CStone Pharmaceuticals

基石藥業

(Incorporated in the Cayman Islands with limited liability)

(**Stock Code: 2616**)

VOLUNTARY ANNOUNCEMENT

CSTONE ANNOUNCES UPDATED RESULTS FROM TWO STUDIES OF ITS ANTI-PD-L1 MONOCLONAL ANTIBODY SUGEMALIMAB (CS1001) AT 2020 CSCO ANNUAL MEETING

CStone Pharmaceuticals (the "**Company**" or "**CStone**") announced the updated results from two studies of its anti-PD-L1 monoclonal antibody sugemalimab (CS1001) at the 2020 Chinese Society of Clinical Oncology ("**CSCO**") annual meeting. These two studies are 1) CS1001-201 clinical trial, which is designed to evaluate sugemalimab as monotherapy in patients with relapsed or refractory extranodal natural killer ("**NK**")/ T-cell lymphoma ("**R/R ENKTL**"), and 2) CS1001-101 study aiming to evaluate sugemalimab in combination with chemotherapy for the treatment of gastric cancer or gastro-oesophageal junction ("**GC/GEJ**"). As an investigational drug developed by CStone, sugemalimab has shown promising efficacy and safety results in a variety of solid tumors and lymphomas as demonstrated by the current study results and those reported previously including the recent positive topline results from a pivotal Phase III trial in patients with stage non-small cell lung cancer ("**NSCLC**").

CS1001-201 Study

CS1001-201 is a single-arm, multi-center, Phase II pivotal study designed to evaluate the efficacy and safety of sugemalimab as a monotherapy for the treatment of R/R ENKTL. The primary endpoint of this study is objective response rate ("**ORR**") as assessed by the Independent Radiology Review Committee ("**IRRC**"), and its secondary endpoints include investigator-assessed ORR, complete response ("**CR**") rate as assessed by IRRC and the investigator, median duration of response ("**mDoR**"), progression-free survival ("**PFS**") and

overall survival ("**OS**"). The study also evaluated the safety, pharmacokinetics ("**PK**") and immunogenicity of sugemalimab.

- As of July 1, 2020, a total of 43 patients were enrolled and received treatment. The demographic profile of patients at enrollment is similar to that of extranodal natural killer/T-cell lymphoma ("**ENKTL**") patients: 74.4% of them had an ECOG score of 1; 72.1% had stage IV disease, and about a half (51.2%) have received second-line or above treatment

- As a monotherapy, sugemalimab has demonstrated robust efficacy with a high CR rate and durable clinical benefits in terms of mDoR and OS, and a well-tolerated safety profile in R/R ENKTL patients

  - The ORR of 38 evaluable patients was 44.7% with a CR rate as high as 31.6%. The mDoR was 16.8 months. Among all the 12 patients who achieved CR, 11 are still in continuous remission

  - The mOS of the 43 patients who received study drug treatment was 19.7 months, and 1-year OS rate was 55.5%

  - The most commonly reported study drug-related adverse event in sugemalimab studies was fever; drug-related adverse events ("**AEs**") of grade 3 or above were observed in 6 patients (14.0%); 10 patients (23.3%) had immune-related AEs, most of which were grade 1; and 3 patients (7.0%) experienced severe adverse events ("**SAEs**") related to the study drug

CS1001-101 Study

CS1001-101 is a Phase I study to evaluate the safety, tolerability, PK and anti-tumor activity of sugemalimab in patients with advanced solid tumors or lymphomas. At the 2020 CSCO annual meeting, CStone presented the proof of concept ("**PoC**") data of Phase Ib cohort study designed to evaluate sugemalimab in combination with capecitabine and oxaliplatin ("**XELOX**") as first-line treatment for locally advanced or metastatic GC/GEJ. The primary endpoint of this study is the preliminary anti-tumor efficacy of this combination therapy.

Sugemalimab in combination with XELOX as a first-line treatment has shown robust anti-tumor activity, as well as a benigh safety and tolerability profile in patients with advanced GC/GEJ. Preliminary biomarker analysis showed that the therapeutic effect of this combination therapy was potentially associated with the PD-L1 expression level.

- As of February 19, 2020, among the 29 patients included in the efficacy analysis set, 18 patients have achieved partial response ("**PR**") and 6 patients have achieved stable disease ("**SD**"). The investigator-assessed ORR was 62.1%; the mDoR was 11.3 months; the mPFS was 8.3 months and the mOS was 17.0 months

- 26 patients in the efficacy analysis set have evaluable combined positive score ("**CPS**") results. The analysis showed that the ORR of the subgroup with CPS $\geq$ 5 (19 patients) was 58%, the mDoR had not yet been reached, and that the mPFS was 13.3 months. In the subgroup with CPS <5 (7 patients), the reported ORR was 71%, the mDoR was 5.0 months, and the mPFS was 6.2 months

Dr. Jason Yang, the chief medical officer of CStone, said, "We are very pleased to see that sugemalimab, whether as a monotherapy or in combination with chemotherapy, has demonstrated promising anti-tumor

activity and a benigh safety profile in R/R ENKTL and GC/GEJ patients. CS1001-201 is the world's first registrational clinical study designed to investigate the efficacy and safety of anti-PD-L1 monoclonal antibody in R/R ENKTL patients, and now we're extending it to the United States ("**U.S.**") The promising efficacy results achieved for sugemalimab in combination with XELOX for the treatment of GC/GEJ patients continues to support our ongoing Phase III study CS1001-303 (NCT03802591). We will continue to make every effort to advance the research and development of sugemalimab, so as to benefit cancer patients at the earliest possible date."

About Sugemalimab (CS1001)

Sugemalimab is an investigational anti-PD-L1 monoclonal antibody discovered by CStone. Authorized by a company based in the U.S., Ligand Pharmaceuticals Inc. (NASDAQ: LGND), 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 ("**IgG4**") 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. CStone plans to submit a new drug application to the China National Medical Products Administration of China soon.

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, September 24, 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.