CStone Pharmaceuticals

基石藥業

(Incorporated in the Cayman Islands with limited liability)

(**Stock Code: 2616**)

VOLUNTARY ANNOUNCEMENT
CSTONE ANNOUNCES CHINA'S NMPA HAS ACCEPTED THE SUPPLEMENTAL BIOLOGICS LICENSE APPLICATION FOR SUGEMALIMAB AS A FIRST-LINE TREATMENT FOR ESOPHAGEAL SQUAMOUS CELL CARCINOMA

CStone Pharmaceuticals (the "**Company**" or "**CStone**") is pleased to announce that 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 of unresectable locally advanced, recurrent, or metastatic esophageal squamous cell carcinoma (ESCC).

Key Highlights

- This supplemental biologics license application filing is the fifth for sugemalimab in China. If approved, sugemalimab would be the first PD-L1 monoclonal antibody in the world for the treatment of unresectable locally advanced, recurrent or metastatic esophageal squamous cell carcinoma.

- In January 2023, the GESMTONE-304 study met its primary endpoints. In this study, sugemalimab in combination with chemotherapy demonstrated a statistically significant and clinically meaningful improvement in the progression-free survival and overall survival of patients with unresectable locally advanced, recurrent, or metastatic esophageal squamous cell carcinoma in the first-line setting.

Professor Li Jin, Principal Investigator of the GEMSTONE-304 study and Director of the Department of Oncology, East Hospital, Tongji University, said, "Esophageal cancer is one of the most common cancer types in China and also one of the malignancies with the highest mortality rates globally. About 70% of patients with esophageal cancer have progressed to locally advanced or advanced stages at the time of initial diagnosis. In addition, 50%-60% of patients with resectable esophageal cancer relapse or develop distant metastases after radical surgery. There are still unmet medical needs for this patient population. The GEMSTONE-304 study demonstrated that sugemalimab in combination with chemotherapy significantly improved progression-free survival (PFS) and overall survival (OS) compared to first-line

chemotherapy for ESCC, with a good safety profile, providing a new treatment option for advanced ESCC patients."

Dr. Jason Yang, Chief Executive Officer and executive director of CStone, said, "CStone is committed to addressing the unmet medical needs, and we are delighted to announce that the NMPA has accepted our application for the fifth indication of sugemalimab in China. If approved, sugemalimab has the potential to become the first PD-L1 monoclonal antibody in the world for the treatment of locally advanced, recurrent, or metastatic ESCC. We will continue to work closely with the NMPA and anticipate the significant benefits that sugemalimab could bring to a large number of patients.

This sBLA of sugemalimab was accepted based on the data from the GEMSTONE-304 study. It is a randomized, double-blind, multi-center, placebo-controlled phase 3 registrational clinical trial designed to evaluate the efficacy and safety of sugemalimab in combination with 5-fluorouracil plus cisplatin as first-line treatment in patients with unresectable locally advanced, recurrent, or metastatic ESCC. The primary endpoints are Blinded Independent Central Review (BICR)-assessed PFS and OS, and secondary endpoints include investigator-assessed PFS, BICR and investigator-assessed objective response rate (ORR) and duration of response (DoR).

In January 2023, the GEMSTONE-304 study met its primary endpoints. The results showed that sugemalimab in combination with chemotherapy demonstrated a statistically significant and clinically meaningful improvement in BICR-assessed PFS and OS compared with placebo in combination with chemotherapy. The safety profile was consistent with previous findings across the studies in additional diseases with sugemalimab and no new safety signal was observed. Detailed data from this study will be presented at an upcoming academic conference.

About Esophageal Cancer

Esophageal cancer is one of the most common cancers globally. According to the GLOBOCAN 2020 data, there were more than 600,000 new cases of esophageal cancer in the world in 2020 (ESCC accounts for about 85%), and 544,000 deaths, with the incidence and mortality ranking 8th and 6th, respectively, among cancers globally. The incidence of esophageal cancer in China accounts for more than half of the world, about 90% of which are ESCC, and most of the patients with ESCC have been diagnosed in the advanced stage and missed the opportunities of curative treatments.

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):

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).

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 accepted and granted priority review to the supplemental new drug application (sNDA) for sugemalimab in the treatment of patients with R/R ENKTL.

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), met its primary endpoints.

In February 2023, the NMPA of China accepted the sNDA of sugemalimab as first-line treatment for patients with locally advanced or metastatic gastric/gastroesophageal junction adenocarcinoma.

The Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom and the European Medicines Agency (EMA) 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.

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, April 6, 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.