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CStone Pharmaceuticals

基石藥業

(Incorporated in the Cayman Islands with limited liability)

(**Stock Code: 2616**)

VOLUNTARY ANNOUNCEMENT
CSTONE PRESENTS UPDATED DATA FROM REGISTRATIONAL CLINICAL STUDY OF SUGEMALIMAB IN PATIENTS WITH STAGE IV NSCLC IN AN ORAL PRESENTATION AT IASLC 2021 WCLC

Key Highlights:

- Data with the longer follow-up showed that sugemalimab plus chemotherapy continued to demonstrate improvement in progression-free survival ("**PFS**"), after the primary efficacy endpoint was met at an interim PFS analysis last year

- The updated data showed that the risk of disease progression or death was reduced by 52%, and an encouraging trend in overall survival ("**OS**") was observed. The two-year survival rate was 47.1%

- Clinical benefits continued to be observed across all the subgroups including different pathologic subtypes and PD-L1 expression levels

CStone Pharmaceuticals (the "**Company**" or "**CStone**") is pleased to announce that that the company presented the final PFS analysis and data results from GEMSTONE-302 study, a registrational clinical study of sugemalimab for the first-line treatment of patients with stage IV non-small cell lung cancer ("**NSCLC**"), in a late-breaking oral presentation at the IASLC 2021 World Conference on Lung Cancer ("**IASLC 2021 WCLC**") hosted by the International Association for the Study of Lung Cancer.

Summary of the Conference:

- Track: Immunotherapy

- Section: MA13 - Building on the Past: What Will Be the Next Immunotherapy Combination?

- Date: 08:10 (Beijing time), September 14, 2021
- Type: Mini Oral Presentation
- Title: GEMSTONE-302: A Phase 3 Study of Platinum-based Chemotherapy with Placebo or Sugemalimab, a PD-L1 mAb, for Metastatic NSCLC
- Presentation number: MA13.07
- Principal Investigator & Presenter: Professor Caicun Zhou, Director, Shanghai Pulmonary Hospital

GEMSTONE-302 is the first randomized, double-blind, Phase 3 study of an anti-PD-L1 monoclonal antibody plus chemotherapy as first-line treatment for stage IV squamous and non-squamous NSCLC. It is designed to evaluate the efficacy and safety of sugemalimab or placebo in combination with chemotherapy as first-line treatment in patients with stage IV NSCLC.

As of March 15, 2021, among the 479 patients enrolled, 79 (24.7%) versus 12 (7.5%) were still on treatment in the sugemalimab plus chemotherapy and placebo plus chemotherapy groups, respectively. In patients with both squamous and non-squamous NSCLC, the results of sugemalimab plus chemotherapy versus placebo plus chemotherapy were as follows:

- The investigator-assessed PFS was 9.0 months vs 4.9 months, HR=0.48
- The median OS was 22.8 months vs 17.7 months, HR=0.67, although the OS events (accounted for 55% of the pre-defined number of events at OS final analysis) have not yet met the pre-defined interim analysis plan
- The 12-month PFS rate was 36.4% vs 14.8%, and 24-month OS rate was 47.1% vs 38.1%
- The objective response rate ("**ORR**") was 63.4% vs 40.3%, and the duration of response ("**DoR**") was 9.8 months vs 4.4 months
- PFS benefits observed in different pathologic types:
    - Squamous: The median PFS was 8.3 months vs 4.8 months, HR=0.34
    - Non-squamous: The median PFS was 9.6 months vs 5.9 months, HR=0.59
- PFS benefits observed in all PD-L1 expression levels:
    - PD-L1<1%: The median PFS was 7.4 months vs 4.9 months, HR=0.55
    - PD-L1 1-49%: The median PFS was 8.8 months vs 4.8 months, HR=0.53
    - PD-L1≥50%: The median PFS was 12.9 months vs 5.1 months, HR=0.41
- Sugemalimab plus chemotherapy had a well-tolerated safety profile, and no new safety signals were observed.
    - The incidences of Grade≥3 treatment emergent adverse events ("**TEAEs**") were reported in 64.1% and 61.6% of patients in the two groups, respectively

- The incidences of Grade≥3 immune-related adverse events ("**irAEs**") were reported in 4.1% and 0% of patients in the two groups, respectively

Professor Caicun Zhou, Principal Investigator of GEMSTONE-302, and Director of the Department of Oncology, Shanghai Pulmonary Hospital, said, "Globally, the mortality of lung cancer ranks first among all malignant tumors. The final PFS analysis of GEMSTONE-302 showed that sugemalimab plus chemotherapy was associated with a significant improvement of PFS in patients with both squamous and non-squamous NSCLC, compared with placebo plus chemotherapy. An encouraging trend in OS was observed. With an estimated 2-year overall survival rate close to 50%. We look forward sugemalimab plus chemotherapy can provide longer survival for patients."

Dr. Jason Yang, Chief Medical Officer of CStone, said, "We are glad that sugemalimab plus chemotherapy continued to provide longer PFS for patients as follow-up extended. Clinical benefits were observed across all subgroups including different pathologic types (squamous and non-squamous) and PD-L1 expression levels, together with an OS benefit trend. Sugemalimab plus chemotherapy had a well-tolerated safety profile, with no significant rise of Grade≥3 TEAEs or irAEs compared with placebo plus chemotherapy. These data of sugemalimab in both locally advanced (stage III) and metastatic (stage IV) NSCLC are very encouraging and suggest sugemalimab is very efficacious in these treatment settings. We will continue to advance the registrational studies of sugemalimab in esophageal squamous cell carcinoma, gastric cancer, relapsed/refractory extranodal natural killer/T-cell lymphoma, so as to benefit more cancer patients."

In November 2020, the National Medical Products Administration ("**NMPA**") of China accepted the new drug application of sugemalimab plus chemotherapy for the first-line treatment of patients with advanced squamous and non-squamous NSCLC. In September 2021, the NMPA of China accepted the new drug application of sugemalimab in patients with unresectable stage III NSCLC without disease progression after concurrent or sequential chemoradiotherapy.

CStone is working closely with Pfizer to advance the commercialization of sugemalimab in Mainland China. Outside of Greater China, CStone is partnering with EQRx to pursue regulatory discussions for sugemalimab on a variety of indications with regulators in multiple countries and regions.

About Sugemalimab (anti-PD-L1 antibody)

Sugemalimab is an investigational anti-PD-L1 monoclonal antibody discovered by CStone. Authorized by the U.S.-based Ligand Corporation, 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 reduces the risk of immunogenicity and potential toxicities in patients, a unique advantage over similar drugs.

Currently, sugemalimab is being investigated in a number of ongoing clinical trials, including one Phase 2 registration study for lymphoma (CS1001-201) and four Phase 3 registrational studies in stage III NSCLC, stage IV NSCLC, gastric cancer, and esophageal cancer, respectively.

CS1001-201 is a single-arm, multicenter, Phase 2 pivotal study designed to evaluate the efficacy and safety of sugemalimab as monotherapy for the treatment of adult patients with relapsed or refractory extranodal natural killer/T-cell lymphoma ("**R/R ENKTL**"). Based on the encouraging preliminary efficacy results, sugemalimab was granted Orphan Drug Designation for the treatment of T-cell lymphoma and Breakthrough Therapy Designation for the treatment of R/R ENKTL by the U.S. Food and Drug Administration. It has also been granted Breakthrough Therapy Designation by the National Medical Products Administration of China. The proposed indication is R/R ENKTL.

CStone formed a strategic collaboration agreement with Pfizer that includes the development and

commercialization of sugemalimab in mainland China, and a framework to bring additional oncology assets to the Greater China market. CStone subsequently formed a strategic collaboration agreement with EQRx, under which EQRx licensed the exclusive rights to two key late-stage immuno-oncology assets, sugemalimab and CS1003 (anti-PD-1 antibody), for development and commercialization outside of Greater China.

About GEMSTONE-302 Study

GEMSTONE-302 (clinicaltrials.gov registration number: NCT03789604; drug clinical trial registration number: CTR20181452) is a randomized, double-blind Phase 3 study, designed to evaluate the efficacy and safety of anti-PD-L1 monoclonal antibody sugemalimab combined with chemotherapy as the first-line treatment in naïve patients with stage IV NSCLC it vs. placebo combined with chemotherapy. The primary endpoint of the study was investigator-assessed PFS. Secondary endpoints included overall survival, blinded independent central review ("**BICR**")-assessed PFS and safety.

In August 2020, GEMSTONE-302 study met its primary endpoint of significantly prolonging PFS and reducing the risk of disease progression or death by 50% with sugemalimab combined with chemotherapy compared to placebo combined with chemotherapy, as assessed by independent Data Monitoring Committee ("**iDMC**") at the planned interim analysis. Specific study data were presented in a Proffered Paper Oral Presentation (Late-Breaking Abstract) at the European Society for Medical Oncology ("**ESMO**") Asia 2020. In November 2020, the NMPA of China accepted the New Drug Application for sugemalimab combined with chemotherapy for the first-line treatment of advanced squamous and non-squamous NSCLC patients.

About GEMSTONE-301 Study

GEMSTONE-301 study (clinicaltrials.gov registration number: NCT03728556; drug clinical trial registration number: CTR20181429) is a multicenter, randomized, double-blind Phase 3 clinical trial, designed to evaluate the efficacy and safety of sugemalimab as consolidation therapy in patients with unresectable stage III NSCLC without disease progression after concurrent or sequential chemoradiotherapy. The trial's primary endpoint was PFS as assessed by BICR according to RECIST v1.1; the secondary endpoints included OS, PFS as assessed by investigators and safety profile.

In May 2021, GEMSTONE-301 study met its primary endpoint at a planned interim analysis reviewed by the iDMC. The findings showed that sugemalimab brought statistically significant and clinically meaningful improvement in the BICR-assessed PFS. Investigator-assessed PFS showed consistent results as those of the primary endpoint. Sugemalimab was well-tolerated with no new safety signals. Subgroup analyses demonstrated that sugemalimab was associated with clinical benefit regardless of whether patients received concurrent or sequential chemoradiotherapy prior to sugemalimab. Specific study data will be presented in a late-breaking oral presentation at the ESMO 2021.

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 Mainland 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 three drug approvals in Greater China, including two in Mainland China and one in Taiwan, China. 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.

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

Suzhou, the People's Republic of China, September 14, 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. Qun Zhao, 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.