CStone Pharmaceuticals

基石藥業

(Incorporated in the Cayman Islands with limited liability)

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VOLUNTARY ANNOUNCEMENT
CSTONE ANNOUNCED FINAL PFS ANALYSIS OF A REGISTRATIONAL STUDY OF SUGEMALIMAB IN PATIENTS WITH STAGE III NSCLC FURTHER DEMONSTRATES ITS ROBUST EFFICACY AND SIGNIFICANT CLINICAL BENEFITS SHOWN IN INTERIM ANALYSIS

CStone Pharmaceuticals (the "**Company**" or "**CStone**") is pleased to announce the pre-planned final progression-free survival ("**PFS**") analysis results from the registrational GEMSTONE-301 study of sugemalimab as a consolidation therapy in patients with unresectable stage III non-small cell lung cancer ("**NSCLC**") without disease progression after concurrent or sequential chemoradiotherapy. The data showed that sugemalimab maintained a statistically significant and clinically meaningful improvement in PFS as assessed by blinded independent central review ("**BICR**"). Subgroup analysis demonstrated clinical benefits in patients receiving either concurrent or sequential chemoradiotherapy prior to sugemalimab. Sugemalimab had a well-tolerated safety profile and no new safety signal was observed. The detailed results will be presented at an upcoming international academic conference.

Key Highlights

- Sugemalimab is the world's first anti-PD-(L)1 monoclonal antibody to significantly improve PFS in patients with stage III NSCLC without disease progression following concurrent or sequential chemoradiotherapy

- The National Medical Products Administration of China ("**NMPA**") is reviewing the new drug application ("**NDA**") of sugemalimab for the treatment of patients with unresectable stage III NSCLC without disease progression following concurrent or sequential chemoradiotherapy.

Professor Yi-Long Wu, a tenured director of Guangdong Provincial People's Hospital, and the Leading Principal Investigator on the GEMSTONE-301 study, said, "Following positive data from last year's interim PFS analysis, final PFS analysis results showed that sugemalimab as a

consolidation therapy demonstrated more durable PFS and overall survival in patients with stage III NSCLC following concurrent or sequential chemoradiotherapy. The 2022 Chinese Society of Clinical Oncology (CSCO) guidelines have recommended sugemalimab as a consolidation therapy for patients with stage III NSCLC after chemoradiotherapy. The updated data will further support sugemalimab to become a standard-of-care for this patient population."

Dr. Jason Yang, Chief Medical Officer of CStone, said, "We are glad that the final PFS analysis of the GEMSTONE-301 study further demonstrated a statistically significant improvement in PFS and clinical benefits were observed in patients receiving either concurrent or sequential chemoradiotherapy. Based on the positive results of the interim PFS analysis, the NDA of sugemalimab for the treatment of stage III NSCLC is under review by the NMPA. Sugemalimab is expected to become the first anti-PD-(L)1 antibody worldwide for patients with stage III NSCLC following prior concurrent or sequential chemoradiotherapy if approved. We are also excited about sustained overall survival benefits. We hope sugemalimab will be approved globally to benefit more and more lung cancer patients with excellent efficacy and safety data."

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 has approved sugemalimab (Cejemly®) 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 September 2021, the NMPA accepted the NDA for sugemalimab as a consolidation therapy in patients with unresectable stage III NSCLC without disease progression after concurrent or sequential chemoradiotherapy.

With its proven therapeutic advantages, sugemalimab is set to be 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 a consolidation therapy in patients with stage III NSCLC after concurrent or sequential chemoradiotherapy.

CStone formed a strategic collaboration agreement with EQRx, Inc ("**EQRx**"), under which EQRx licensed the exclusive rights to sugemalimab for development and commercialization in the U.S., U.K., Europe and regions outside of Greater China.

About the GEMSTONE-301 study

The GEMSTONE-301 study (clinicaltrials.gov registration number: NCT03728556; drug clinical trial registration number: CTR20181429) is a multicenter, randomized, double-blind Phase III clinical trial, designed to evaluate the efficacy and safety of sugemalimab as consolidation therapy in patients with unresectable stage III NSCLC without disease progression after concurrent or sequential chemoradiotherapy. The trial's primary endpoint was PFS as assessed by BICR according to RECIST v1.1; the secondary endpoints included overall survival, PFS as assessed by investigators and safety, etc.

In May 2021, the GEMSTONE-301 study met its primary endpoint at a pre-planned interim analysis reviewed by the independent data monitoring committee (iDMC). The findings showed that sugemalimab brought statistically significant and clinically meaningful improvement in the BICR assessed PFS. Investigator-assessed PFS showed consistent results as those of the primary endpoint. Sugemalimab was well-tolerated with no new safety signals. Subgroup analyses demonstrated that sugemalimab was associated with clinical benefit regardless of whether patients received concurrent or sequential chemoradiotherapy prior to sugemalimab. The data were reported in the late-breaking abstract (LBA) presentation at the 2021 ESMO Annual Meeting, and 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 seven NDA approvals for 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.

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

Suzhou, the People's Republic of China, May 17, 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.