CStone Pharmaceuticals

基石藥業

(Incorporated in the Cayman Islands with limited liability)

(**Stock Code: 2616**)

VOLUNTARY ANNOUNCEMENT
CSTONE ANNOUNCED CHINA'S NMPA HAS ACCEPTED AND GRANTED PRIORITY REVIEW TO THE SUPPLEMENTAL NEW DRUG APPLICATION (SNDA) FOR SUGEMALIMAB IN THE TREATMENT OF PATIENTS WITH RELAPSED OR REFRACTORY EXTRANODAL NATURAL KILLER/T-CELL LYMPHOMA (R/R ENKTL)

CStone Pharmaceuticals (the "**Company**" or "**CStone**") is pleased to announce that the National Medical Products Administration ("**NMPA**") of China has accepted and granted priority review to the supplemental new drug application (sNDA) for sugemalimab in the treatment of patients with relapsed or refractory extranodal natural killer/T-cell lymphoma ("**R/R ENKTL**").

Key Highlights

- This is the third supplemental new drug application (sNDA) that CStone has submitted for sugemalimab after the prior two for stage III and IV non-small cell lung cancer. Sugemalimab has the potential to become the world's first immuno-oncology therapy to be approved for patients with R/R ENKTL.

- GEMSTONE-201 is the largest registrational clinical study of an anti-PD-(L)1 antibody reported so far in patients with R/R ENKTL. In January 2022, CStone announced that it met the primary endpoint of objective response rate ("**ORR**") as assessed by the Independent Radiology Review Committee ("**IRRC**").

- The U.S. Food and Drug Administration ("**FDA**") and the NMPA of China have both granted the Breakthrough Therapy Designation (BTD) to sugemalimab for the treatment of adult patients with R/R ENKTL.

Professor Huiqiang Huang of Sun Yat-sen University Cancer Center, the Principal Investigator of the GEMSTONE-201 study, said, "For a long time, there was limited option of effective therapeutic

drug in the clinic for R/R ENKTL, leading to a low cure rate and poor patient survival. The US National Comprehensive Cancer Network and the Chinese Society of Clinical Oncology guidelines for lymphomas recommend patients to participate in clinical trials in this setting. The success of the GEMSTONE-201 study demonstrated that sugemalimab had robust efficacy in patients with R/R ENKTL as a potential new treatment option to fulfil the extremely urgent medical needs. We very much look forward to seeing the approval of this sNDA."

Dr. Jason Yang, CEO and executive director of CStone, said, "We are very glad that the supplementary new drug application for sugemalimab in treatment of R/R ENKTL has been accepted by the NMPA of China. Sugemalimab had demonstrated notable anti-tumor activity, durable objective response and well-tolerated safety in patients with R/R ENKTL. Until now, no anti-PD-(L)1 monoclonal antibody has been approved for R/R ENKTL. We will continue to work closely with the NMPA and feel very excited to see that more patients would benefit from sugemalimab."

The acceptance of this sNDA of sugemalimab treating R/R ENKTL is based on the GEMSTONE-201 study, designed to evaluate the efficacy and safety of sugemalimab as monotherapy for the treatment of R/R ENKTL in adults. In January 2022, the GEMSTONE-201 study met the predefined primary endpoint as assessed by the IRRC. The results showed that sugemalimab significantly improved ORR compared to historical controls. In 78 evaluable patients, ORR assessed by IRRC was 46.2% with a complete response ("**CR**") rate of 37.2%. The investigator-assessed ORR was highly consistent with IRRC's evaluation. Meanwhile, subgroup analyses indicated that sugemalimab is likely to be efficacious across a broad range of patients with ENKTL, including those who were heavily pretreated, regardless of objective response to prior therapies. Sugemalimab also demonstrated a well-tolerated safety profile in patients with R/R ENKTL, and no new safety signals were observed. The primary results from GEMSTONE-201 were presented as an oral presentation at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting in June.

About ENKTL

ENKTL is a subtype of mature T cell and NK cell lymphoma. In 2012, a multicenter pathological classification survey of 10,002 lymphoma patients from China showed that ENKTL accounted for approximately 6% of all lymphomas and 28% of mature T-cell and NK-cell lymphomas. There is no existing approved effective salvage treatment for patients with R/R ENKTL whose disease has progressed on an L-asparaginase-based standard regimen. Patients also typically respond poorly to conventional treatments. Clinicians often have limited treatment options for such patients due to rapid disease progression and poor survival outcomes with a one-year survival rate of less than 20%. In China, the currently available targeted monotherapy for these patients has a CR rate of approximately 6%. Thus, there are significant unmet medical needs in patient who did not respond to first-line treatment. There were also researches showing broadly similarity in clinical presentation and treatment outcomes in the Western and Asian populations for ENKTL, although ENKTL is more prevalent in East Asia and Latin America.

About Sugemalimab

The anti-PD-L1 monoclonal antibody sugemalimab was discovered 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 the risk of immunogenicity and toxicity for patients, a unique advantage over similar drugs.

Currently, the NMPA of China has approved sugemalimab (Cejemly®)

- In combination with pemetrexed and carboplatin as first-line treatment of patients with

metastatic non-squamous non-small cell lung cancer ("**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 non-small cell lung cancer whose disease has not progressed following platinum-based concurrent or sequential 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.

In addition, in January 2022, two key phase III registrational clinical trials completed patient enrollment, one for the first-line treatment of metastatic gastric adenocarcinoma (GC) / gastro-esophageal junction (GEJ) adenocarcinoma, and the other for the first-line treatment of metastatic esophageal squamous cell carcinoma (ESCC).

About the GEMSTONE-201 study

GEMSTONE-201 study is a single-arm, multicenter, Phase II pivotal study designed to evaluate the efficacy and safety of sugemalimab as monotherapy for the treatment of adult patients with R/R ENKTL. Based on the encouraging preliminary efficacy results, sugemalimab was granted Orphan Drug Designation for the treatment of T-cell lymphoma and BTD for the treatment of R/R ENKTL by the U.S. FDA in October 2020. It has also been granted BTD by the NMPA of China. The study includes investigational sites in both China and the U.S.

About CStone

CStone is a biopharmaceutical company focused on research, development, and commercialization of 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 its 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.

Cautionary Statement required by Rule 18A.05 of the Listing Rules: THE COMPANY CANNOT GUARANTEE THAT WE MAY BE ABLE TO ULTIMATELY DEVELOP AND MARKET SUGEMALIMAB SUCCESSFULLY. Shareholders of the Company and potential investors are advised to exercise due care when dealing in the shares of the Company

By Order of the Board
CStone Pharmaceuticals
Dr. Wei Li
Chairman

Suzhou, the People's Republic of China, September 13, 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. Jianxin Yang 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.