CStone Pharmaceuticals

基石藥業

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VOLUNTARY ANNOUNCEMENT
CSTONE ANNOUNCES PUBLICATION OF GEMSTONE-201 STUDY RESULTS FOR SUGEMALIMAB MONOTHERAPY IN THE TREATMENT OF RELAPSED/REFRACTORY EXTRANODAL NK/T-CELL LYMPHOMA IN JOURNAL OF CLINICAL ONCOLOGY

CStone Pharmaceuticals (the "**Company**" or "**CStone**") is pleased to announce that the Journal of Clinical Oncology (JCO), an internationally renowned, core oncology journal, has published the results of the registrational clinical study (GEMSTONE-201) of sugemalimab for the treatment of relapsed or refractory extranodal NK/T-cell lymphoma (R/R ENKTL). This study has once again been recognized on a top-tier international academic platform, following its oral presentation at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting, demonstrating its scientific and clinical significance. The GEMSTONE-201 study is a single-arm, multicenter, phase 2 pivotal trial led by principal investigator, Professor Huaiqiang Huang from Sun Yat-Sen University Cancer Center. GEMSTONE-201 has demonstrated that sugemalimab has notable anti-tumor activity, durable tumor response, and is well-tolerated in patients with R/R ENKTL. GEMSTONE-201 study is also the largest registrational clinical trial of an anti-PD-(L)1 antibody reported so far for patients with R/R ENKTL.

Key Highlights

- The GEMSTONE-201 study is the largest registrational clinical trial of an anti-PD-(L)1 antibody reported so far in patients with relapsed or refractory extranodal NK/T-cell lymphoma (R/R ENKTL).
- In the GEMSTONE-201 study, sugemalimab has demonstrated notable anti-tumor activity, durable objective response, and is well-tolerated in patients with R/R ENKTL.
- Sugemalimab has been granted Breakthrough Therapy Designation (BTD) by both the U.S. Food and Drug Administration (FDA) and the National Medical Products Administration (NMPA) of China for the treatment of adult patients with R/R ENKTL.
- The supplementary new drug application (sNDA) of sugemalimab for R/R ENKTL has been accepted

by the NMPA of China, granted with priority review and is currently under review.

GEMSTONE-201 study was designed to evaluate the efficacy and safety of sugemalimab in the treatment of adult patients with R/R ENKTL. As of February 23, 2022, a total of 80 patients were enrolled in the study and received sugemalimab monotherapy. As of the data cut-off date, the median follow-up duration was 18.7 months, with 22 patients remaining on sugemalimab treatment in the study. The key results from the study are as follows:

- The primary analysis demonstrated that sugemalimab significantly improved objective response rate (ORR) compared to historical controls; the ORR assessed by Independent Radiology Review Committee (IRRC) was 44.9%, with a complete response (CR) rate of 35.9%.

- Based on the IRRC evaluation, durable efficacy was observed in patients who achieved objective responses; the median duration of response (DoR) has not been reached; DoR rates at 6, 12, and 18 months were 91.3%, 82.5%, and 82.5%, respectively.

- The investigator-assessed efficacy was highly consistent with that of IRRC. The concordance rate between the ORR assessed by the investigators and that of IRRC was 95.7%.

- The overall survival (OS) data suggested a potential survival benefit with sugemalimab monotherapy in patients with R/R ENKTL; OS rates at 6, 12, and 18 months were 79.2%, 67.5%, and 57.9%, respectively.

- Sugemalimab was well-tolerated in patients with R/R ENKTL, and no new safety signals were observed.

Professor Huang Huiqiang from Sun Yat-sen University Cancer Center, the corresponding author of this paper and the leading principal investigator of GEMSTONE-201 study, said, “Patients with R/R ENKTL have urgent and unmet medical needs due to low cure rates and short survival periods. The publication of the GEMSTONE-201 study in the JCO further confirms the remarkable efficacy and safety of sugemalimab in treating R/R ENKTL patients. We look forward to sugemalimab’s approval for R/R ENKTL indication and available for clinical use in the near future, providing new treatment options for the R/R ENKTL population.”

Dr. Jason Yang, Chief Executive Officer and executive director of CStone, said, “The publication of GEMSTONE-201 results in JCO represents the exceptional clinical significance of sugemalimab. With over 40 results publications and presentations for multiple research in international academic conferences and journals, including ASCO, ESMO, WCLC, and The Lancet Oncology, we have demonstrated our R&D capabilities and academic contributions to the industry. No anti-PD-1/L1 antibodies have been approved so far for R/R ENKTL worldwide. Sugemalimab’s sNDA for this indication is under review, and we will work closely with the NMPA of China to make it accessible to more patients.”

About ENKTL

Extranodal natural killer/T-cell lymphoma (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 a 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 complete response (CR) rate of approximately 6% . Thus, there are significant unmet medical needs in patients who do not respond to

first-line treatment. In addition, research , shows broad similarity in the 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 GEMSTONE-201 study

The GEMSTONE-201 study 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 R/R ENKTL. Based on the encouraging preliminary efficacy results, sugemalimab has been granted Orphan Drug Designation and BTD by the U.S. FDA for the treatment of T-cell lymphoma and adults with R/R ENKTL respectively. It has also been granted BTD by the NMPA of China. In January 2022, the GEMSTONE-201 study, as assessed by the Independent Radiology Review Committee, met its pre-specified primary endpoint. In June 2022, the full results of the GEMSTONE-201 study were reported in an oral presentation at the American Society of Clinical Oncology (ASCO) Annual Meeting.

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 reduce the risk of immunogenicity and toxicity for patients, a unique advantage over similar drugs.

Currently, the NMPA of China has approved sugemalimab (Cejemly®) for non-small cell lung cancer (NSCLC):

Combination Therapy

- In combination with pemetrexed and carboplatin as first-line treatment of patients with metastatic non-squamous non-small cell lung cancer (NSCLC), with no known EGFR and ALK genomic tumor aberrations.

- In combination with paclitaxel and carboplatin as first-line treatment of patients with metastatic squamous non-small cell lung cancer (NSCLC).

Monotherapy

- For the treatment of patients with unresectable stage III non-small cell lung cancer (NSCLC) 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 consolidation therapy in patients with stage III NSCLC following concurrent or sequential platinum-based chemoradiotherapy.

In September 2022, the NMPA of China accepted and granted priority review to the supplemental new drug application (sNDA) for sugemalimab in the treatment of patients with R/R ENKTL.

In January 2023, the GEMSTONE-304 study, in which sugemalimab in combination with chemotherapy is used as first-line treatment of unresectable locally advanced, recurrent, or metastatic esophageal squamous cell carcinoma (ESCC), met its primary endpoints.

In February 2023, the NMPA of China accepted the sNDA of sugemalimab as first-line treatment for

patients with locally advanced or metastatic gastric/gastroesophageal junction adenocarcinoma.

The Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom and the European Medicines Agency (EMA) accepted the marketing authorization application (MAA), submitted by CStone's ex-China partner EQRx, for sugemalimab in combination with chemotherapy as first-line treatment of patients with metastatic non-small cell lung cancer.

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 ten 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 CEJEMLY® (SUGEMALIMAB) SUCCESSFULLY. Shareholders of the Company and potential investors are advised to exercise due care when dealing in the shares of the Company.

Forward Looking Statement

There is no assurance that any forward-looking statements regarding the business development of the Group in this announcement or any of the matters set out herein are attainable, will actually occur or will be realised or are complete or accurate. The financial and other data relating to the Group as disclosed in this announcement has also not been audited or reviewed by its auditors. Shareholders and/or potential investors of the Company are advised to exercise caution when dealing in the securities of the Company and not to place any excessive reliance on the information disclosed herein. Any shareholder or potential investor who is in doubt is advised to seek advice from professional advisors.

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

Suzhou, the People's Republic of China, March 31, 2023

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. 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.