CStone Pharmaceuticals
基石藥業
(Incorporated in the Cayman Islands with limited liability)
(Stock Code: 2616)

VOLUNTARY ANNOUNCEMENT
CSTONE ANNOUNCES NMPA APPROVAL OF SUGEMALIMAB FOR PATIENTS WITH RELAPSED OR REFRACTORY EXTRANODAL NK/T-CELL LYMPHOMA, THE FIRST ANTI-PD-1/PD-L1 MAB APPROVED FOR THIS INDICATION

CStone Pharmaceuticals (the "**Company**" or "**CStone**") is pleased to announce that the National Medical Products Administration (NMPA) of China has approved the anti-PD-L1 antibody sugemalimab (Cejemly®) for the treatment of relapsed or refractory extranodal NK/T-cell lymphoma (R/R ENKTL). Sugemalimab becomes the world's first anti-PD-1/PD-L1 monoclonal antibody approved specifically for R/R ENKTL.

Key Highlights

- Sugemalimab is the world's first anti-PD-1/PD-L1 monoclonal antibody approved for relapsed or refractory extranodal NK/T-cell lymphoma (R/R ENKTL) indication.
- This marks sugemalimab's third indication approved in China following stage III and IV non-small cell lung cancer (NSCLC) and the 12th NDA approval obtained by CStone.
- The GEMSTONE-201 study has demonstrated notable anti-tumor activity, durable objective response, and manageable safety of sugemalimab 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 NMPA of China for the treatment of adult patients with R/R ENKTL.

Dr. Jason Yang, Chief Executive Officer and executive director of CStone, said, "We are excited to obtain approval of sugemalimab for R/R ENKTL from the NMPA of China. This marks another milestone for sugemalimab following the prior approvals for stage III and IV NSCLC and years of intensive effort and innovation by CStone's research and development team on this rare disease area. We have always believed

that the unmet medical needs of patients with cancer should not be overlooked just because of a small population. In addition to lung cancer, sugemalimab also covers other indications in the first-line setting, such as gastric cancer, and esophageal cancer, and the biologics license applications are currently under review by NMPA. We are also maintaining close and smooth communications with the FDA to accelerate the registration of sugemalimab in the U.S."

Professor Huang Huiqiang from Sun Yat-sen University Cancer Center, the leading principal investigator of GEMSTONE-201 study, said, "We very much appreciate the attention from the NMPA of China to the rare disease like NK/T-cell lymphoma. Patients with R/R ENKTL have had no standard of care and very limited treatment options over the years, leading to very short survival durations, and therefore, significantly unmet medical needs. In the GEMSTONE-201 study, sugemalimab monotherapy has demonstrated notable anti-tumor activity, durable objective response, and manageable safety in patients with R/R ENKTL. Following this approval, we look forward to seeing more patients with R/R ENKTL having access to sugemalimab in the near future."

The approval of sugemalimab for R/R ENKTL is supported by the GEMSTONE-201 study, which was designed to evaluate the efficacy and safety of sugemalimab as monotherapy for the treatment of adult patients with R/R ENKTL. The results showed that sugemalimab significantly improved the objective response rate (ORR) compared to historical controls. In 78 evaluable patients, ORR assessed by Independent Radiology Review Committee (IRRC) was 44.9% with a complete response (CR) rate of 35.9%. The investigator-assessed ORR was highly consistent with IRRC's evaluation. Subgroup analyses also indicated that sugemalimab is likely to be efficacious across a broad range of patients with R/R 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. These primary results from GEMSTONE-201 were presented as an oral presentation at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting and published by the internationally renowned oncology journal, the *Journal of Clinical Oncology* (JCO), in March 2023.

About Sugemalimab

The anti-PD-L1 monoclonal antibody sugemalimab was discovered by CStone using the 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.

The NMPA of China has approved three indications for sugemalimab for the treatment of patients with unresectable stage III NSCLC whose disease has not progressed following concurrent or sequential platinum-based chemoradiotherapy, and in combination with chemotherapy for the first-line treatment of patients with metastatic squamous and non-squamous NSCLC, and for the treatment of patients with R/R ENKTL.

The supplemental biologics license applications for sugemalimab in combination with chemotherapy for first-line treatment of locally advanced or metastatic gastric or gastroesophageal junction (G/GEJ) adenocarcinoma, and in combination with chemotherapy for first-line treatment of unresectable locally advanced, recurrent, or metastatic esophageal squamous cell carcinoma have been accepted by the NMPA of China and are currently under review.

In addition, the European Medicines Agency (EMA) and the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom have both accepted the marketing authorization applications (MAAs) for sugemalimab in combination with chemotherapy as a first-line treatment for metastatic NSCLC, and the two applications are currently under review.

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

commercialization of sugemalimab in mainland China, and a framework to bring additional oncology medicines to the Greater China market.

About GEMSTONE-201 Study

The 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 has been granted Orphan Drug Designation and BTD by the 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. In March 2023, the prestigious international oncology journal, the Journal of Clinical Oncology (JCO), published the results of the registrational trial for sugemalimab in the treatment of R/R ENKTL (GEMSTONE-201).

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[1]. 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%[2]. In China, the currently available targeted monotherapy for these patients has a complete response (CR) rate of approximately 6%[3]. Thus, there are significant unmet medical needs in patients who do not respond to first-line treatment. In addition, research [4,5] 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 CStone

CStone (HKEX: 2616) 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 management team with extensive experience in innovative drug development, clinical research, and commercialization. The company has built an oncology-focused pipeline of 14 drug candidates with a strategic emphasis on immuno-oncology combination therapies. Currently, CStone has received 12 NDA approvals for its four drugs. Multiple late-stage drug candidates are now under pivotal clinical trials or registration. CStone's vision is to bring 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

[1] 李小秋等. "中国淋巴瘤亚型分布:国内多中心性病例 10002 例分析." 诊断学理论与实践 11.2(2012):5.
[2] Bellei M, et al. Haematologica 2018; 103(7): 1191-7.
[3] Shi Y, et al. Ann Oncol 2015; 26(8): 1766-71.
[4] Haverkos BM, et al. Curr Hematol Malig Rep 2016;11:514-27.
[5] Qi S, et al. Leuk Lymphoma 2016;57:2575-83.

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.

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 realized 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, October 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.