The forward-looking statements made in this announcement relate only to the events or information as of the date on which the statements are made in this announcement. Except as required by law, we undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise, after the date on which the statements are made or to reflect the occurrence of unanticipated events. You should read this announcement completely and with the understanding that our actual future results or performance may be materially different from what we expect. In this announcement, statements of, or references to, our intentions or those of any of our directors and/or our Company are made as of the date of this announcement. Any of these intentions may alter in light of future development.

CStone Pharmaceuticals

基石藥業

(Incorporated in the Cayman Islands with limited liability)

(**Stock Code: 2616**)

VOLUNTARY ANNOUNCEMENT

CHINA'S NMPA HAS ACCEPTED NDA FOR ANTI-PD-L1 MONOCLONAL ANTIBODY SUGEMALIMAB (CS1001) IN FIRST-LINE ADVANCED NSCLC

CStone Pharmaceuticals (the "**Company**" or "**CStone**") announced National Medical Products Administration ("**NMPA**") of China has accepted the new drug application ("**NDA**") for sugemalimab (CS1001), an anti-PD-L1 monoclonal antibody combined with chemotherapy for the first-line treatment of advanced squamous and non-squamous non-small cell lung cancer ("**NSCLC**") patients. This is the first NDA for sugemalimab submitted by CStone worldwide and also the sixth NDA worldwide and the third in mainland China submitted by CStone in 2020.

The acceptance of NDA was based on the results of CS1001-302, a Phase III trial of sugemalimab combined with chemotherapy for the first-line treatment of squamous and non-squamous NSCLC patients. This study enrolled both squamous and non-squamous NSCLC in the same study, which saved time and cost of development significantly. As reported in August 2020, in the planned interim analysis of this clinical trial, the pre-specified primary endpoint was reached as assessed by independent data monitoring committee. Compared with placebo in combination with chemotherapy, sugemalimab in combination with chemotherapy significantly improved progression-free survival ("**PFS**") and reduced the risk of disease progression or death by 50%. Subgroup analysis showed that sugemalimab has demonstrated its clinical benefits in squamous or non-squamous NSCLC patients with PD-L1 expression equals to or is more than 1% or PD-L1 expression is less than 1%. Sugemalimab in combination with chemotherapy showed a favorable safety profile and no new safety signals have been found. An oral presentation of specific clinical trial data will be given in Proffered Paper session of European Society for Medical Oncology Asia Congress on November 21st, 2020.

Professor Caicun Zhou, the principal investigator of CS1001-302 Study and Director of the Department of Oncology of Shanghai Pulmonary Hospital, said, “We are very excited to see that NMPA has accepted the NDA of sugemalimab. In Phase III clinical trial with the inclusion of squamous and non-squamous NSCLC patients, sugemalimab showed potent antitumor activity and a favorable safety profile. Advanced squamous and non-squamous NSCLC still faced a significant unmet medical need in China. We are looking forward to the launch of sugemalimab and its clinical benefits for patients.”

Dr. Frank Ningjun Jiang, chairman, executive director and chief executive officer of CStone, said, “The NDA acceptance of sugemalimab marks another important milestone for CStone, demonstrating our commitment to bring innovative oncology therapies to cancer patients worldwide. We expect sugemalimab can be launched as soon as possible and benefit more cancer patients in China and potentially abroad.”

Dr. Jason Yang, Chief Medical Officer of CStone, said, “With the unique mechanism of action and best-in-class clinical data in multiple tumors, sugemalimab has the potential to become the best-in-class PD-L1 monoclonal antibody. We appreciate the dedication of our CStone team and the strong support from clinical investigators and patients, which made it possible to accomplish this Phase III study from first patient enrollment to NDA acceptance in less than two years. Currently, registrational studies of sugemalimab for hematological malignancy, stage III NSCLC, advanced gastric cancer and esophageal cancer are progressing smoothly.”

About NSCLC

In recent years, the incidence of lung cancer has been continuously increasing in China. As reported, in 2018, there were approximately 770,000 new cases of lung cancer in China and 690,000 death cases caused by lung cancer. Lung cancer is the leading cause of cancer-related death in both men and women, and non-small cell lung cancer comprises the most common form of lung cancer in China.

CS1001-302 Study

CS1001-302 is a multicenter, randomized, double-blind Phase III clinical trial, designed to evaluate the efficacy and safety of CS1001 in combination with chemotherapy versus placebo in combination with chemotherapy in first-line naive patients with stage IV NSCLC. The primary endpoint of the trial was PFS as assessed by the investigators; the secondary endpoints include overall survival, PFS and the safety profile as assessed by blinded independent central review committee.

About Sugemalimab (CS1001)

Sugemalimab is an investigational anti-PD-L1 monoclonal antibody discovered by CStone. Authorized by Ligand Pharmaceuticals Inc. (NASDAQ: LGND), a company based in the U.S., 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 human antibody, which can reduce the risk of immunogenicity and potential toxicities in patients, a unique advantage over similar drugs.

Sugemalimab has completed a Phase I dose-escalation study in China. During Phase Ia and Ib stages of the study, sugemalimab showed good antitumor activity and good tolerability in multiple tumor types.

Currently, sugemalimab is being investigated in a number of ongoing clinical trials. In addition to a Phase I bridging study in the U.S., the clinical program in China includes one multi-arm Phase Ib study for several tumor types, one Phase II registrational study for lymphoma, and four Phase III registrational studies, respectively, for stage III/IV NSCLC, gastric cancer, and esophageal cancer. The Phase III clinical trial of sugemalimab in patients with stage IV NSCLC has reached its primary endpoint. China's NMPA has accepted the Company's NDA for sugemalimab.

Cautionary statement required by Rule 18A.05 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited: We cannot guarantee that we will be able to develop, or ultimately market sugemalimab successfully. Shareholders of the Company and potential investors are advised to exercise due care when dealing in the shares of the Company.

About CStone

CStone is a biopharmaceutical company focused on developing and commercializing innovative immuno-oncology and precision medicines to address the unmet medical needs of cancer patients in China and worldwide. Established at the end of 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 16 drug candidates with a strategic emphasis on immuno-oncology combination therapies. Currently, five late-stage candidates are at pivotal trials. With an experienced team, a rich pipeline, a robust clinical development-driven business model and substantial funding, CStone's vision is to become a world-renowned biopharmaceutical company that is leading the way to conquering cancer.

For more information about CStone, please visit: www.cstonepharma.com.

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

Suzhou, People's Republic of China, November 12, 2020

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. Guobin Zhang and Dr. Lian Yong Chen as non-executive Directors, and Dr. Paul Herbert Chew, Mr. Ting Yuk Anthony Wu and Mr. Hongbin Sun as independent non-executive Directors.