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CStone Pharmaceuticals

基石藥業

(Incorporated in the Cayman Islands with limited liability)

(**Stock Code: 2616**)

VOLUNTARY ANNOUNCEMENT

CSTONE ANNOUNCES THE RESULTS OF GEMSTONE-302 SUGEMALIMAB HAS THE POTENTIAL TO PROVIDE A NEW TREATMENT OPTION FOR PATIENTS WITH ADVANCED NSCLC

CStone Pharmaceuticals (the "**Company**" or "**CStone**") is pleased to announce that positive clinical data based on a pre-planned interim analysis of GEMSTONE-302 study were disclosed in an oral presentation at European Society for Medical Oncology Asia Virtual Congress 2020. The results showed sugemalimab plus chemotherapy as first-line treatment for advanced non-small cell lung cancer ("**NSCLC**") demonstrated statistically significant and clinically meaningful. Benefit in progression-free survival ("**PFS**") combination with a well-tolerated safety profile compared to chemotherapy across PD-L1 expression levels and histologies.

GEMSTONE-302 is the first randomized, double-blind, Phase III study of anti-PD-L1 monoclonal antibody plus platinum-based chemotherapy as first-line treatment for stage IV squamous or NSCLC. The study aimed to evaluate the efficacy and safety of sugemalimab combined with chemotherapy versus placebo combined with chemotherapy in first-line treatment naïve patients with stage IV NSCLC. The primary endpoint of the study was investigator-assessed PFS. Secondary endpoints included overall survival, blinded independent central review ("**BICR**")-assessed PFS and safety.

As of June 8, 2020, a total of 479 patients were enrolled in the study. The data from the interim analysis showed that compared with placebo plus chemotherapy, sugemalimab plus chemotherapy significantly prolonged PFS and reached the primary endpoint of this study. In all the patients with squamous or non-squamous NSCLC,

- Investigator-assessed median PFS: 7.8 months vs 4.9 months, hazard ratio ("**HR**") is 0.50 (95% CI: 0.39, 0.64), $p<0.0001$

- BICR-assessed median PFS: 8.9 months vs 4.9 months, HR is 0.54 (95% CI: 0.41, 0.70), $p<0.0001$

- Clinical benefits of sugemalimab plus chemotherapy were demonstrated with median PFS of 7.16 vs 4.70 months (HR is 0.33) and 8.57 months vs 5.16 months (HR is 0.66) for patients with squamous and non-squamous NSCLC, respectively

- Sugemalimab plus chemotherapy showed clinical benefits across all PD-L1 subgroups. Investigator-assessed PFS was 8.9 months vs. 4.9 months (HR is 0.42) in patients with PD-L1 tumor proportion score ("**TPS**") ≥1% and 6.97 months vs. 4.93 months (HR is 0.66) in patients with PD-L1 TPS <1%

- Higher objective response rate ("**ORR**") (61.4% vs 39.2%, $p<0.0001$) and longer duration of response (9.69 months vs 3.68 months) were observed in sugemalimab-combination group

- Clinical benefits were observed in poor prognosis patients with brain or liver metastases, with the investigator-assessed median PFS of 10.1 months vs 4.5 months and 6.0 months vs 3.9 months, respectively

- The overall survival data were immature, but showed overall survival benefit in sugemalimab plus chemotherapy group (HR is 0.66, p is 0.0338)

- Sugemalimab combined with chemotherapy had a well-tolerated safety profile and no new safety signals were identified. The incidence of adverse events in sugemalimab-combination group was comparable to placebo-combination group. The most common any grade treatment-emergent adverse events ("**TEAE**") were anemia (73.8% vs 70.4%), neutrophil count decreased (56.3% vs. 59.1%) and white blood cell count decreased (55.3% vs 57.9%). The incidence of ≥grade 3 TEAE was 61.9% vs 61.6%, while the incidence of TEAE leading to death was 5.6% vs 5.7%. The frequency of immune-related adverse events ("**irAE**") was low, most of which were mild in severity (CTCAE grade ≤2). The irAE occurred in more than 5% of patients included hyperthyroidism and hypothyroidism

Professor Caicun Zhou, Principal Investigator of the GEMSTONE-302 study and Director of the Department of Oncology, Shanghai Pulmonary Hospital, said, "With an innovative design, GEMSTONE-302 study enrolled both squamous and non-squamous NSCLC to evaluate the efficacy and safety of sugemalimab combined with chemotherapy versus placebo combined with chemotherapy. The study reached the primary endpoint in a planned interim analysis and demonstrated clinical benefits in patients with squamous and non-squamous NSCLC. Lung cancer is one of the worldwide malignancies with the highest incidence and mortality. With the excellent efficacy and safety profiles observed in the current study, sugemalimab in combination with platinum-based chemotherapy provides a potential new option for the first line treatment of the patients with advanced NSCLC."

Dr. Jason Yang, Chief Medical Officer of CStone, said: "We are very excited with the results of GEMSTONE-302 study. Sugemalimab in combination with chemotherapy reduced the risk of disease progression or death by 50% and produced an ORR of 61.4%. The combination therapy was well-tolerated with no new safety signal detected. These data are amongst the best of those reported by other PD-(L)1 monoclonal antibodies.

China's National Medical Products Administration has accepted the New Drug Application for sugemalimab recently and we hope it will be approved as soon as possible to benefit cancer patients in China and abroad."

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 NSCLC comprises the most common form of lung cancer in China.

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 United States (**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 23, 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.