Administrative Region, Macau Special Administrative

Region and Taiwan. Blueprint Medicines retains development and commercial rights for pralsetinib for the rest of the world.

About CStone

CStone is a biopharmaceutical company focused on developing and commercializing innovative immuno-oncology and precision medicines to address the unmet medical needs of cancer patients in China and worldwide. Established at the end of 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, five late-stage candidates are at pivotal trials. With an experienced team, a rich pipeline, a robust clinical development-driven business model and substantial funding, CStone's vision is to become globally recognized as a leading Chinese 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, People's Republic of China, July 9, 2020

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. Guobin Zhang 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.