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)

INSIDE INFORMATION ANNOUNCEMENT

CSTONE ANNOUNCED THE REGISTRATIONAL CLINICAL TRIAL OF SUGEMALIMAB AS FIRST-LINE TREATMENT IN PATIENTS WITH ESOPHAGEAL SQUAMOUS CELL CARCINOMA MET PRIMARY ENDPOINTS AND PLANS TO SUBMIT A SUPPLEMENTAL NDA TO NMPA

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**", together with its subsidiaries, the "**Group**") is pleased to announce that the GEMSTONE-304 study, in which sugemalimab in combination with chemotherapy is used as first-line treatment of unresectable locally advanced, recurrent, or metastatic esophageal squamous cell carcinoma (or "**ESCC**"), has met its primary endpoints. Sugemalimab in combination with chemotherapy demonstrated a statistically significant and clinically meaningful improvement in Blinded Independent Central Review ("**BICR**")-assessed progression-free survival ("**PFS**") and overall survival ("**OS**") compared with placebo in combination with chemotherapy. The safety profile was consistent with previous findings across the studies in additional diseases with sugemalimab and no new safety signal was observed.

Key Highlights

- Sugemalimab became the first anti-PD-L1 monoclonal antibody that achieved positive results in the study of patients with unresectable locally advanced, recurrent, or metastatic esophageal squamous cell carcinoma.

- Sugemalimab in combination with chemotherapy demonstrated a statistically significant and clinically meaningful improvement in the PFS and OS of patients with unresectable locally advanced, recurrent, or metastatic esophageal squamous cell carcinoma in the first-line setting.

- Sugemalimab has achieved positive results in five registrational clinical trials.

The GEMSTONE-304 study is a randomized, double-blind, multi-center, placebo-controlled phase 3 registrational clinical trial designed to evaluate the efficacy and safety of sugemalimab in combination with 5-fluorouracil plus cisplatin (FP) as first-line treatment in patients with unresectable locally advanced, recurrent, or metastatic ESCC. The primary endpoints are BICR-assessed PFS and OS, and secondary endpoints include investigator-assessed PFS, BICR and investigator-assessed objective response rate ("**ORR**") and duration of response ("**DoR**"). In a phase Ib trial in this population, sugemalimab in combination with FP achieved an ORR of 67.6% (25/37) and a disease control rate (DCR) of 89.2%, along with durable responses as first-line treatment of ESCC patients.

Professor Li Jin, Principal Investigator of the GEMSTONE-304 study and director of the Department of Oncology, East Hospital, Tongji University, said, "Esophageal cancer is a common malignancy in China. About 70% of patients with esophageal cancer had progressed to locally advanced or advanced stages and metastatic stages at the time of initial diagnosis. Even 50%-60% of patients with resectable esophageal cancer relapse or develop distant metastases after surgery. The results of the GEMSTONE-304 study showed that sugemalimab in combination with chemotherapy demonstrated robust antitumor efficacy and well-tolerated safety in the first-line treatment of patients with esophageal squamous cell carcinoma. We expect this immunotherapy to provide additional treatment options for more patients with esophageal cancer."

Dr. Jason Yang, Chief Executive Officer and executive director of CStone, said, "We are excited that sugemalimab achieved positive results in esophageal cancer, which is a common cancer worldwide. This represents the fifth registrational study with positive results for sugemalimab, which came on the heels of studies in patients with stage III and stage IV non-small cell lung cancer (or "**NSCLC**"), extranodal natural killer/T-cell lymphoma (or "**R/R ENKTL**") and gastric cancer. No anti-PD-L1 antibody has yet been approved for the treatment of esophageal cancer. We are looking forward to bringing this new treatment option to patients. As a biopharmaceutical company focused on immuno-oncology therapies and precision medicines, CStone will continue to accelerate research and development of potential first-in-class and best-in-class medicines and provide patients with more innovative therapeutic options."

Based on the top-line data of GEMSTONE-304 study, CStone plans to submit a supplemental new drug application ("**sNDA**") on this new indication to the National Medical Products Administration ("**NMPA**") of China in the near future. In addition, CStone plans to present detailed data from the trial at an upcoming international academic conference.

About esophageal cancer

Esophageal cancer is one of the most common cancers globally. According to the GLOBOCAN 2020 data, there were more than 600,000 new cases of esophageal cancer in the world in 2020 (esophageal squamous cell carcinoma accounts for about 85%), and 544,000 deaths, with the incidence and mortality ranking 8th and 6th, respectively, among cancers globally. The incidence of esophageal cancer in China accounts for more than half of the world, about 90% of which are esophageal squamous cell carcinoma, and most of the patients with esophageal squamous cell carcinoma have been diagnosed in the advanced stage and missed the opportunities of curative treatments.

About Sugemalimab

The anti-PD-L1 monoclonal antibody sugemalimab was discovered by CStone using OmniRat® transgenic animal platform, which allows creation of fully human antibodies in one step. Sugemalimab is a fully human, full-length anti-PD-L1 immunoglobulin G4 (IgG4) monoclonal antibody, which may reduce the risk of immunogenicity and toxicity for patients, a unique advantage over similar drugs.

Currently, the NMPA of China has approved sugemalimab (Cejemly®).

Non-small cell lung cancer (NSCLC):

1. Combination Therapy:

    - In combination with pemetrexed and carboplatin as first-line treatment of patients with metastatic non-squamous NSCLC, with no known EGFR and ALK genomic tumor aberrations.

    - In combination with paclitaxel and carboplatin as first-line treatment of patients with metastatic squamous NSCLC.

2. Monotherapy:

    - For the treatment of patients with unresectable stage III NSCLC whose disease has not progressed following platinum-based concurrent or sequential chemoradiotherapy.

With its proven therapeutic advantages, sugemalimab is recommended by the 2022 Chinese Society of Clinical Oncology (CSCO) clinical guidelines for the diagnosis and treatment of NSCLC, in combination with chemotherapy as the first-line treatment of patients with stage IV non-squamous/ squamous NSCLC without driver alterations; or as a consolidation therapy in patients with stage III NSCLC following concurrent or sequential platinum-based chemoradiotherapy.

The NMPA of China has accepted and granted priority review to the sNDA for sugemalimab in the treatment of patients with relapsed or refractory extranodal natural killer/T-cell lymphoma (R/R ENKTL).

In addition, the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom has accepted the marketing authorization application (MAA) for sugemalimab in combination with chemotherapy as first-line treatment of patients with metastatic non-small cell lung cancer.

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.

Cautionary Statement required by Rule 18A.05 of the Listing Rules: THE COMPANY CANNOT GUARANTEE THAT WE MAY BE ABLE TO ULTIMATELY DEVELOP AND MARKET CEJEMLY® (SUGEMALIMAB) SUCCESSFULLY. Shareholders of the Company and potential investors are advised to exercise due care when dealing in the shares of the Company.

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, January 3, 2023

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.