CStone Pharmaceuticals

基石藥業

(Incorporated in the Cayman Islands with limited liability)

(**Stock Code: 2616**)

VOLUNTARY ANNOUNCEMENT
CSTONE ANNOUNCED THE NMPA OF CHINA HAS ACCEPTED THE SUPPLEMENTARY NEW DRUG APPLICATION OF SUGEMALIMAB AS FIRST-LINE TREATMENT FOR PATIENTS WITH LOCALLY ADVANCED OR METASTATIC GASTRIC/GASTROESOPHAGEAL JUNCTION ADENOCARCINOMA

CStone Pharmaceuticals (the "**Company**" or "**CStone**") is pleased to announce that the National Medical Products Administration ("**NMPA**") of China has accepted the supplementary new drug application ("**sNDA**") for sugemalimab in combination with chemotherapy as a first-line treatment of unresectable locally advanced or metastatic gastric/gastroesophageal junction adenocarcinoma.

Key Highlights

- This supplementary new drug application was filed for the fourth indication for sugemalimab in China, following applications for stage III and stage IV non-small cell lung cancer and relapsed or refractory extranodal NK/T cell lymphoma. If approved, sugemalimab would be the first PD-L1 monoclonal antibody to treat gastric/gastroesophageal junction adenocarcinoma.

- In November 2022, the GEMSTONE-303 study met its progression-free survival primary endpoint. The study showed that sugemalimab in combination with chemotherapy, as first-line treatment for advanced gastric/gastroesophageal junction adenocarcinoma with PD-L1 expression level ≥ 5%, significantly improved progression-free survival, with an encouraging trend towards overall survival benefit.

Professor Lin Shen, the principal investigator of the GEMSTONE-303 study and vice president of Peking University Cancer Hospital, said, "Gastric cancer is one of the most common malignancies in China, and more than 90% of gastric cancer is gastric adenocarcinoma. Clinically, most patients are already at a late stage when diagnosed with gastric adenocarcinoma. These patients, in particular those with unresectable locally advanced or metastatic disease, need new treatment options, as there are currently limited approved

medicines for this form of cancer in China. GEMSTONE-303 study has demonstrated that sugemalimab in combination with chemotherapy significantly improved the progression-free survival of such patients, along with an encouraging trend observed in overall survival. We look forward to another treatment option provided by this immunotherapy for patients with advanced gastric/gastroesophageal junction adenocarcinoma."

Dr. Jason Yang, Chief Executive Officer and executive director of CStone Pharmaceuticals, said, "We are very glad that NMPA has accepted the supplementary application of sugemalimab for gastric/gastroesophageal junction adenocarcinoma, which is one of the most common cancers. Sugemalimab would be the world's first PD-L1 monoclonal antibody approved for the treatment of gastric/gastroesophageal junction adenocarcinoma, if approved. We will work closely with the National Medical Products Administration of China, and we hope to make sugemalimab available for more patients. CStone is committed to addressing unmet clinical needs and will continue to cultivate its efforts in oncology to offer patients many more first-in-class, best-in-class innovative therapies."

This sNDA of sugemalimab was accepted based on data from the GEMSTONE-303 study. It is a multicenter, randomized, placebo-controlled phase III registrational clinical trial designed to evaluate the efficacy and safety of sugemalimab in combination with chemotherapy (oxaliplatin + capecitabine) as a first-line treatment for unresectable locally advanced or metastatic gastric adenocarcinoma or gastroesophageal junction adenocarcinoma with PD-L1 expression level ≥ 5%. The primary endpoints include investigator-assessed progression-free survival (PFS) and overall survival (OS), and the secondary endpoints include blinded independent central review (BICR)-assessed PFS and investigator-assessed objective response rate (ORR) and duration of response (DoR).

In November 2022, GEMSTONE-303, the registrational clinical study of sugemalimab in combination with chemotherapy as a first-line treatment of locally advanced or metastatic gastric/gastroesophageal junction adenocarcinoma, met its PFS primary endpoint. 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 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.

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 NMPA of China has approved sugemalimab (Cejemly®) for

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 non-small cell lung cancer (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 non-small cell lung cancer (NSCLC).

2. Monotherapy

- For the treatment of patients with unresectable stage III non-small cell lung cancer (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 consolidation therapy in patients with stage III NSCLC following concurrent or sequential platinum-based chemoradiotherapy.

In September 2022, 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).

In November 2022, GEMSTONE-303, the registrational clinical study of sugemalimab in combination with chemotherapy as a first-line treatment of locally advanced or metastatic gastric/gastroesophageal junction adenocarcinoma, met its progression-free survival primary endpoint.

In December 2022, the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom accepted the marketing authorization application (MAA), submitted by CStone's ex-China partner EQRx, for sugemalimab in combination with chemotherapy as first-line treatment of patients with metastatic non-small cell lung cancer.

In January 2023, 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 (ESCC), has met its primary endpoints.

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 ten 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, February 28, 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. 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.