CStone Pharmaceuticals

基石藥業

(Incorporated in the Cayman Islands with limited liability)

(**Stock Code: 2616**)

VOLUNTARY ANNOUNCEMENT
CSTONE ANNOUNCES REGISTRATIONAL TRIAL OF SUGEMALIMAB IN FIRST-LINE GASTRIC OR GASTROESOPHAGEAL JUNCTION ADENOCARCINOMA MET PRIMARY ENDPOINT OF OVERALL SURVIVAL

CStone Pharmaceuticals (the "**Company**" or "**CStone**") is pleased to announce that the Phase 3 GEMSTONE-303 study of sugemalimab in combination with chemotherapy as a first-line treatment for unresectable locally advanced or metastatic gastric or gastroesophageal junction (G/GEJ) adenocarcinoma with PD-L1 expression ≥5%, met its primary endpoint of overall survival (OS). Sugemalimab in combination with chemotherapy demonstrated a statistically significant and clinically meaningful improvement in OS, compared with placebo plus chemotherapy. The safety profile was consistent with previous reports of sugemalimab studies, and no new safety signals were identified.

Key Highlights

- In the GEMSTONE-303 study, sugemalimab in combination with chemotherapy as a first-line treatment of locally advanced or metastatic gastric or gastroesophageal junction (G/GEJ) adenocarcinoma has demonstrated a statistically significant and clinically meaningful improvement in overall survival (OS).

- The GEMSTONE-303 study has met both pre-specified primary endpoints of progression-free survival (PFS) and OS and key secondary endpoints: BICR-PFS and ORR.

- The National Medical Products Administration (NMPA) of China has accepted the supplemental biologics license application (sBLA) for sugemalimab in combination with chemotherapy as a first-line treatment for locally advanced or metastatic G/GEJ adenocarcinoma. The application is currently under review.

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 a first-line treatment in patients with unresectable locally advanced or metastatic G/GEJ adenocarcinoma with PD-L1 expression ≥5%. The dual primary endpoints were 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).

Dr. Jason Yang, Chief Executive Officer and executive director of CStone, said, "We are excited that sugemalimab demonstrated remarkable clinical efficacy as the first-line treatment for gastric cancer after achieving successes in stage III and IV NSCLC, esophageal cancer and R/R-ENKTL. The NMPA of China is currently reviewing the sugemalimab sBLA for the first-line G/GEJ adenocarcinoma, positioning sugemalimab to potentially become the world's first anti-PD-L1 monoclonal antibody approved in the first-line setting of this indication. We also plan to communicate with the United States Food and Drug Administration (FDA) and the European Medicines Agency (EMA) to explore the global registrational pathway to bring this innovative therapy to patients with gastric cancer worldwide."

Professor Lin Shen, Peking University Cancer Hospital, the principal investigator of the GEMSTONE-303 study, said, "Clinically, most patients are already at a late stage when diagnosed with gastric adenocarcinoma, and those with unresectable or metastatic gastric cancer usually have poor prognosis and huge unmet medical needs. Today, we are pleased to see the positive OS results from the GEMSTONE-303 study. Sugemalimab in combination with chemotherapy can significantly prolong the OS and PFS of patients with G/GEJ adenocarcinoma and combination was well tolerated, and we believe that sugemalimab will provide an attractive treatment option to this patient population."

In November 2022, the GEMSTONE-303 study met the primary endpoint of PFS and also showed a clear trend toward benefit for OS. 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.

In February 2023, the NMPA of China accepted the sBLA for sugemalimab in combination with chemotherapy as the first-line treatment of unresectable locally advanced or metastatic G/GEJ adenocarcinoma, which is currently under review. The GEMSTONE-303 study results will be presented at an upcoming international academic conference.

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 gastroesophageal 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 the 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.

The NMPA of China has approved two indications for sugemalimab for the treatment of patients with unresectable Stage III non-small cell lung cancer (NSCLC) whose disease has not progressed following concurrent or sequential platinum-based chemoradiotherapy and in combination with chemotherapy for

the first-line treatment of patients with metastatic squamous and non-squamous NSCLC.

The supplemental biologics license applications for sugemalimab for the treatment of patients with relapsed/refractory extranodal NK/T-cell lymphoma, as well as in combination with chemotherapy for first-line treatment of locally advanced or metastatic G/GEJ adenocarcinoma, and in combination with chemotherapy for first-line treatment of unresectable locally advanced, recurrent, or metastatic ESCC have been accepted by the NMPA of China and are currently under review.

In addition, the EMA and the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom have both accepted the marketing authorization applications (MAAs) for sugemalimab in combination with chemotherapy as a first-line treatment for metastatic NSCLC, and the two MAAs are currently under review.

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 management team with extensive experience in innovative drug development, clinical research, and commercialization. The company has built an oncology-focused pipeline of 14 drug candidates with a strategic emphasis on immuno-oncology combination therapies. Currently, CStone has received 11 NDA approvals for its four drugs. Multiple late-stage drug candidates are now under pivotal clinical trials or registration. CStone's vision is to bring 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 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 realized 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, August 29, 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.