CStone Pharmaceuticals
基石藥業
(Incorporated in the Cayman Islands with limited liability)
(**Stock Code: 2616**)

VOLUNTARY ANNOUNCEMENT
CSTONE ANNOUNCES THE FIFTH INDICATION APPROVED FOR SUGEMALIMAB IN CHINA AS FIRST-LINE TREATMENT OF GASTRIC CANCER

CStone Pharmaceuticals (the "**Company**" or "**CStone**") is pleased to announce that the National Medical Products Administration (NMPA) of China has approved the supplemental biologics license application (sBLA) for sugemalimab (Cejemly®) in combination with fluoropyrimidine- and platinum-containing chemotherapy as a first-line treatment for unresectable locally advanced or metastatic gastric or gastroesophageal junction (G/GEJ) adenocarcinoma with a PD-L1 expression (Combined Positive Score [CPS] ≥5). Sugemalimab becomes the world's first PD-L1 monoclonal antibody approved for this indication.

Key Highlights

- Sugemalimab is the world's first anti-PD-L1 monoclonal antibody approved for the treatment of gastric or gastroesophageal junction (G/GEJ) adenocarcinoma.

- This marks the 13th New Drug Application (NDA) approval obtained by CStone and sugemalimab's fifth indication approved in China, following stage III and IV non-small cell lung cancer (NSCLC), relapsed or refractory extranodal NK/T-cell lymphoma and esophageal squamous cell carcinoma.

- The GEMSTONE-303 study has met both pre-specified co-primary endpoints of progression-free survival (PFS) and overall survival (OS). Sugemalimab in combination with chemotherapy as a first-line treatment of locally advanced or metastatic G/GEJ adenocarcinoma has demonstrated statistically significant and clinically meaningful improvement in PFS and OS.

Dr. Jason Yang, CEO and executive director of CStone, said, "We are excited that sugemalimab in combination with chemotherapy has been approved in China as first-line treatment of gastric cancer, which further stresses the clinical value and potential of sugemalimab. In addition to the prior approvals obtained in China for stage III and IV NSCLC, extranodal NK/T-cell lymphoma and esophageal squamous

cell carcinoma (ESCC), sugemalimab has achieved great success in all five target indications. Now we are discussing in details with the U.S. Food and Drug Administration (FDA) regarding the registration pathways in the U.S. We will also communicate with the European Medicines Agency (EMA) and other regulatory authorities to accelerate the global marketing process for sugemalimab. We look forward to seeing sugemalimab benefiting more patients with cancer worldwide."

Professor Lin Shen, Peking University Cancer Hospital, the leading principal investigator of the GEMSTONE-303 study said, "China is one of the countries with the highest burden of gastric cancer in the world. In clinical practice, most patients are already at a late stage when diagnosed with gastric adenocarcinoma, and those with unresectable or metastatic gastric cancer usually had poor prognosis and huge unmet medical needs. Sugemalimab is the world's first anti-PD-L1 monoclonal antibody approved for the treatment of G/GEJ adenocarcinoma, providing a new treatment option for this population. We believe sugemalimab can be put into clinical use as soon as possible, offering new hope to more gastric cancer patients."

This sBLA of sugemalimab was approved based on the data from the GEMSTONE-303 study. It is a multi-center, randomized, double-blinded, 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 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.

The results of GEMSTONE-303, have been accepted as a late-breaking abstract (LBA) and showcased in an oral presentation session at the European Society for Medical Oncology (ESMO) Congress 2023.

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 sugemalimab for five indications:

- In combination with chemotherapy for first-line treatment of patients with metastatic squamous and non-squamous NSCLC;
- For the treatment of patients with unresectable Stage III NSCLC whose disease has not progressed following concurrent or sequential platinum-based chemoradiotherapy;
- For the treatment of patients with relapsed or refractory extranodal NK/T-cell lymphoma;
- In combination with fluorouracil and platinum-based chemotherapy for first-line treatment of patients with unresectable locally advanced, recurrent or metastatic ESCC; and
- In combination with fluoropyrimidine- and platinum-containing chemotherapy as first-line treatment for unresectable locally advanced or metastatic gastric or gastroesophageal junction (G/GEJ) adenocarcinoma with a PD-L1 expression (Combined Positive Score [CPS] ≥5).

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.

CStone formed a strategic collaboration agreement with Pfizer that includes the development and commercialization of sugemalimab in mainland China, and a framework to bring additional Oncology medicines to the Greater China market.

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 13 drug candidates with a strategic emphasis on immuno-oncology combination therapies. Currently, CStone has received 13 NDA approvals for its three 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, March 15, 2024

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.