CStone Pharmaceuticals
基石藥業

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 2616)

INSIDE INFORMATION
BUSINESS UPDATES

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 that its anti-PD-L1 mAb CS1001 combined with platinum-based chemotherapy met its pre-specified primary endpoint, as assessed by the independent Data Monitoring Committee at the planned interim analysis of the CS1001-302, a randomized, double-blind phase III clinical trial for the first-line treatment of stage IV squamous and non-squamous non-small cell lung cancer ("**NSCLC**") patients.

Key Highlight

- In the overall population containing both squamous and non-squamous NSCLC patients, investigator-assessed progression-free survival ("**PFS**") HR (95% CI) was 0.50 (0.39, 0.64), p<0.0001. The median PFS was 7.8 months vs. 4.9 months in CS1001 combined with chemotherapy and placebo combined with chemotherapy, respectively;

- Subgroup analyses showed clinical benefit across histology subtypes and PD-L1 expression levels;

- Blinded independent central review ("**BICR**")-assessed PFS as a secondary endpoint was consistent with the investigator-assessed PFS. Other secondary endpoints also supported the primary endpoint result; and

- CS1001 in combination with chemotherapy was well tolerated, no new safety signal detected.

Professor Caicun Zhou, the principal investigator of the CS1001-302 study and director of the department of oncology of Shanghai Pulmonary Hospital, said, "We are gratified to see that the CS1001-302 study met its pre-specified primary endpoint at the interim analysis. CS1001 in combination with chemotherapy significantly improved PFS in patients with squamous and non-squamous NSCLC and was well tolerated.

This study is the first anti-PD-L1 mAb to demonstrate overwhelming efficacy as first-line treatment of stage IV NSCLC in a randomized, double-blind phase III trial."

Dr. Frank Ningjun Jiang, Chairman, executive Director and Chief Executive Officer of CStone, said, "Currently, there is no anti-PD-L1 monoclonal antibody approved for NSCLC in China. CS1001 is the first anti-PD-L1 monoclonal antibody combined with chemotherapy that demonstrates significant improvement in PFS in Chinese NSCLC patients. It has the potential of becoming the world's first anti-PD-L1 monoclonal antibody that can be combined with chemotherapy as the first-line treatment of both squamous and non-squamous NSCLC patients. This further strengthens our confidence in the development of CS1001 and greatly expediate CStone's commercialization progress."

Dr. Jason Yang, Chief Medical Officer of CStone, said: "Compared with other published results of anti-PD-1/PD-L1 monoclonal antibodies in combination with chemotherapy in first-line NSCLC trials, the CS1001-302 study, with an innovative design, is the first phase III clinical study in China for the first-line treatment of both squamous and non-squamous NSCLC subtypes. We will continue to make every effort to promote and more extensively evaluate the potential clinical benefit of this product in patients with hematological malignancies, stage III NSCLC, advanced gastric cancer, liver cancer and esophageal cancer."

CStone plans to submit a new drug application to the National Medical Products Administration of China in the near future for CS1001 in combination with platinum-containing chemotherapy for the first-line treatment of NSCLC. Specific study data will be presented at an upcoming academic conference.

About Non-Small Cell Lung Cancer

In contrast to most Western countries, where lung cancer death rates are decreasing, lung cancer incidence rates are still increasing in China. There were approximately 770,000 new cases of lung cancer in China in 2018, and it is the leading cause of cancer-related death in both men and women, with approximately 690,500 deaths in China in 2018. 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 platinum-containing chemotherapy versus placebo in combination with platinum-containing chemotherapy in first-line naïve 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 BICR.

About CS1001

CS1001 is an investigational anti-PD-L1 monoclonal antibody discovered by CStone. Authorized by a company based in the United States, Ligand Pharmaceuticals Inc. (NASDAQ: LGND), CS1001 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, CS1001 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.

CS1001 has completed a phase I dose-escalation study in China. During phase Ia and phase Ib of the study, CS1001 showed good antitumor activity and tolerability in multiple tumor types.

Currently, CS1001 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, two phase II registrational studies for lymphoma, and four phase III registrational studies, respectively, for stage III/IV NSCLC, gastric cancer, and esophageal cancer.

Cautionary Statement required by Rule 18A.05 of the Listing Rules: THE COMPANY MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET CS1001 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 15 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 globally recognized as a leading Chinese 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, People's Republic of China, August 6, 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.