CStone Pharmaceuticals

基石藥業

(Incorporated in the Cayman Islands with limited liability)

(**Stock Code: 2616**)

VOLUNTARY ANNOUNCEMENT

CSTONE ANNOUNCES ANOTHER BREAKTHROUGH THERAPY DESIGNATION GRANTED FOR SUGEMALIMAB REPRESENTING A NEW BREAKTHROUGH IN THE TREATMENT OF RELAPSED AND REFRACTORY LYMPHOMA

CStone Pharmaceuticals (the "**Company**" or "**CStone**") is pleased to announce today that that anti-PD-L1 antibody sugemalimab has been granted Breakthrough Therapy Designation ("**BTD**") by the China National Medical Products Administration ("**NMPA**") Center for Drug Evaluation for the treatment of patients with relapsed or refractory extranodal natural killer/T-cell lymphoma ("**R/R ENKTL**"). In addition to this major milestone, sugemalimab was granted Orphan Drug Designation for the treatment of T-cell lymphoma and BTD for the treatment of R/R ENKTL by the United States ("**U.S.**") Food and Drug Administration ("**FDA**") in October 2020.

The NMPA's BTD is designed to facilitate the development and expedite the review of novel medicines to treat serious conditions and fill an unmet medical need, specifically for novel or "me-better" candidates at the clinical stage, which has demonstrated significant clinical advantages over the available treatment options. The BTD approval from the NMPA is expected to substantially accelerate the development and commercialization of sugemalimab in China.

The BTD is supported by the promising CS1001-201 Phase II results in patients with R/R ENKTL, which were presented at the annual meeting of the Chinese Society of Clinical Oncology in 2020. Among 38 evaluable patients, the objective response rate ("**ORR**") was 44.7%, the complete response ("**CR**") rate was 31.6%, and the median duration of response was 16.8 months. Of all 43 patients who received sugemalimab, the median

overall survival was 19.7 months, and the one-year OS rate was 55.5%. Additionally, sugemalimab demonstrated favorable safety and tolerability.

Professor Huiqiang Huang of Sun Yat-sen University Cancer Center, the principal investigator of CS1001-201 study said, "R/R ENKTL is a highly malignant and aggressive disease, in addition to the lack of efficacious treatment options, which often leads to poor prognosis, low cure rate, and severe unmet medical needs of patients. The preliminary results have indicated that sugemalimab could potentially become a new treatment option for patients with R/R ENKTL."

Dr. Jason Yang, Chief Medical Officer of CStone, commented, "We are excited that sugemalimab has been granted BTD by the China NMPA, which also makes sugemalimab one of the very few domestic novel drugs that have obtained BTD from the Agencies in both the U.S. and China. This designation underscores the remarkable clinical value of sugemalimab, and we look forward to working closely with the NMPA in China to maximize the benefit of sugemalimab to patients in the nearest future."

About ENKTL

Extranodal natural killer/T-cell lymphoma ("**ENKTL**") is a subtype of mature T cell and NK cell lymphoma. There is no existing effective salvage treatment for patients with R/R ENKTL who failed L-asparaginase-based standard regimen. Patients also 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 failed first-line treatment.

About CS1001-201 Study

CS1001-201 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. The primary endpoint of this study is ORR as assessed by the Independent Radiology Review Committee ("**IRRC**"). On August 14th, 2020, CS1001-201 has received a Study May Proceed letter from the U.S. FDA for the Investigational New Drug application. CS1001-201 was currently ongoing in the U.S. and China.

About Sugemalimab

Sugemalimab is an investigational anti-PD-L1 monoclonal antibody discovered by CStone. Authorized by the U.S.-based Ligand Corporation, sugemalimab 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 reduce the risk of immunogenicity and potential toxicities in patients, a unique advantage over similar drugs.

Sugemalimab has completed a Phase 1 dose-escalation study in China. During Phase 1a and Phase 1b of the study, sugemalimab showed good antitumor activity and tolerability in multiple tumor types.

Currently, sugemalimab is being investigated in a number of ongoing clinical trials. In addition to a Phase 1 bridging study in the U.S., the clinical program in China includes one multi-arm Phase 1b study for several tumor types, one Phase 2 registration studies for lymphoma, and four Phase 3 registration studies, respectively,

for stage III/IV NSCLC, gastric cancer, and esophageal cancer. The phase 3 trial of sugemalimab in the treatment of stage IV non-small cell lung cancer reached the primary endpoint. The U.S. FDA has granted BTD to anti-PD-L1 antibody sugemalimab for the treatment of adult patients with R/R ENKTL in October 2020. The NMPA has accepted the company's New Drug Application for sugemalimab.

Cautionary statement required by Rule 18A.05 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited: We cannot guarantee that we will be able to develop, or ultimately market sugemalimab successfully. Shareholders of the Company and potential investors are advised to exercise due care when dealing in the shares of the Company.

About CStone

CStone is a biopharmaceutical company focused on the development and commercialization of innovative tumor immunotherapy and precision medicines to meet the ardent medical needs of cancer patients in China and worldwide. Established at the end of 2015, CStone Pharmaceuticals has assembled a world-class management team with extensive experience in innovative drug development, clinical research, and commercialization. With a strategic emphasis on immuno-oncology combination therapies, the Company has built an oncology-focused pipeline of 14 drug candidates, including 6 late-stage candidates at pivotal clinical trials or registrational stages. CStone's vision is to become a world-renowned biopharmaceutical company leading the way to conquering cancer.

For more information about CStone, please visit: www.cstonepharma.com.

By order of the Board
CStone Pharmaceuticals
Dr. Frank Ningjun Jiang
Chairman

Suzhou, People's Republic of China, February 8, 2021

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. Qun Zhao, Mr. Yanling Cao, Mr. Xianghong Lin and Dr. Lian Yong Chen as non-executive Directors, and Dr. Paul Herbert Chew, Mr. Ting Yuk Anthony Wu and Mr. Hongbin Sun as independent non-executive Directors.