CStone Pharmaceuticals

基石藥業

(Incorporated in the Cayman Islands with limited liability)

(**Stock Code: 2616**)

VOLUNTARY ANNOUNCEMENT
CSTONE ANNOUNCES ORAL PRESENTATION AT ESMO WORLD GI 2023 FOR PIVOTAL PHASE 3 CLINICAL STUDY OF SUGEMALIMAB IN FIRST-LINE ESOPHAGEAL SQUAMOUS CELL CARCINOMA

CStone Pharmaceuticals (the "**Company**" or "**CStone**"), announced that the data from a pivotal Phase 3 clinical trial (GEMSTONE-304), evaluating sugemalimab in combination with chemotherapy as the first-line treatment for unresectable locally advanced, recurrent, or metastatic esophageal squamous cell carcinoma ("**ESCC**"), will be presented in an oral session at the European Society for Medical Oncology (the "**ESMO**") World Congress on Gastrointestinal Cancer 2023. The congress, organized by the ESMO, will be held in Barcelona, Spain, from June 28 to July 1, 2023.

- Session: Esophageal and Gastric Cancers
- Date and Time: June 29, 2023, 3:10-3:20 p.m. (Beijing Time) / June 29, 2023, 8:10-8:20 a.m. (European Time)
- Presentation Type: Oral Presentation
- Title: GEMSTONE-304: a phase 3 study of sugemalimab plus chemotherapy versus chemotherapy as first-line treatment of patients with unresectable locally advanced, recurrent, or metastatic ESCC
- Abstract number: O-4
- Presenter: Professor Jin Li, Director of Oncology Department, Shanghai East Hospital (East Hospital affiliated to Tongji University)
- Principal Investigators: Jin Li, Zhendong Chen, Yuxian Bai, Bo Liu, Qingshan Li, Jun Zhou, Jingdong Zhang, Ting Deng, Fuyou Zhou, Shegan Gao, Shujun Yang, Feng Ye, Long Chen, Wei Bai, Xianli Yin, et al (71 principal investigators in total)

The GEMSTONE-304 study 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 the first-line treatment in patients with unresectable locally advanced, recurrent, or metastatic ESCC. The dual primary endpoints are Blinded Independent Central Review (BICR)-assessed progression-free survival ("**PFS**") and overall survival ("**OS**"). Secondary endpoints include investigator-assessed PFS, BICR and investigator-assessed objective response rate and duration of response, etc.

In January 2023, the GEMSTONE-304 study met both primary endpoints. 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 reports of sugemalimab and no new safety signal was observed. The supplemental biologics license application for sugemalimab in combination with chemotherapy as a first-line treatment of unresectable locally advanced, recurrent, or metastatic ESCC has been accepted by the National Medical Products Administration ("**NMPA"**) of China and is currently under review. Sugemalimab potentially could become the first anti-PD-L1 monoclonal antibody worldwide approved for the first-line treatment of unresectable locally advanced, recurrent or metastatic ESCC.

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 (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 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.

The marketing authorization applications (MAAs) 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.

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 13, 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.