CStone Pharmaceuticals

基石藥業

(Incorporated in the Cayman Islands with limited liability)

(**Stock Code: 2616**)

VOLUNTARY ANNOUNCEMENT
CSTONE SHOWCASED, IN AN ORAL SESSION, LATE-BREAKING RESULTS FROM PHASE 3 STUDY OF SUGEMALIMAB IN FIRST-LINE GASTRIC OR GASTROESOPHAGEAL JUNCTION ADENOCARCINOMA AT ESMO 2023

CStone Pharmaceuticals (the "**Company**" or "**CStone**") is pleased to announce that the results from a pivotal phase III clinical trial (GEMSTONE-303), evaluating sugemalimab in combination with chemotherapy as a first-line treatment for locally advanced or metastatic gastric or gastroesophageal junction (G/GEJ) adenocarcinoma, has been accepted as a late-breaking abstract (LBA) and showcased in an oral session at the European Society for Medical Oncology (ESMO) Congress 2023.

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 statistically significant and clinically meaningful improvement in progression-free survival (PFS) and overall survival (OS).

- The National Medical Products Administration (NMPA) of China is currently reviewing 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. Sugemalimab would become the world's first PD-L1 monoclonal antibody for this indication, if approved.

- CStone plan to consult with global regulatory agencies on regulatory pathways to bring sugemalimab to patients with G/GEJ adenocarcinoma.

The GEMSTONE-303 study is a multi-center, randomized, double-blinded, placebo-controlled phase III 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 co-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). This study has met its pre-specified co-primary endpoints.

Dr. Jason Yang, CEO and executive director of CStone, said, "we are glad that the GEMSTONE-303 study data has been selected as a LBA at this ESMO Congress and reported as an oral presentation. This indicates the attention from global academic community to the progress of gastric cancer research while acknowledging the clinical significance of sugemalimab in first-line gastric cancer. To date, no anti-PD-L1 antibody has been approved for first-line treatment of G/GEJ adenocarcinoma worldwide. The sBLA for sugemalimab in combination with chemotherapy for first-line treatment of G/GEJ adenocarcinoma is currently under review by the NMPA of China. We will continue to work closely with global regulatory authorities to bring this innovative and effective treatment option to more patients with gastric cancer soon."

Professor Lin Shen, Peking University Cancer Hospital, the leading principal investigator of the GEMSTONE-303 study said, "China accounts for nearly half of the global new cases and deaths of gastric cancer per year. Patients with advanced or metastatic gastric cancer, in particular, bear huge disease burden. In clinical practice, most patients are already at a late stage when initially diagnosed, leading to ineligibility for surgery. These patients typically have a poor prognosis, highlighting a significant unmet medical need. The GEMSTONE-303 data shows that sugemalimab in combination with chemotherapy has significantly prolonged PFS and OS of patients with G/GEJ adenocarcinoma while maintaining a good safety profile. We believe that sugemalimab can become a new treatment option for this patient population."

The data presented at the ESMO Congress 2023 is based on the final analyses of PFS as of August 6, 2022, and OS as of July 9, 2023. The results show that the GEMSTONE-303 study has met its pre-specified co-primary endpoints. In patients with PD-L1 expression≥5%, sugemalimab in combination with chemotherapy has demonstrated statistically significant and clinically meaningful improvement in PFS and OS, compared with placebo plus chemotherapy.

Key findings are as follows:

- The investigator-assessed median PFS was 7.6 months in the sugemalimab treatment group compared with 6.1 months in the placebo group, with a hazard ratio (HR) of 0.66 (95% CI, 0.54-0.81), $P<0.0001$.
- Median OS was 15.6 months in the sugemalimab treatment group versus 12.6 months in the placebo group, with an HR of 0.75 (95% CI, 0.61-0.92), $P=0.0060$.
- Subgroup analyses has demonstrated clinical benefits across all pre-defined subgroups, including PD-L1 expression status.
- Sugemalimab treatment resulted in an investigator-assessed ORR of 68.6% compared with 52.7% in the placebo group, with a median DoR of 6.9 months versus 4.6 months.
- Sugemalimab in combination with chemotherapy appears safe and tolerable, with no new safety signal identified.

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 esophageal squamous cell carcinoma have been accepted by the NMPA of China and are currently under review.

In addition, the European Medicines Agency (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 (HKEX: 2616) 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 eleven 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, October 24, 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.