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 SUCCESSFULLY SUBMITTED A NDA FOR IVOSIDENIB IN SINGAPORE FOR IDH1-MUTATED R/R AML

CStone Pharmaceuticals (the "**Company**" or "**CStone**") announced it has submitted a new drug application ("**NDA**") for ivosidenib to the Health Sciences Authority of Singapore, for the treatment of adult patients with relapsed or refractory ("**R/R**") acute myeloid leukemia ("**AML**") with a susceptible isocitrate dehydrogenase-1 ("**IDH1**") mutation. Ivosidenib is a first-in-class, oral, highly selective and potent IDH1 inhibitor developed by Agios Pharmaceuticals, Inc. (NASDAQ: AGIO) ("**Agios**"), a CStone partner. It has been approved by the United States ("**U.S.**") Food and Drug Administration ("**FDA**") since July 2018 for the treatment of AML with a susceptible IDH1 mutation as detected by a U.S. FDA-approved test in adult patients with R/R AML, and since May 2019 for the treatment of adult patients with newly diagnosed AML who are more than 75 years old or who have comorbidities that preclude use of intensive chemotherapy ("**IC**").

AML, marked by rapid disease progression, is the most common acute leukemia found in adults and its patients are typically older. It affects adults with approximately 20,000 new cases in the U.S. each year and the five-year survival rate is approximately 29%. In Singapore, the annual incidence is increasing. Typically, older patients and R/R AML patients have a poor prognosis, and approximately 6% to 10% of AML patients carry IDH1 mutations.

The current standard of care treatment for newly diagnosed AML patients mainly includes intensive chemotherapy for induction therapy, approximately 35% to 40% of treated young patients achieve complete remission, while only about 10% of elderly patients achieve survival of three years or longer. The majority of

AML patients develop acquired resistance to treatment or eventually relapse, making R/R AML extremely difficult for follow-up clinical treatment in the absence of a global care treatment standard. With the emergence of DNA sequencing technology, the detection of genetic mutations has presented new opportunities and challenges in AML treatment.

Ivosidenib, an oral, targeted inhibitor of the IDH1 enzyme, is globally the first and only U.S. FDA-approved therapy for patients with R/R AML and an IDH1 mutation. Ivosidenib was developed by Agios. In 2018, CStone and Agios announced an exclusive collaboration and license agreement stating that CStone is responsible for the clinical development and commercialization of ivosidenib in the mainland China, the Special Administrative Region of Hong Kong, the Special Administrative Region of Macau and Taiwan (the "**Greater China Region**"). In March 2020, CStone and Agios revised the agreement to expand its clinical development and commercialization area from the Greater China Region to Singapore.

Dr Frank Ningjun Jiang, chairman, executive director and chief executive officer of CStone, commented: "We are very pleased to see that the Company has successfully submitted a NDA for ivosidenib in Singapore for the treatment of R/R AML with an IDH1 mutation. This is the first time CStone has submitted a NDA outside theGreater China Region, which is of great significance to the Company's global commercialization process. We will continue to work to benefit more cancer patients from innovative anti-tumor therapies."

Dr Jason Yang, Chief Medical Officer of CStone, noted: "The treatment of AML is facing urgent drug development needs, especially for IDH1-mutated R/R AML patients who lack effective drugs. At present, ivosidenib is the only U.S. FDA-approved therapy targeting IDH1 mutation for patients with R/R AML. We earnestly hope that ivosidenib will be approved in Singapore soon, thus benefiting these patients."

About TIBSOVO®(ivosidenib)

TIBSOVO® was developed by Agios, a partner of CStone, and received its first marketing approval in the U.S. in 2018 for the treatment of R/R AML with susceptible IDH1 gene mutations. In 2019, the drug approval was extended by the U.S. FDA to include the treatment of newly-diagnosed AML adult patients more than 75 years of age or AML patients who have comorbidities that preclude the use of intensive IC. In addition, the U.S. FDA has granted breakthrough therapy designation for TIBSOVO® in combination with azacytidine for this supplemental indication.

The efficacy of TIBSOVO® was evaluated in 174 adult patients with R/R AML with an IDH1 mutation. TIBSOVO® was administered orally at a starting dose of 500 mg daily until disease progression, development of unacceptable toxicity, or undergoing hematopoietic stem cell transplantation. Data from the marketing application for TIBSOVO® in the U.S. show that TIBSOVO® monotherapy for R/R AML patients with IDH1 mutations, resulted in a complete remission ("**CR**") or complete remission with partial hematological ("**CRh**") improvement rate of 32.8%, and the median duration of CR and CRh was 8.2 months.

The safety profile of TIBSOVO® was evaluated in 179 patients with R/R AML with an IDH1 mutation who received an oral dose of 500 mg daily. The median duration of exposure to TIBSOVO® was 3.9 months. In the clinical trial, 19% of patients treated with TIBSOVO® experienced differentiation syndrome, which can be fatal if not treated. The most common adverse reactions of any grade included fatigue, leukocytosis, arthralgia, diarrhea, dyspnea, edema, nausea, microsites, electrocardiogram QT prolonged, rash, pyrexia, cough, and

constipation. The most frequent serious adverse reactions were differentiation syndrome, leukocytosis, and electrocardiogram QT prolonged.

In June 2018, CStone and Agios announced an exclusive collaboration and license agreement stating that CStone is responsible for the clinical development and commercialization of TIBSOVO® in mainland China, Hong Kong Special Administration Region, Macau Special Administration Region and Taiwan. In March 2020, CStone and Agios revised the agreement to expand its clinical development and commercialization area from the Greater China Region to also include Singapore.

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 16 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 a world-renowned biopharmaceutical company that is 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, November 10, 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.