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

VOLUNTARY ANNOUNCEMENT
CSTONE ANNOUNCES PUBLICATION OF GEMSTONE-303 STUDY RESULTS FOR SUGEMALIMAB (CEJEMLY®) IN JAMA

CStone Pharmaceuticals (the "**Company**" or "**CStone**") is pleased to announce the publication of the GEMSTONE-303 study results of sugemalimab (brand name: Cejemly®) in the prestigious Journal of the American Medical Association (JAMA).

Screenshot from JAMA Network: https://jamanetwork.com/journals/jama/article-abstract/2830739

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. The GEMSTONE-303 study results strongly support sugemalimab in combination with chemotherapy as a new standard first-line treatment for patients with PD-L1 combined positive score (CPS) ≥5.
- Sugemalimab is the first anti-PD-L1 monoclonal antibody demonstrating superior overall survival (OS) and progression free survival (PFS) with a manageable safety profile in combination with chemotherapy compared to placebo in combination with chemotherapy in patients with locally advanced or metastatic G/GEJ adenocarcinoma who have not received prior systemic treatment for advanced disease with PD-L1 CPS ≥5.
- Sugemalimab has received approvals for five indications in China, and for first-line treatment of Stage IV non-small cell lung cancer (NSCLC) in China, Europe and the UK. CStone will continue to engage with health authorities in Europe and other regions for regulatory expansion.

GEMSTONE-303 is a Phase III, randomized, double-blind, placebo-controlled registrational study designed to evaluate the efficacy and safety of sugemalimab in combination with capecitabine and oxaliplatin (CAPOX) compared to placebo in combination with CAPOX as first-line treatment for patients with unresectable locally advanced or metastatic G/GEJ adenocarcinoma with PD-L1 CPS ≥5. The dual primary endpoints were OS and investigator-assessed PFS. Key secondary endpoints included PFS assessed by Blinded Independent Central Review Committee (BICR), objective response rate (ORR), and duration of response (DoR).

The GEMSTONE-303 article published in JAMA highlights the following key efficacy and safety findings:

- In patients with PD-L1 CPS ≥ 5, sugemalimab in combination with chemotherapy group demonstrated statistically significant and clinically meaningful improvements in OS and PFS compared with placebo in combination with chemotherapy group.
- Median OS was 15.6 months in the sugemalimab in combination with chemotherapy group compared with 12.6 months in the control group, with a hazard ratio (HR) of 0.75 (95% CI, 0.61-0.92), P=0.006, indicating that sugemalimab in combination with CAPOX could reduce the risk of death by 25%.
- Median PFS was 7.6 months in the sugemalimab in combination with chemotherapy group compared with 6.1 months in the control group, with a HR of 0.66 (95% CI, 0.54-0.81), P<0.001.
- Grade ≥ 3 treatment-related adverse events (TRAE) occurred in 53.9% of patients in the sugemalimab in combination with chemotherapy group and 50.6% in the control group, indicating that the safety of the sugemalimab in combination with chemotherapy regiment was manageable.

Subgroup analyses demonstrated consistent clinical benefits of sugemalimab in combination with chemotherapy across all pre-defined subgroups, including patients with varying PD-L1 expression levels:

- Sugemalimab in combination with chemotherapy CAPOX significantly prolonged OS in patients with PD-L1 CPS ≥ 10; median OS was 17.8 months in the sugemalimab in combination with chemotherapy group compared with 12.5 months in the control group, with a HR of 0.64 (95%CI, 0.48-0.85), P=0.002.
- In patients with PD-L1 CPS ≥10, median PFS was 7.8 months in the sugemalimab in combination with chemotherapy group compared with 5.5 months in the control group, with a HR of 0.58 (95%CI,

0.43-0.77), P<0.001.

- In patients with PD-L1 CPS ≥10, ORR was 71.4% in the sugemalimab in combination with chemotherapy group compared with 48.6% in the control group.

Dr. Jason Yang, CEO, President of R&D, and Executive Director at CStone, stated: "We are honored that the GEMSTONE-303 study results are published in the prestigious JAMA. This study establishes sugemalimab in combination with chemotherapy as the new standard first-line treatment for patients with PD-L1 CPS ≥5 G/GEJ adenocarcinoma. To date, sugemalimab has been approved for five indications in China. Meanwhile, we have expanded its regulatory pathways and forged commercialization partnerships in various international markets. The compelling clinical data from GEMSTONE-303 reinforce our confidence in advancing the global registration and commercialization of sugemalimab. We are committed to unlocking sugemalimab's further clinical potential and providing greater survival benefits to patients worldwide."

Professor Lin Shen, Peking University Cancer Hospital, the leading principal investigator of the GEMSTONE-303 study, said: "Prior to the application of PD-1 inhibitors, chemotherapy was the standard first-line therapy for unresectable, locally advanced or metastatic G/GEJ adenocarcinoma, with median OS rarely exceeding one year. The combination of anti-PD-1 antibodies with chemotherapy as the new standard first-line treatment has significantly extended survival for these patients. The GEMSTONE-303 study builds on this progress. As the first anti-PD-L1 antibody approved for this patient population, sugemalimab specifically targeted the PD-L1-expressing population in its pivotal study, achieving significant efficacy with a manageable safety profile. The acceptance and publication of these results in JAMA affirm the innovation of GEMSTONE-303 and the valuable contributions of all researchers and participants involved."

About Sugemalimab

The anti-PD-L1 monoclonal antibody sugemalimab was developed 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.

To date, the National Medical Products Administration (NMPA) of China has approved sugemalimab for five indications:

- In combination with chemotherapy as 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 as 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 (CPS ≥5).

The European Commission (EC) has approved sugemalimab (brand name: Cejemly®) in combination with platinum-based chemotherapy for the first-line treatment of patients with metastatic NSCLC with no sensitizing EGFR mutations, or ALK, ROS1 or RET genomic tumor aberrations.

The Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom has approved the marketing authorization application for sugemalimab in combination with platinum-based

chemotherapy for first-line treatment of metastatic NSCLC with no sensitizing EGFR mutations, or ALK, ROS1 or RET genomic tumor aberrations.

About CStone

CStone (HKEX: 2616), established in late 2015, is an innovation-driven biopharmaceutical company focused on the research and development of anti-cancer therapies. Dedicated to addressing patients' unmet medical needs in China and globally, the Company has made significant strides since its inception. To date, the Company has successfully launched 4 innovative drugs and secured approvals for 16 new drug applications (NDAs) covering 9 indications. The Company's pipeline is balanced by 16 promising candidates, featuring potentially first-in-class or best-in-class antibody-drug conjugates (ADCs), multispecific antibodies, immunotherapies and precision medicines. CStone also prides itself on a management team with comprehensive experiences and capabilities that span the entire drug development spectrum, from preclinical and translational research to clinical development, drug manufacturing, business development, and commercialization.

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, February 25, 2025

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, Mr. Hongbin Sun and Ms. Yip Betty Ho independent non-executive directors.