CStone Pharmaceuticals

基石藥業

(Incorporated in the Cayman Islands with limited liability)

(**Stock Code: 2616**)

VOLUNTARY ANNOUNCEMENT
CSTONE ANNOUNCED THE CLINICAL DATA FROM REGISTRATIONAL STUDY OF Cejemly® (SUGEMALIMAB) IN STAGE III NON-SMALL CELL LUNG CANCER PUBLISHED IN THE LANCET ONCOLOGY

CStone Pharmaceuticals (the "**Company**" or "**CStone**") is pleased to announce that the registrational clinical data from Cejemly® (sugemalimab) (the GEMSTONE-301 study) in stage III non-small cell lung cancer ("**NSCLC**") were published in the world-leading clinical oncology journal, The Lancet Oncology. Cejemly® as a consolidation therapy demonstrated a statistically significant and clinically meaningful improvement in progression-free survival ("**PFS**") in patients with unresectable stage III NSCLC without disease progression after concurrent or sequential chemoradiotherapy. After being selected as a late-breaking abstract (LBA) at the European Society of Medical Oncology ("**ESMO**") Congress 2021, this study has been honored on the international academic stage, fully demonstrating its great academic value and clinical potential. The leading principal investigator of GEMSTONE-301 is Professor Yi-Long Wu from Guangdong Provincial People's Hospital. This randomized, double-blind phase III trial was done in 50 hospitals and research centers in China. With an innovative study design, this study enrolled patients with either concurrent or sequential chemoradiotherapy to better reflect real-world clinical practice and covered a broad NSCLC patient population.

The GEMSTONE-301 study is designed to evaluate the efficacy and safety of Cejemly® as consolidation therapy in patients with unresectable stage III NSCLC without disease progression after concurrent or sequential chemoradiotherapy.

GEMSTONE-301 study met its primary endpoint at a pre-planned interim analysis. The findings showed that Cejemly® demonstrated statistically significant and clinically meaningful improvement in PFS as assessed by blinded independent central review ("**BICR**"). The BICR-assessed median PFS was 9.0 months vs 5.8 months, stratified HR=0.64 (95% CI: 0.48, 0.85), p-value=0.0026. Consistent PFS benefit favoring sugemalimab was observed in patients who received either concurrent or sequential chemoradiotherapy prior to randomization. The median PFS was 10.5

months vs. 6.4 months in the concurrent radiotherapy group, HR=0.66 (95% CI: 0.44, 0.99), and 8.1 months vs. 4.1 months in the sequential radiotherapy group, HR=0.59 (95% CI: 0.39, 0.91). Cejemly® had a well-tolerated safety profile with no new safety signals observed.

Professor Yi-Long Wu, Guangdong Provincial People's Hospital, the corresponding author and leading principal investigator on the GEMSTONE-301 study, said, "The publication of the results from the GEMSTONE-301 study in The Lancet Oncology demonstrates the international medical community has fully affirmed the study's forward-looking design, research quality and clinical value. It also showcases that Chinese researchers have taken a broad scientific perspective to explore and conduct high-quality innovative research that fits in with the real clinical needs in China."

Dr. Jason Yang, Chief Medical Officer of CStone, said, "The Lancet Oncology is an international trusted source that is devoted to publishing high-quality research papers to help advance practice in clinical oncology and potentially reshape the landscape of cancer control and prevention. The publication of data from the GEMSTONE-301 study in The Lancet Oncology is powerful proof of CStone's clinical development capabilities and research quality. It also highlights the outstanding clinical value of Cejemly®. The new drug application ("**NDA**") of Cejemly® in patients with stage III NSCLC is under review by the National Medical Products Administration ("**NMPA**") of China, and we expect it to benefit more Chinese patients."

The NMPA of China has approved the NDA of sugemalimab (Cejemly®) in combination with chemotherapy for treatment-naïve metastatic (stage IV) NSCLC patients. Based on the positive data in patients with locally advanced (stage III) and metastatic (stage IV) NSCLC, Cejemly® has the potential to become the world's first anti-PD(L)1 monoclonal antibody approved for the treatment of all-comer patients from both stage III and stage IV NSCLC.

About Cejemly® (sugemalimab)

The potential best-in-class anti-PD-L1 monoclonal antibody Cejemly® is an investigational anti-PD-L1 monoclonal antibody discovered by CStone. Authorized by the U.S.-based Ligand Corporation, Cejemly® 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, Cejemly® 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, the NMPA of China has approved sugemalimab (Cejemly®) in combination with pemetrexed and carboplatin as first-line treatment of patients with metastatic non-squamous NSCLC, with no EGFR or ALK genomic tumor aberrations; and in combination with paclitaxel and carboplatin as first-line treatment of patients with metastatic squamous NSCLC. Sugemalimab is being investigated in a number of ongoing clinical trials, including one Phase II registration study for lymphoma and four Phase III registrational studies in stage III NSCLC, stage IV NSCLC, gastric cancer, and esophageal cancer, respectively.

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 Cejemly® 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 Cejemly® brought statistically significant and clinically meaningful improvement in the BICR assessed PFS. Investigator-assessed PFS showed consistent results as those of the primary endpoint. Cejemly® 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 Cejemly®. The data were reported in the late-breaking abstract (LBA) presentation at the 2021 ESMO Annual Meeting.

In September 2021, the NMPA of China accepted the NDA for Cejemly® as consolidation therapy in patients with unresectable stage III NSCLC without disease progression after concurrent or sequential chemoradiotherapy.

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 III study, designed to evaluate the efficacy and safety of anti-PD-L1 monoclonal antibody Cejemly® combined with chemotherapy as the first-line treatment in treatment-naïve patients with stage IV NSCLC 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, the GEMSTONE-302 study met its primary endpoint of significantly prolonging PFS and reducing the risk of disease progression or death by 50% with Cejemly® combined with chemotherapy compared to placebo combined with chemotherapy, as assessed by the iDMC at the planned interim analysis. Specific study 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 Cejemly® in combination with chemotherapy demonstrated continued improvement in PFS and the risk of disease progression or death was reduced by 52%, together with a trend of overall survival benefits. Data were presented as a Mini Oral Presentation (Late-Breaking Abstract) at the IASLC 2021 World Conference on Lung Cancer.

About CStone

CStone is a leading biopharmaceutical company focused on researching, developing and commercializing innovative immuno-oncology and precision medicines to address the unmet medical needs of cancer patients in Mainland 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 therapies and precision medicines. Currently, CStone has received five drug approvals in Greater China, including three in Mainland China, one in Hong Kong, and one in Taiwan, China. 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 16, 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.