CStone Pharmaceuticals

基石藥業

(Incorporated in the Cayman Islands with limited liability)

(**Stock Code: 2616**)

VOLUNTARY ANNOUNCEMENT

U.S. FDA GRANTED BREAKTHROUGH THERAPY DESIGNATION TO ANTI-PD-L1 ANTIBODY SUGEMALIMAB FOR THE TREATMENT OF ADULT PATIENTS WITH R/R ENKTL

CStone Pharmaceuticals (the "**Company**" or "**CStone**") announced the United States ("**U.S.**") Food and Drug Administration ("**FDA**") has granted breakthrough therapy designation ("**BTD**") to anti-PD-L1 antibody sugemalimab (CS1001) for the treatment of adult patients with relapsed or refractory extra-nodal natural killer/T-cell lymphoma ("**R/R ENKTL**"). This represents another major breakthrough for CStone after the U.S. FDA granted Orphan Drug Designation ("**ODD**") to its anti-PD-L1 antibody sugemalimab to treat T-cell lymphoma in October 2020.

BTD is a process designed to expedite the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint. Receiving the BTD will greatly accelerate the development and commercialization of sugemalimab in the U.S.

Extra-nodal natural killer cell/T-cell lymphoma ("**ENKTL**") is a subtype of mature T cell and NK cell lymphoma. R/R ENKTL is highly malignant and aggressive with a poor prognosis. There is a lack of effective salvage treatments for patients with R/R ENKTL if standard L-asparaginase-based regimens fail. Patients also respond poorly to conventional treatments. Clinicians often have limited treatment options for such patients, as the disease progresses rapidly, and the survival period is extremely short with a one-year survival rate of less than 20%. In China, the current approved targeted monotherapy for these patients has a complete response ("**CR**") rate of approximately 6%. Thus, there are significant unmet medical needs in this patient population

in which first-line treatment has failed. An oral presentation of data from the CS1001-201 study, in which sugemalimab monotherapy was evaluated in adult patients with R/R ENKTL, was presented by the leading principle investigator Professor Huiqiang HUANG of Sun Yat-sen University Cancer Center at the 2020 annual meeting of the Chinese Society of Clinical Oncology. According to the data presented, the objective response rate ("**ORR**") of 38 evaluable patients was 44.7%, with a CR rate of 31.6%; the median duration of response was 16.8 months. Median overall survival of the 43 patients who received study drug treatment was 19.7 months, and the one-year overall survival rate was 55.5%. Sugemalimab is expected to become a new treatment option for these patients.

Dr. Jason Yang, the chief medical officer of CStone, said, "We have seen significant unmet needs for treatment among R/R ENKTL patients. Compared with data from other existing drugs, the efficacy data for sugemalimab represents a remarkable breakthrough. The BTD granted by the U.S. FDA recognizes the clinical value of sugemalimab. We are committed to advancing the development of sugemalimab, including by working closely with the U.S. FDA and the National Medical Products Administration of China, and will bring sugemalimab to R/R ENKTL patients across the globe as soon as possible."

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 R/R ENKTL. The primary endpoint of this study is ORR as assessed by the independent radiology review committee. On August 31, 2020, the Phase II pivotal study has received clearance from the U.S. FDA for the investigational new drug application, and a study may proceed letter.

About Sugemalimab (CS1001)

Sugemalimab is an investigational anti-PD-L1 monoclonal antibody discovered by CStone. Authorized by Ligand Pharmaceuticals Inc. (NASDAQ: LGND), a company based in the U.S., 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 human antibody, which can reduce the risk of immunogenicity and potential toxicities in patients, a unique advantage over similar drugs.

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

Currently, sugemalimab is being investigated in a number of ongoing clinical trials. In addition to a Phase I bridging study in the U.S., the clinical program in China includes one multi-arm Phase Ib study for several tumor types, one Phase II registrational study for lymphoma, and four Phase III registrational studies, respectively, for stage III/IV non-small cell lung cancer ("**NSCLC**"), gastric cancer, and esophageal cancer. The Phase III clinical trial of sugemalimab in patients with stage IV NSCLC has reached its primary endpoint. CStone plans to submit a new drug application to the National Medical Products Administration of China soon.

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 developing and commercializing innovative immuno-oncology and precision medicines to address the unmet medical needs of cancer patients in China and worldwide. Established at the end of 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, five late-stage candidates are at pivotal trials. With an experienced team, a rich pipeline, a robust clinical development-driven business model and substantial funding, CStone's vision is to become globally recognized as a leading Chinese 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, People's Republic of China, October 23, 2020

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. Guobin Zhang 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.