CStone Pharmaceuticals

基石藥業

(Incorporated in the Cayman Islands with limited liability)

(**Stock Code: 2616**)

VOLUNTARY ANNOUNCEMENT
CSTONE ANNOUNCED PHASE II GEMSTONE-201 TRIAL OF CEJEMLY® (SUGEMALIMAB) MET PRIMARY ENDPOINT OF OBJECTIVE RESPONSE RATE (ORR) IN 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 registrational clinical study (GEMSTONE-201) of Cejemly® in patients with relapsed or refractory extranodal natural killer/T-cell lymphoma ("**R/R ENKTL**") met the primary endpoint. Results showed that Cejemly® significantly enhanced the objective response rate ("**ORR**"), as assessed by the Independent Radiology Review Committee ("**IRRC**"), compared with historical control. The investigator-assessed ORR was consistent with the evaluation by IRRC. Cejemly® also demonstrated a well-tolerated safety profile in patients with R/R ENKTL, and no new safety signals were observed. CStone plans to submit a new drug application ("**NDA**") in the near term to the National Medical Products Administration ("**NMPA**") of China for sugemalimab as the treatment of R/R ENKTL and will present the topline results at an upcoming international academic conference.

Key Highlights

- Cejemly® has the potential to become the world's first immunotherapy to be approved for patients with R/R ENKTL.
- The NMPA of China has granted the Breakthrough Therapy Designation (BTD) to Cejemly® for the treatment of adult patients with R/R ENKTL.
- GEMSTONE-201 is the first successful registrational clinical study to date evaluating an anti-PD-L1 antibody targeting patients with R/R ENKTL.
- The topline data has demonstrated notable anti-tumor activity, durable objective response, and well-tolerated safety profile of Cejemly® in patients with R/R ENKTL.

Professor Huiqiang Huang of Sun Yat-sen University Cancer Center, the Principal Investigator of the GEMSTONE-201 study, said, "R/R ENKTL is highly malignant and aggressive. For a long time, there was no effective therapeutic drug in clinic, leading to a low cure rate and poor prognosis. The success of the GEMSTONE-201 study demonstrated that Cejemly® may become a new treatment option for patients with R/R ENKTL to fulfill the extremely urgent medical needs of this patient population."

Dr. Jason Yang, Chief Medical Officer of CStone, said, "We are very glad that the registrational study of Cejemly® in treatment of R/R ENKTL met the primary endpoint. This is the third success in pivotal clinical studies of sugemalimab after the prior two Phase III trials in stage III and stage IV non-small cell lung cancer ("**NSCLC**") also met the primary endpoint. Until now, no anti-PD-(L)1 monoclonal antibody has been approved for R/R ENKTL, so we very much look forward to seeing that more patients would benefit from Cejemly®."

The NMPA of China has approved the NDA of Cejemly® in combination with chemotherapy for treatment-naïve metastatic (stage IV) NSCLC patients. In addition, another NDA of sugemalimab in stage III NSCLC is under regulatory review. Cejemly® is expected to provide a new treatment option for both stage III and stage IV NSCLC patents in the future. Cejemly® has also demonstrated the tremendous potential with its unique mechanism of action and attractive clinical data in the treatment of lung cancer, lymphoma and other tumors.

About extranodal natural killer/T-cell lymphoma ("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 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 complete response (CR) rate of approximately 6%. Thus, there are significant unmet medical needs in patient who did not respond to first-line treatment.

About Cejemly® (sugemalimab)

The potential best-in-class anti-PD-L1 monoclonal antibody Cejemly® (sugemalimab) is an investigational anti-PD-L1 monoclonal antibody discovered by CStone. Authorized by the U.S.-based Ligand Corporation, Cejemly® 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, the NMPA of China has approved Cejemly® in combination with pemetrexed and carboplatin as first-line treatment of patients with metastatic non-squamous NSCLC, with no EGFR or ALK genomic tumor aberrations; and in combination with paclitaxel and carboplatin as first-line treatment of patients with metastatic squamous NSCLC. In addition, Cejemly® is being investigated in a number of ongoing clinical trials, including one Phase II registrational study for lymphoma and four Phase III registrational studies in stage III NSCLC, stage IV NSCLC, gastric cancer, and esophageal cancer, respectively.

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 Cejemly® as monotherapy for the treatment of adult patients with R/R ENKTL. Based on the encouraging preliminary efficacy results, Cejemly® 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 leading 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 five drug approvals in Greater China, including three in Mainland China, one in Hong Kong, 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, January 13, 2022

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. 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.