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 REGISTRATIONAL STUDY OF SUGEMALIMAB FOR FIRST-LINE TREATMENT OF LOCALLY ADVANCED OR METASTATIC GASTRIC ADENOCARCINOMA/GASTROESOPHAGEAL JUNCTION ADENOCARCINOMA MET PRIMARY ENDPOINT

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-303 study, in which sugemalimab in combination with chemotherapy is used as a first-line treatment of unresectable locally advanced or metastatic gastric adenocarcinoma/gastro-esophageal junction ("**GEJ**") adenocarcinoma with PD-L1 expression ≥5%, has met one of its primary endpoints, progression-free survival ("**PFS**"). Sugemalimab in combination with chemotherapy demonstrated statistically significant and clinically meaningful improvement in investigator-assessed PFS, compared with placebo plus chemotherapy, HR=0.66 (95% CI: 0.54, 0.81), p-value <0.0001. Median PFS in the sugemalimab arm was 7.6 months v.s. 6.1 months in the placebo arm. Data also showed a clear trend toward benefit for overall survival ("**OS**") with HR=0.75 (95% CI: 0.59, 0.96). Median OS was 14.6 months in the sugemalimab arm v.s. 12.5 months in the placebo arm. The safety profile was consistent with previous findings across the studies for sugemalimab, and no new safety signals were observed.

Key Highlights

- Sugemalimab in combination with chemotherapy as first-line treatment of locally advanced or metastatic gastric adenocarcinoma/gastroesophageal junction adenocarcinoma with PD-L1 expression ≥5% demonstrated statistically significant and clinically meaningful improvement in PFS. The risk of disease progression or death was reduced by 34%. An encouraging trend in OS was also observed. Clinical benefit was demonstrated across all pre-specified subgroups.

- Sugemalimab became the world's first anti-PD-L1 monoclonal antibody to achieve positive results in a phase 3 study in gastric adenocarcinoma/gastro-esophageal junction adenocarcinoma.

- Sugemalimab has achieved positive results in four registrational studies.

The GEMSTONE-303 study is a multi-center, randomized placebo-controlled phase 3 registrational clinical trial designed to evaluate the efficacy and safety of sugemalimab plus capecitabine and oxaliplatin (CAPOX) as the first-line treatment in patients with unresectable locally advanced or metastatic gastric adenocarcinoma or GEJ adenocarcinoma with PD-L1 expression ≥5%. The primary endpoints are investigator-assessed PFS and OS. Secondary endpoints include blinded independent central review (BICR)-assessed PFS, investigator-assessed objective response rate (ORR) and duration of response (DoR).

Professor Lin Shen, the lead Principal Investigator of the GEMSTONE-303 study and vice president of Peking University Cancer Hospital, said, “Gastric cancer is a common cancer in China, and gastric adenocarcinoma accounted for over 90% of gastric malignancies. Most patients with gastric adenocarcinoma were diagnosed at an advanced stage, and those with unresectable or metastatic gastric cancer had poor prognosis, so they urgently need new solutions. Today, we are excited about the PFS positive results of the GEMSTONE-303 study in patients with gastric adenocarcinoma/gastro-esophageal junction adenocarcinoma and very confident for the OS result. We have high expectations that the drug will provide an optimized treatment option for this patient population.”

Dr. Jason Yang, Chief Executive Officer and executive Director of CStone, said, “We are pleased that the registrational study of sugemalimab for the treatment of gastric cancer achieved positive results after it previously demonstrated robust efficacy in patients with non-small cell lung cancer (NSCLC) and extranodal NK/T cell lymphoma. We expect to hold regulatory discussions in China to enable this potential new treatment to benefit gastric cancer patients. CStone is committed to addressing unmet clinical needs, and we will strive to bolster oncology research and bring forward more first-in-class or best-in-class therapies.”

About gastric cancer

Gastric cancer is one of the most common cancers globally. According to the GLOBOCAN 2020 data, there were more than 1 million new cases of gastric cancer worldwide and 769,000 deaths in 2020. The incidence and mortality of gastric cancer ranked 5th and 4th respectively among all common cancers worldwide. With the highest burden on gastric cancer, China accounts for nearly half of the world's new cases and deaths of gastric cancer every year. Gastric adenocarcinoma accounted for more than 90% of all gastric malignancies, and the incidence of gastro-esophageal junction adenocarcinoma has also shown a rising trend in recent years.

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 National Medical Products Administration ("**NMPA**") of China has approved sugemalimab (Cejemly®):

Non-small cell lung cancer:

1. Combination Therapy

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

    - In combination with paclitaxel and carboplatin as first-line treatment of patients with metastatic squamous non-small cell lung cancer.

2. Monotherapy

    - For the treatment of patients with unresectable stage III non-small cell lung cancer 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 non-small cell lung cancer, in combination with chemotherapy as the first-line treatment of patients with stage IV non-squamous/squamous non-small cell lung cancer without driver alterations; or as a consolidation therapy in patients with stage III non-small cell lung cancer following concurrent or sequential platinum-based chemoradiotherapy.

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

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, November 11, 2022

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.