Forward-Looking Statements

The forward-looking statements made in this article relate only to the events or information as of the date on which the statements are made in this article. Actual results may differ materially from those indicated in the forward-looking statements as a result of various factors, including the clinical results for our drug candidates, which may not support further development or marketing approval; Our reliance on third parties to conduct drug development, manufacturing and other services; our limited operating history and our ability to obtain additional funding for operations and to complete the development and commercialization of our drug candidates; Our ability to achieve commercial success for our drug candidates, if approved; our ability to obtain and maintain protection of intellectual property for our technology and drugs; And actions of regulatory agencies, which may affect the initiation, timing and progress of our future clinical trials and marketing approval. 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. This article should be read completely and with the understanding that our actual future results or performance may be materially different from what we expect. In this article, statements of, or references to, our intentions or those of any of our Directors or our Company are made as of the date of this article. Any of these intentions may alter in light of future development.

基石药业
CSTONE
PHARMACEUTICALS

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

CSTONE RECEIVES APPROVAL IN CHINA TO INITIATE PHASE 1 CLINICAL TRIAL FOR RET INHIBITOR BLU-667 (CS3009)

The following announcement is made by CStone Pharmaceuticals (the "**Company**" or "**Cstone**", together with its subsidiaries, the "**Group**") on a voluntary basis to inform the shareholders and potential investors of the Company about the latest business updates of the Group:

CStone announced in Suzhou, China on March 21, 2019 that China's National Medical Products Administration (NMPA) has approved the clinical trial application to begin a Phase 1 trial in China for BLU-667 (CS3009), a highly selective and potent RET inhibitor discovered by CStone's partner Blueprint Medicines. The study is part of Blueprint Medicines' ongoing, global Phase 1 ARROW clinical trial for patients with RET-altered non-small cell lung cancer (NSCLC), medullary thyroid cancer (MTC) and other advanced solid tumors. Trial objectives include overall clinical response, duration of response, pharmacokinetics, pharmacodynamics and safety.

In June 2018, CStone and Blueprint Medicines entered into a license and collaboration agreement in which Blueprint Medicines granted CStone exclusive rights to develop and commercialize BLU-667 (CS3009) and two other drug candidates in Mainland China, Hong Kong, Macau and Taiwan.

Recently, BLU-667 (CS3009) was granted Breakthrough Therapy Designation by the U.S. Food and Drug Administration (FDA) for the treatment of RET-mutation-positive MTC that requires systemic treatment and for which there are no acceptable alternative treatments.

Based on the early clinical data and regulatory feedback, Blueprint Medicines has announced plans to submit a New Drug Application (NDA) to the U.S. FDA for BLU-667 (CS3009) in the first half of 2020.

"BLU-667 (CS3009) has already demonstrated its potential to produce clinical responses in several RET-altered tumor types, and there are currently no selective RET inhibitors approved globally," noted CStone Chairman and CEO Dr. Frank Jiang. "If the data generated in Chinese patients are consistent with global results, we plan to use the global and China data from the ARROW study to support NDA filings in China."

CStone's Chief Medical Officer Dr. Jason Yang commented: "Currently available data show that non-small cell lung cancer and medullary thyroid cancer patients with RET altered tumors may benefit from BLU-667 (CS3009), with the potential to advance standards of care in these genetically defined populations. We will move forward on development of BLU-667 (CS3009) in China and hope to make this drug candidate available to Chinese patients as quickly as possible."

About BLU-667 (CS3009)

BLU-667 (CS3009) is an investigational, once-daily oral precision therapy specifically designed for highly potent and selective targeting of oncogenic RET alterations. In preclinical studies, BLU-667 (CS3009) consistently demonstrated sub-nanomolar potency against the most common RET fusions, activating mutations and predicted resistance mutations. In addition, BLU-667 (CS3009) demonstrated markedly improved selectivity for RET compared to approved multi-kinase inhibitors, including more than 80-fold improved potency for RET versus VEGFR2. By suppressing primary and secondary mutants, BLU-667 (CS3009) has the potential to overcome and prevent the emergence of clinical resistance. This approach is expected to enable durable clinical responses across the range of RET alterations, with a favorable safety profile.

BLU-667 (CS3009) was designed by Blueprint Medicines' research team, leveraging the company's proprietary compound library. Blueprint Medicines is developing BLU-667 (CS3009) for the treatment of people with RET-altered NSCLC, MTC and other solid tumors. The U.S. FDA has granted Breakthrough Therapy Designation to BLU-667 (CS3009) for the treatment of RET-mutation-positive MTC.

Cautionary Statement required by Rule 18A.05 of the Rules Governing the Listing of Securities of The Stock Exchange of Hong Kong Limited: The Company cannot guarantee that it will be able to develop, or ultimately market, BLU-667 (CS3009) successfully. Shareholders and potential investors of the Company are advised to exercise due care when dealing in the shares of the Company.

About CStone

CStone is a biopharmaceutical company focused on developing and commercializing innovative immuno-oncology and precision medicine 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 with a strategic emphasis on immune-oncology combination therapies. Currently, 4 late-stage candidates are at or near 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 Pharmaceuticals, please visit: www.cstonepharma.com.

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

Hong Kong, 21 March 2019

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. Xiaomeng Tong, 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.