CStone Pharmaceuticals

基石藥業

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 2616)

VOLUNTARY ANNOUNCEMENT
CSTONE ANNOUNCED THE GEMSTONE-302 STUDY OF SUGEMALIMAB MET THE ENDPOINT OF OVERALL SURVIVAL IN THE FIRST-LINE TREATMENT OF METASTATIC NSCLC PATIENTS

CStone Pharmaceuticals (the "**Company**" or "**CStone**") is pleased to announce that the GEMSTONE-302 registrational clinical study of sugemalimab for the first-line treatment of metastatic (stage IV) non-small cell lung cancer ("**NSCLC**") met the overall survival ("**OS**") endpoint. The results demonstrated that sugemalimab in combination with chemotherapy showed statistically significant and clinically meaningful OS improvement in patients. Based on the previously reported impressive progression-free survival ("**PFS**") data, the National Medical Products Administration ("**NMPA**") of China approved the new drug application ("**NDA**") of sugemalimab in combination with chemotherapy for the first-line treatment of patients with metastatic squamous and non-squamous NSCLC in December 2021. A detailed presentation of the OS analysis will be reported at an upcoming international academic conference.

Key Highlights

- Sugemalimab is the world's first PD-L1 monoclonal antibody that when administered along with chemotherapy improved OS of first-line metastatic squamous and non-squamous NSCLC patients in a statistically significant and clinically meaningful manner.

- Survival benefits across all the subgroups including different tumor pathology type and PD-L1 expression levels.

- The NMPA of China has approved sugemalimab in combination with chemotherapy for the first-line treatment of patients with metastatic squamous and non-squamous NSCLC.

- The updated data from the GEMSTONE-302 study, together with clinical data in other indications, will be used to support NDAs for sugemalimab in this indication in multiple countries and regions outside of Greater China.

Professor Caicun Zhou, Principal Investigator of the GEMSTONE-302 registrational clinical study of sugemalimab and Director of the Department of Oncology, Shanghai Pulmonary Hospital, Tongji University, said, "Globally, the mortality of lung cancer ranks first among all malignant tumors. The goal of first-line treatment for advanced lung cancer is to maximally prolong survival benefits for patients and to delay disease progression. The prespecified OS analysis data further confirmed that sugemalimab in combination with chemotherapy provided durable survival benefits to patients. Sugemalimab has the potential to reshape the first-line treatment landscape of advanced NSCLC and could become the preferred immune-oncology therapy for the treatment of advanced NSCLC."

Dr. Jason Yang, Chief Medical Officer of CStone, said, "We've had exciting news about sugemalimab successively in recent days. After being approved in China last month and with the first batch of prescriptions issued recently, now the OS analysis of the GEMSTONE-302 study demonstrated that sugemalimab in combination with chemotherapy brought significant improvement to the OS of patients, even with high percentage of patients in the chemotherapy control group received subsequent PD-1/PD-L1 inhibitors, including crossover treatment based on the protocol design, after disease progression. As OS represents the gold standard efficacy endpoint in cancer clinical trials, the achievement of the OS endpoint further demonstrates the important value of sugemalimab in the first-line treatment of NSCLC. sugemalimab is a PD-(L)1 monoclonal antibody addressing both stage III and stage IV NSCLC in all comer settings, and the NDA of sugemalimab in stage III NSCLC is under regulatory review and a pivotal phase II trial just met its primary endpoint of overall response rate in patients with relapsed and refractory natural killer/T-cell lymphoma. In addition, we are advancing the registrational studies of sugemalimab in gastric cancer, esophageal squamous cell carcinoma, and lymphoma, so as to enable sugemalimab to benefit a broader population of cancer patients."

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 allow a reduced risk of immunogenicity and toxicity for patients, a unique advantage over similar drugs.

Currently, the NMPA of China has approved sugemalimab in combination with pemetrexed and carboplatin as first-line treatment of patients with metastatic non-squamous NSCLC, lacking EGFR and ALK genomic tumor aberrations; and in combination with paclitaxel and carboplatin as first-line treatment of patients with metastatic squamous NSCLC. In addition, sugemalimab is being investigated in a number of ongoing clinical trials, including one Phase II registrational study for lymphoma and four Phase III registrational studies in stage IV NSCLC, stage III NSCLC, gastric cancer, and esophageal cancer, respectively.

CStone formed a strategic collaboration agreement with Pfizer Inc. (NYSE: PFE) 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 the GEMSTONE-302 study

The GEMSTONE-302 study (ClinicalTrials.gov registration number: NCT03789604; drug clinical trial registration number: CTR20181452) is a randomized, double-blind Phase 3 study, designed to evaluate the efficacy and safety of sugemalimab in combination with chemotherapy as a first-line treatment in patients with stage IV NSCLC as compared to placebo in combination with chemotherapy. The primary endpoint of the study was investigator-assessed PFS. Secondary endpoints included OS, blinded independent central review ("**BICR**")-assessed PFS and safety.

In August 2020, the GEMSTONE-302 study met its primary endpoint of significantly prolonged PFS, with the risk of disease progression or death reduced by 50% with sugemalimab combined with chemotherapy, as compared to placebo combined with chemotherapy, as assessed by independent Data Monitoring Committee ("**iDMC**") at the planned interim analysis. PFS data were presented in a Proffered Paper Oral Presentation (Late-Breaking Abstract) at the ESMO Asia 2020.

In July 2021, the final analysis of PFS from the GEMSTONE-302 study showed that sugemalimab in combination with chemotherapy demonstrated further improvement in PFS, with the risk of disease progression or death reduced by 52%, together with a trend toward improved OS. Data were presented in a Mini Oral Presentation (Late-Breaking Abstract) at the IASLC 2021 World Conference on Lung Cancer. The results of the GEMSTONE-302 study were published in The Lancet Oncology in January 2022.

About CStone

CStone is a biopharmaceutical company focused on researching, developing and commercializing 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 five drug approvals in Greater China, including three in Mainland China, one in Hong Kong, and one in Taiwan. 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.

By Order of the Board
CStone Pharmaceuticals
Dr. Frank Ningjun Jiang
Chairman

Suzhou, the People's Republic of China, January 19, 2022

As at the date of this announcement, the Board of Directors of the Company comprises Dr. Frank Ningjun Jiang as Chairman and executive Director, Dr. Wei Li, Mr. Kenneth Walton Hitchner III, Mr. Yanling Cao, 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.