CStone Pharmaceuticals

基石藥業

(Incorporated in the Cayman Islands with limited liability)

(**Stock Code: 2616**)

VOLUNTARY ANNOUNCEMENT
CSTONE ANNOUNCED CHINA'S NMPA HAS ACCEPTED ITS NEW DRUG APPLICATION FOR SUGEMALIMAB IN THE TREATMENT OF STAGE III NSCLC

CStone Pharmaceuticals (the "**Company**" or "**CStone**") is pleased to announce that the National Medical Products Administration (the "**NMPA**") of China has accepted the new drug application (the "**NDA**") for sugemalimab as a consolidation therapy in patients with unresectable stage III NSCLC non-small cell lung cancer (the "**NSCLC**") without disease progression after concurrent or sequential chemoradiotherapy. It is the eighth NDA/supplemental NDA submitted by CStone.

Key Highlights

- Sugemalimab becomes the world's first anti-PD-1/PD-L1 monoclonal antibody to significantly improve substantially progression-free survival (the "**PFS**") in patients with stage III NSCLC without disease progression after concurrent or sequential chemoradiotherapy.

- The NDA for sugemalimab in the treatment of metastatic (stage IV) NSCLC is currently under review by the NMPA. Sugemalimab has the potential to become the world's first anti-PD-1/PD-L1 monoclonal antibody approved for both locally advanced/unresectable (stage III) and metastatic (stage IV) NSCLC patients.

Professor Yi-long Wu of Guangdong Provincial People's Hospital, the Leading Principal Investigator on the GEMSTONE-301 study, said "Globally, there remain huge unmet medical needs in patients with stage III NSCLC, particularly in those patients without disease progression after sequential chemoradiotherapy. In the phase III clinical study covering NSCLC patients after concurrent or sequential chemoradiotherapy, Sugemalimab has demonstrated superior efficacy in PFS and well-tolerated safety. We look forward to the successful launch of sugemalimab and the clinical benefits it will bring to patients."

Dr. Jason Yang, Chief Medical Officer of CStone, said, "This is the second NDA filing for sugemalimab in the treatment of NSCLC which has the highest incidence among all cancers in China. The first NDA for stage IV NSCLC was accepted by the NMPA in November 2020. Sugemalimab has the potential to become the world's first immunotherapy approved for the treatment of all-comer patients from both stage III and stage IV NSCLC, providing a more convenient clinical treatment option for these patients. We will continue working with EQRx to hold regulatory discussions regarding stage III and stage IV NSCLC with regulators in multiple countries and regions, including the U.S. Food and Drug Administration (FDA) to bring this innovative immunotherapy to patients as early as possible."

The NDA acceptance is based on GEMSTONE-301 study, a multicenter, randomized, double-blind Phase III clinical trial designed to evaluate the efficacy and safety of sugemalimab as a consolidation therapy in patients with locally advanced/unresectable stage III NSCLC without disease progression after concurrent or sequential chemoradiotherapy. In May 2021, GEMSTONE-301 study met its primary endpoint at a planned interim analysis reviewed by the independent Data Monitoring Committee (the "**iDMC**"). The findings showed that sugemalimab as a consolidation therapy brought statistically significant and clinically meaningful improvement in the Blinded Independent Central Review (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 benefits regardless of whether patients received concurrent or sequential chemoradiotherapy prior to sugemalimab. The data will be presented at the 2021 European Society for Medical Oncology (the "**ESMO**") Congress.

CStone has formed a strategic partnership with Pfizer that includes the development and commercialization of sugemalimab in mainland China, and a framework to bring additional oncology assets to the Greater China market.

CStone has also reached a strategic collaboration agreement with EQRx, under which EQRx licensed the exclusive rights to two key late-stage immuno-oncology assets, sugemalimab and CS1003 (anti-PD-1 antibody), for global development and commercialization outside of the Greater China.

About Sugemalimab (anti-PD-L1 antibody)

Sugemalimab is an investigational anti-PD-L1 monoclonal antibody discovered by CStone. Authorized by the U.S.-based Ligand Corporation, sugemalimab is developed by the OmniRat® transgenic animal platform, which can generate fully human antibodies in one stop. As a fully human, full-length anti-PD-L1 monoclonal antibody, sugemalimab mirrors the natural G-type immunoglobulin 4 (IgG4) human antibody, which reduces the risk of immunogenicity and potential toxicities in patients, a unique advantage over similar drugs.

Currently, sugemalimab is being investigated in a number of ongoing clinical trials, including one Phase II registration study for lymphoma (CS1001-201) and four Phase III registrational studies in stage III NSCLC, stage IV NSCLC, gastric cancer, and esophageal cancer, respectively.

CS1001-201 is a single-arm, multicenter, Phase II pivotal study designed to evaluate the efficacy and safety of sugemalimab as monotherapy for the treatment of adult patients with relapsed or refractory extranodal natural killer/T-cell lymphoma (R/R ENKTL). Based on the encouraging preliminary efficacy results, sugemalimab was granted Orphan Drug Designation for the treatment of T-cell lymphoma and Breakthrough Therapy Designation for the treatment of R/R ENKTL by the U.S. Food and Drug Administration. It has also been granted Breakthrough Therapy Designation by the NMPA. The proposed indication is R/R ENKTL.

About GEMSTONE-301 Study

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 locally advanced/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.

In May 2021, GEMSTONE-301 study met its primary endpoint at a 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 Blinded Independent Central Review (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.

Currently, the NMPA has accepted the NDA for sugemalimab in stage III NSCLC. CStone is working closely with EQRx to pursue regulatory discussions for stage III NSCLC in multiple countries.

About GEMSTONE-302 Study

GEMSTONE-302 (clinicaltrials.gov registration number: NCT03789604; drug clinical trial registration number: CTR20181452) is a randomized, double-blind Phase III study, designed to evaluate the efficacy and safety of anti-PD-L1 monoclonal antibody sugemalimab combined with chemotherapy as the first-line treatment in naïve patients with stage IV NSCLC it vs. placebo combined with chemotherapy. The primary endpoint of the study was investigator-assessed PFS. Secondary endpoints included overall survival, BICR-assessed PFS and safety.

In August 2020, GEMSTONE-302 study met its primary endpoint of significantly prolonging PFS and reducing the risk of disease progression or death by 50% with sugemalimab combined with chemotherapy compared to placebo combined with chemotherapy, as assessed by iDMC at the planned interim analysis.

Subgroup analysis showed clinical benefit in patients with squamous versus non-squamous NSCLC, and in patients with PD-L1 expression $\geqslant$ 1% versus PD-L1 expression <1%.

Sugemalimab in combination with chemotherapy was well tolerated, no new safety signals were identified. Specific study data were presented in a Proffered Paper Oral Presentation (Late-Breaking Abstract) at ESMO Asia 2020.

In November 2020, the NMPA of China accepted the NDA for sugemalimab combined with chemotherapy for the first-line treatment of advanced squamous and non-squamous NSCLC patients.

In July 2021, the recently conducted final PFS analysis results showed that sugemalimab plus chemotherapy demonstrated further improvement in PFS, following the previously reported positive readout in interim PFS analysis. Meanwhile, data with the longer follow-up further demonstrated that sugemalimab plus chemotherapy brought patients with long term overall survival benefits.

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 three drug approvals in Greater China, including two in Mainland China 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, September 2, 2021

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. Qun Zhao, 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.