**CStone Pharmaceuticals**

**基石藥業**

*(Incorporated in the Cayman Islands with limited liability)*

(**Stock Code: 2616**)

# VOLUNTARY ANNOUNCEMENT
# CSTONE PRESENTS UPDATED RESULTS OF A REGISTRATIONAL STUDY OF SUGEMALIMAB IN PATIENTS WITH STAGE III NSCLC VIA ORAL PRESENTATION AT WCLC 2022

CStone Pharmaceuticals (the "**Company**" or "**CStone**") is pleased to announce the presentation of the final progression-free survival ("**PFS**") analysis results from the registrational GEMSTONE-301 study of sugemalimab as a consolidation therapy in patients with unresectable stage III non-small cell lung cancer ("**NSCLC**") whose disease had not progressed after concurrent or sequential chemoradiotherapy at the IASLC 2022 World Conference on Lung Cancer ("**WCLC**"). The data showed sugemalimab maintained a statistically significant and clinically meaningful improvement in the PFS as assessed by blinded independent central review ("**BICR**"). Subgroup analysis demonstrated clinical benefits in patients who had received either concurrent or sequential chemoradiotherapy prior to sugemalimab.

**Key Highlights**

- GEMSTONE-301 study result was presented at IASLC 2022 WCLC. The leading Principal Investigator Professor Yi-Long Wu was invited to give a brief introduction in the press conference.

- In the final PFS analysis, sugemalimab showed sustained clinical benefits in patients with unresectable stage III NSCLC whose disease had not progressed following concurrent or sequential chemoradiotherapy compared with placebo.

- Sugemalimab has been approved in China for the treatment of patients with unresectable stage III NSCLC whose disease had not progressed following concurrent or sequential chemoradiotherapy.

The GEMSTONE-301 study is a multicenter, randomized, double-blind phase III clinical trial, designed to evaluate the efficacy and safety of sugemalimab as a consolidation therapy in patients with unresectable stage III NSCLC whose disease had not progressed after concurrent or sequential

chemoradiotherapy. In May 2021, the GEMSTONE-301 study met its primary endpoint at pre-planned interim analysis. The findings showed that sugemalimab demonstrated a statistically significant and clinically meaningful improvement in PFS as compared to placebo. Subgroup analyses demonstrated that sugemalimab was associated with clinical benefits regardless of whether patients received concurrent or sequential chemoradiotherapy prior to sugemalimab.

The results presented at the WCLC 2022 were based on the PFS final analysis data. As of March 1, 2022, key results of this study are the following:

- BICR-assessed median PFS: 10.5 months for sugemalimab vs 6.2 months for placebo (HR= 0.65, 95% CI 0.50-0.84)
    - For patients who received sequential chemoradiotherapy: the median PFS was 8.1 months vs 4.1 months, HR=0.57
    - For patients who received concurrent chemoradiotherapy: the median PFS was 15.7 months vs 8.3 months, HR=0.71
- Preliminary overall survival ("**OS**") data showed a trend for benefit favoring sugemalimab, median OS: not reached for sugemalimab vs 25.9 months for placebo (HR= 0.69, 95% CI 0.49-0.97)
    - For patients who received sequential chemoradiotherapy: the median OS was not reached vs 24.1 months, HR=0.60
    - For patients who received concurrent chemoradiotherapy: the median OS was not reached vs 32.4 months, HR=0.75
- Similar objective response rate ("**ORR**") was seen between sugemalimab and placebo but duration of overall response ("**DoR**") was longer with sugemalimab
    - ORR: 24.5% vs 25.2%
    - DoR: 24.1 months vs 6.9 months
- Sugemalimab had a well-tolerated safety profile; no new safety signals were observed in PFS final analysis

Professor Yi-Long Wu, a tenured director of Guangdong Provincial People's Hospital, and the Leading Principal Investigator on the GEMSTONE-301 study, said, "The final PFS results from GEMSTONE-301 showed that sugemalimab as a consolidation therapy demonstrated PFS and OS benefits in patients with unresectable stage III NSCLC following concurrent or sequential chemoradiotherapy. The overall benefit was consistent with that in the PACIFIC study. Sugemalimab could be safely and effectively used after concurrent or sequential chemoradiotherapy and become a standard of care in this setting for unresectable stage III NSCLC. Sugemalimab has been approved in China for the treatment of patients with stage III NSCLC and recommended by 2022 Chinese Society of Clinical Oncology (CSCO) Clinical Guidelines for Primary NSCLC as a preferred treatment option."

Dr. Jason Yang, Chief Medical Officer of CStone, said, "We are delighted that the updated results of GEMSTONE-301 are presented at WCLC 2022 and highlighted in the press conference session. In the final PFS analysis, sugemalimab demonstrated clinical benefits in patients receiving either concurrent or sequential chemoradiotherapy, while preliminary OS benefits were also observed. The

interim PFS data has been published in the journal of The Lancet Oncology. We are working with our partner to engage regulatory agencies worldwide and to bring sugemalimab to more cancer patients with its robust efficacy and safety profile."

**About the GEMSTONE-301 study**

The GEMSTONE-301 study (clinicaltrials.gov registration number: NCT03728556; drug clinical trial registration number: CTR20181429) is a multicenter, randomized, double-blind phase III clinical trial, designed to evaluate the efficacy and safety of sugemalimab as consolidation therapy in patients with unresectable stage III NSCLC whose disease had not progressed following 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.

In May 2021, the GEMSTONE-301 study met its primary endpoint at a pre-planned interim analysis reviewed by the Independent Data Monitoring Committee (iDMC). The findings showed that sugemalimab demonstrated 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. The data were reported in the late-breaking abstract (LBA) presentation at the 2021 ESMO Annual Meeting and published in The Lancet Oncology in January 2022.

**About Sugemalimab**

The anti-PD-L1 monoclonal antibody sugemalimab was developed by CStone using OmniRat® transgenic animal platform, which allows creation of fully human antibodies in one step. Sugemalimab is a fully human, full-length anti-PD-L1 immunoglobulin G4 (IgG4) monoclonal antibody, which may allow a reduced risk of immunogenicity and toxicity for patients, a unique advantage over similar drugs.

Currently, the National Medical Products Administration of China has approved sugemalimab (Cejemly®):

- In combination with pemetrexed and carboplatin as first-line treatment of patients with metastatic non-squamous NSCLC, lacking EGFR and ALK genomic tumor aberrations; and in combination with paclitaxel and carboplatin as first-line treatment of patients with metastatic squamous NSCLC

- For the treatment of patients with unresectable stage III NSCLC whose disease had not progressed following concurrent or sequential platinum-based chemoradiotherapy

With its proven therapeutic advantages, sugemalimab is recommended by the 2022 Chinese Society of Clinical Oncology (CSCO) clinical guidelines for the diagnosis and treatment of NSCLC, in combination with chemotherapy as the first-line treatment of patients with stage IV non-squamous/squamous NSCLC without driver alterations; or as a consolidation therapy in patients with stage III NSCLC following concurrent or sequential platinum-based chemoradiotherapy.

CStone formed a strategic collaboration agreement with EQRx, under which EQRx were licensed the exclusive rights to sugemalimab for development and commercialization outside of Greater China.

**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 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 nine NDA approvals for four drugs. Multiple late-stage drug candidates are now under pivotal clinical trials or registration. 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. Wei Li**
*Chairman*

Suzhou, the People's Republic of China, August 8, 2022

*As at the date of this announcement, the board of directors of the Company comprises Dr. Wei Li as Chairman and non-executive director, Dr. Frank Ningjun Jiang as executive director, Mr. Kenneth Walton Hitchner III, 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.*