CStone Pharmaceuticals

基石藥業

(Incorporated in the Cayman Islands with limited liability)

(**Stock Code: 2616**)

INSIDE INFORMATION ANNOUNCEMENT

CSTONE ANNOUNCED NEW DRUG APPROVAL OF CEJEMLY® (SUGEMALIMAB) IN CHINA TO POTENTIALLY RESHAPE THE LANDSCAPE OF IMMUNO-ONCOLOGY THERAPY IN LUNG CANCER

This announcement is issued pursuant to Rule 13.09 of the Rules Governing the Listing of the Securities on The Stock Exchange of Hong Kong Limited (the "**Listing Rules**") and the inside information provision (as defined in the Listing Rules) under Part XIVA of the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong).

CStone Pharmaceuticals (the "**Company**" or "**CStone**") is pleased to announce that the National Medical Products Administration ("**NMPA**") of China has approved the new drug application ("**NDA**") of anti-PD-L1 monoclonal antibody Cejemly® (sugemalimab) in combination with chemotherapy for treatment-naïve metastatic (stage IV) non-small cell lung cancer ("**non-small cell lung cancer**" or "**NSCLC**") patients.

Key Highlights

- Anti-PD-L1 monoclonal antibody Cejemly® approved in combination with pemetrexed and carboplatin as first-line treatment of patients with metastatic nonsquamous 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.

- It is the first anti-PD-L1 plus chemotherapy approved for the first-line treatment of metastatic non-squamous and squamous NSCLC patients worldwide.

- The NDA of Cejemly® in stage III NSCLC is under regulatory review, and the product has the potential to provide an anti-PD-L1 monoclonal antibody option for both stage III and stage IV non-small cell lung cancer patents in the future.

- Cejemly® is CStone's third new drug approval in China in 2021, following two first-in-class precision medicines GAVRETO® and AYVAKIT®.

Globally, the incidence of lung cancer continues to rise, and it is still the leading cause of cancer death worldwide, with huge unmet medical needs. According to statistics, there were 2.21 million new lung cancer cases worldwide in 2020. NSCLC accounts for about 85% of all lung cancer cases, and about 66% of patients are diagnosed with stage III/IV NSCLC. According to IQVIA's Global Oncology Trends, the size of global oncology drug market is estimated to reach US$269 billion by 2025, of which immuno-oncology drugs will contribute about 20%.

Dr. Frank Jiang, Chairman and CEO of CStone, said: "Cejemly® is our third approved new drug in China this year. This further demonstrates CStone's ability and track record in developing and commercializing high-quality new drugs. As a drug supported by China's national science innovation program, Cejemly® is a globally leading anti-PD-L1 monoclonal antibody. We will work closely with Pfizer to leverage resources and advantages of both sides to accelerate commercialization so that more Chinese patients can benefit from this innovative therapy soon."

Professor Caicun Zhou, Principal Investigator of the GEMSTONE-302 registrational phase III clinical study of Cejemly® and Director of the Department of Oncology, Shanghai Pulmonary Hospital, said, "The latest data show that Cejemly® plus chemotherapy further prolonged progression-free survival ("**PFS**") of treatment-naïve patients with stage IV NSCLC. Compared with chemotherapy alone, Cejemly® plus chemotherapy demonstrated durable survival benefits with lower toxicity and immunogenicity risks. With a unique dual mechanism of action, Cejemly® mobilizes both T cells and macrophages to destroy tumor cells. Therefore, Cejemly® is expected to reshape the landscape of lung cancer treatment."

Dr. Jason Yang, Chief Medical Officer of CStone, said, "We are thrilled that Cejemly® has been approved in Mainland China. It took only four years for Cejemly® to obtain the first NDA approval in lung cancer from the initiation of the phase I clinical trial in humans. It comprehensively showcased CStone's robust clinical strategy, innovative trial design and rapid execution, while once again demonstrating the 'CStone Speed'. We will continue to work with our partner to pursue regulatory discussions for Cejemly® on the NDAs of stage III and stage IV NSCLC with regulators in multiple countries and regions, including the U.S. Food and Drug Administration, and bring this innovative immunotherapy to more lung cancer patients soon. We will also continue to advance the registrational studies of Cejemly® in esophageal squamous cell carcinoma, gastric cancer, relapsed/refractory extranodal natural killer/T-cell lymphoma, to benefit more cancer patients."

The NMPA approval is based on the positive data of GEMSTONE-302 study, a multi-center, randomized, double-blind, phase III study that evaluated the efficacy and safety of Cejemly® or placebo in combination with chemotherapy in first-line stage IV NSCLC patients. Compared with placebo plus chemotherapy, Cejemly® plus chemotherapy lowered the risk of disease progression or death by 52%, significantly prolonged the patients' PFS and an encouraging trend in overall survival ("**OS**") was observed. The clinical benefit was irrespective of NSCLC pathologies and PD-L1 expression levels. Cejemly® has a well-tolerated safety profile, and no new safety signals were found.

Apart from the approved indication, the NMPA accepted the NDA of Cejemly® as consolidation therapy in patients with unresectable stage III NSCLC without disease progression after concurrent or sequential chemoradiotherapy in September 2021. The product has the potential to become an anti-PD-L1 monoclonal antibody approved to cover stage III and stage IV NSCLC in all-comer settings.

About Cejemly® (sugemalimab)

The potential best-in-class anti-PD-L1 monoclonal antibody Cejemly® (sugemalimab) 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 China NMPA has approved the potential best-in-class anti-PD-L1 monoclonal antibody Cejemly® in combination with chemotherapy for the treatment of treatment-naïve patients with stage IV NSCLC. In addition, Cejemly® 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 III NSCLC, stage IV NSCLC, gastric cancer, and esophageal cancer, respectively.

CStone formed a strategic collaboration agreement with Pfizer that includes the development and commercialization of Cejemly® in mainland China, and a framework to bring additional oncology assets 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 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 OS, BICR-assessed PFS and safety, etc.

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 Cejemly® combined with chemotherapy compared to placebo combined with chemotherapy, as assessed by 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 further improvement in PFS and the risk of disease progression or death was reduced by 52%, together with a trend of OS benefits. Data were presented in a Mini Oral Presentation (Late-Breaking Abstract) at the IASLC 2021 World Conference on Lung Cancer.

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 four drug approvals in Greater China, including three 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.

About Pfizer: Breakthroughs That Change Patients' Lives

At Pfizer, 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 health care 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 our responsibility as one of the world's premier innovative biopharmaceutical companies, Pfizer collaborates with health care 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 Pfizer.

For more information about Pifzer, please visit www.pfizer.com.cn.

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 CEJEMLY® (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. Frank Ningjun Jiang
Chairman

Suzhou, the People's Republic of China, December 21, 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. 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.