CStone Pharmaceuticals

基石藥業

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 2616)

VOLUNTARY ANNOUNCEMENT
CSTONE ANNOUNCES PUBLICATION IN NATURE CANCER HIGHLIGHTING THE OVERALL SURVIVAL RESULTS OF SUGEMALIMAB IN NON-SMALL CELL LUNG CANCER

CStone Pharmaceuticals (the "**Company**" or "**CStone**") is pleased to announce that Nature Cancer, a prestigious journal from the Nature Group, has published the results of the overall survival ("**OS**") interim analysis from the registrational clinical study GEMSTONE-302 that evaluated sugemalimab in the first-line stage IV non-small cell lung cancer ("**NSCLC**"). This publication represents one additional recognition from the international academic community since the prior presentations at the American Society of Clinical Oncology (ASCO) annual meeting, World Conference on Lung Cancer (WCLC), and publication in The Lancet Oncology, and highlights the significant academic and clinical value of sugemalimab.

Dr. Jason Yang, Chief Executive Officer and executive director of CStone, said, "We are very pleased that the OS results of GEMSTONE-302 have been published again by a renowned academic journal. The innovative trial design and the outstanding clinical results of sugemalimab are the two key factors leading to the acceptance of GEMSTONE-302 by these prestigious journals, by The Lancet Oncology and now in Nature Cancer. Sugemalimab has been approved in China for the first-line treatment of stage IV NSCLC, and the marketing authorization applications (MAAs) are currently under review by the regulatory agencies in the United Kingdom and European Union. In addition, the review of other supplemental biologics license applications of sugemalimab, such as in lymphoma, gastric cancer, and esophageal cancer, are currently in progress with the National Medical Products Administration ("**NMPA**") of China. We will continue to work closely with global regulatory authorities including U.S. Food and Drug Administration and look forward to seeing more patients world-wide benefitting from sugemalimab."

Professor Caicun Zhou, Principal Investigator of the GEMSTONE-302 study, the corresponding author of this publication, and Director of the Department of Oncology at Shanghai Pulmonary Hospital, Tongji University, said, "The prolongation of OS is the ultimate goal of cancer treatment

and the gold standard of efficacy evaluation. The publication in Nature Cancer further demonstrates the durable clinical benefits and manageable safety profile of sugemalimab-chemotherapy regimen in both advanced squamous and non-squamous NSCLC patients, and the prolongation of median OS is very significant clinically. Based on the data from GEMSTONE-302, we believe sugemalimab can help more patients with lung cancer achieve long-term survival."

GEMSTONE-302 is a multicenter, randomized and double-blind Phase 3 clinical trial designed to evaluate the efficacy and safety of sugemalimab in combination with chemotherapy in treatment-naïve patients with stage IV NSCLC as compared to placebo in combination with chemotherapy. The primary endpoint of the study was investigator-assessed progression-free survival (PFS). Secondary endpoints included OS, Blinded Independent Central Review (BICR) -assessed PFS, investigator-assessed PFS in patients with PD-L1 expression ≥1%, objective response rate (ORR), duration of response (DoR) and safety.

As of the data cutoff date of November 22, 2021, among 479 enrolled patients, 51 and 7 patients remained on treatment with sugemalimab in combination with chemotherapy or placebo in combination with chemotherapy, respectively. The median follow-up durations were 25.4 months for the sugemalimab group and 24.9 months for the placebo group. The median OS was 25.4 months in the sugemalimab group compared to 16.9 months in the placebo group, with a hazard ratio ("**HR**") of 0.65. The 2-year OS rates were 51.7% and 35.6% for the sugemalimab and placebo groups, respectively. In patients with baseline brain metastasis, sugemalimab improved OS compared to the placebo group, with median OS of 22.1 months vs 9.0 months (HR=0.45). Additionally, OS benefits were observed in all subgroups, including different tumor histology subtypes and PD-L1 expression levels.

In the intention-to-treat population, the median PFS was 9.0 months for the sugemalimab group compared to 4.9 months for the placebo group (HR=0.49). The 2-year PFS rates were 20.8% and 7.3% for the sugemalimab and placebo groups, respectively. Subgroup analysis showed that in patients with PD-L1≥1%, the median PFS was 10.9 months for sugemalimab group vs 4.9 months for the placebo group (HR=0.48). The safety data were consistent with previous reports.

Nature Cancer aims to publish the most significant advances across the full spectrum of cancer research in the life, physical, applied and social sciences, spanning basic preclinical, translational and clinical work. The journal's broad scope covers all cancer research offering new insights into cancer biology and genetics, new approaches for the development and delivery of diagnostics and therapies, and new ways of understanding the global societal impact of cancer.

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.

Sugemalimab is approved by the NMPA of China for the treatment of patients with unresectable Stage III non-small cell lung cancer 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 marketing authorization applications with the European Medicines Agency (EMA) and the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom for sugemalimab as a

first-line treatment for metastatic NSCLC are under review.

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 gastric/gastroesophageal junction 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.

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 15 drug candidates with a strategic emphasis on immuno-oncology combination therapies. Currently, CStone has received seven NDA approvals for four drugs. 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 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 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, June 16, 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.