CStone Pharmaceuticals

基石藥業

(Incorporated in the Cayman Islands with limited liability)

(**Stock Code: 2616**)

VOLUNTARY ANNOUNCEMENT
CSTONE AND PFIZER ANNOUNCED NMPA APPROVAL OF SUGEMALIMAB IN PATIENTS WITH UNRESECTABLE STAGE III NON-SMALL CELL LUNG CANCER

CStone Pharmaceuticals (the "**Company**" or "**CStone**") and Pfizer Inc. (NYSE: PFE) ("**Pfizer**") are pleased to announce that the National Medical Products Administration of China ("**NMPA**") has approved sugemalimab 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. Together with the previous approval of the treatment for first-line stage IV NSCLC patients, sugemalimab is now the only anti-PD-1/PD-L1 monoclonal antibody for both stage III and stage IV NSCLC patients.

Key Highlights

- The NMPA approved sugemalimab for the treatment of patients with unresectable stage III NSCLC whose disease has not progressed following concurrent or sequential platinum-based chemoradiotherapy.

- Sugemalimab became the first anti-PD-1/PD-L1 monoclonal antibody approved for stage III NSCLC following concurrent or sequential chemoradiotherapy. It's also the only anti-PD-(L)1 monoclonal antibody approved for both stage III and stage IV NSCLC.

- This is the eighth approved new drug application ("**NDA**") for CStone.

Dr. Frank Jiang, CEO of CStone, said, "We appreciate the NMPA for granting the new approval which is an important milestone in our journey to lead the treatment of lung cancer as China steps up efforts to support innovative therapies and address unmet needs. As a leading biopharma company in fostering precision medicines and immuno-oncology therapies, CStone has been spearheading multiple medical breakthroughs. With this approval, it will provide a new treatment option for stage III NSCLC patients, while demonstrating our prowess in advancing lung cancer treatments and

bringing forward transformative drugs to the market. Partnerships are crucial to meet massive clinical needs of cancer patients. We will continue to work closely with Pfizer to deliver cutting-edge oncology therapies and improve the health of cancer patients in China."

Professor Yi-Long Wu of Guangdong Provincial People's Hospital, the Leading Principal Investigator on the GEMSTONE-301 study, said, "Patients with stage III NSCLC urgently need new treatment options, and the NMPA approval of sugemalimab brings them hope. The results from GEMSTONE-301 demonstrated that sugemalimab as a consolidation therapy had robust efficacy and a well-tolerated safety profile. It is now recommended by the Chinese Society of Clinical Oncology (CSCO) guidelines for this patient population. With proven clinical benefits, sugemalimab will potentially reshape the treatment landscape as a preferred immuno-oncology therapy for patients with mid- and late-stage lung cancer."

Dr. Jason Yang, Chief Medical Officer of CStone, said, "We are thrilled that sugemalimab has become the first anti-PD-1/PD-L1 monoclonal antibody approved for stage III NSCLC patients after concurrent or sequential chemoradiotherapy. The GEMSTONE-301 study has an innovative study design that enrolled patients with either concurrent or sequential chemoradiotherapy to better reflect real-world clinical practice and cover a broad patient population. We've also made significant progress in the registrational studies of sugemalimab in patients with esophageal squamous cell carcinoma, gastric cancer, and relapsed or refractory extranodal natural killer/T-cell lymphoma in a bid to benefit more cancer patients."

The NMPA approval is based on the 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 unresectable stage III NSCLC without disease progression after concurrent or sequential chemoradiotherapy. Sugemalimab significantly improved patients' progression-free survival ("**PFS**"), the risk of disease progression or death was reduced by 36%; together with encouraging overall survival ("**OS**"), the risk of death was reduced by 56%. Subgroup analyses demonstrated clinical benefits regardless of whether patients received prior concurrent or sequential chemoradiotherapy. Sugemalimab had a well-tolerated safety profile, and no new safety signals were observed. The results of the GEMSTONE-301 study were published in The Lancet Oncology in January 2022.

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 in combination with pemetrexed and carboplatin as first-line treatment of patients with metastatic non-squamous NSCLC, lacking epidermal growth factor receptor (EGFR) and anaplastic lymphoma kinase (ALK) genomic tumor aberrations; and in combination with paclitaxel and carboplatin as first-line treatment of patients with metastatic squamous NSCLC; for the treatment of patients with unresectable stage III NSCLC whose disease has not progressed following concurrent or sequential platinum-based chemoradiotherapy.

With its proven therapeutic advantages, sugemalimab is set to be recommended by the 2022 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 Pfizer 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-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 blinded independent central review ("**BICR**") according to RECIST v1.1; the secondary endpoints included OS, 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.

In May 2022, the final PFS analysis results from the registrational GEMSTONE-301 study of sugemalimab showed that sugemalimab maintained a statistically significant and clinically meaningful improvement in PFS as assessed by 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 signals were observed. The detailed results will be presented at an upcoming international academic conference.

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 eight 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.

About Pfizer: Breakthroughs That Change Patients' Lives

Pfizer applies science and our global resources to bring therapies to people that extend and significantly improve their lives. Pfizer strives to set the standard for quality, safety and value in the discovery, development and manufacture of healthcare products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with Pfizer's responsibility as one of the world's premier innovative biopharmaceutical companies, Pfizer collaborates with healthcare providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 170 years, Pfizer has worked to make a difference for all who rely on us.

For more information about Pfizer, please visit www.pfizer.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 SUGEMALIMAB SUCCESSFULLY. Shareholders of the Company and potential investors are advised to exercise due care when dealing in the shares of the Company

By Order of the Board
CStone Pharmaceuticals
Dr. Wei Li
Chairman

Suzhou, the People's Republic of China, June 6, 2022

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. Frank Ningjun Jiang as executive director, 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.