CStone Pharmaceuticals

基石藥業

(Incorporated in the Cayman Islands with limited liability)

(**Stock Code: 2616**)

VOLUNTARY ANNOUNCEMENT

CSTONE AND BAYER ANNOUNCE GLOBAL CLINICAL COLLABORATION TO EVALUATE PD-L1 MONOCLONAL ANTIBODY CS1001 IN COMBINATION WITH REGORAFENIB

CStone Pharmaceuticals (the "**Company**" or "**CStone**") announces that the Company has entered into a global clinical collaboration with China focus with Bayer HealthCare LLC ("**Bayer**") to evaluate the safety, tolerability, pharmacokinetics and antitumor activity of its immunooncology drug, PD-L1 monoclonal antibody CS1001, in combination with Bayer's regorafenib, an oral multi-kinase inhibitor (targeting VEGFR, FGFR and CSF1R, etc.), as a treatment for multiple cancers including gastric cancer. This is the first global proof of concept study carried out as a collaboration between the two companies. CStone will be the study sponsor and Bayer will provide regorafenib throughout the clinical trial program.

Professor Lin Shen, Vice President at the Peking University Cancer Hospital, commented: "At present, patients with advanced gastric cancer lack safe and effective therapies. Preclinical and clinical evidence suggests that the combination of PD-1/PD-L1 antibodies with multi-kinase inhibitors that target VEGFR can induce significant synergistic anti-tumor effects. We hope this combination therapy can provide a new treatment option for patients suffering from gastric cancer and other serious malignancies."

CS1001 is one of CStone's backbone immuno-oncology pipeline candidates, having demonstrated that it is well-tolerated and has promising anti-tumor activities across a variety of tumor types in clinical studies. Currently, CS1001 is being evaluated in 7 clinical trials, including 5 registrational trials. Regorafenib is

approved in over 90 countries for the treatment of metastatic colorectal cancer and metastatic gastrointestinal stromal tumors and in more than 80 countries for the second-line treatment of advanced hepatocellular.

Dr. Frank Ningjun Jiang, chairman, executive director and chief executive officer of CStone, commented: "We are very pleased that Bayer has chosen CStone as its partner and recognizes CS1001's potential. We hope, by complementing our two companies' pipelines via this combination therapy, that we can develop better cancer treatments for patients. In addition, this collaboration will be a big step forward for CStone's global strategy when we generate positive data."

Scott Z. Fields, M.D., Senior Vice President and Head of Oncology Development at Bayer's Pharmaceutical Division, commented: "Combining multi-kinase inhibitors, such as regorafenib, with checkpoint inhibitors is a rising trend in cancer therapy in order to find new solutions for the many treatment gaps that still remain for patients. We look forward to collaborating with CStone, an innovative biopharmaceutical company, and exploring regorafenib's potential."

About CS1001

CS1001 is an investigational monoclonal antibody directed against PD-L1 being developed by CStone. Authorized by the U.S.-based company, Ligand Pharmaceuticals Inc. (NASDAQ: LGND), CS1001 is developed by the OMT transgenic animal platform, which can generate fully human antibodies in one step. As a fully human, full-length anti-PD-L1 monoclonal antibody, CS1001 mirrors natural G-type immune globulin 4 (IgG4) human antibody, which can reduce the risk of immunogenicity and potential toxicities in patients, potentially representing a unique advantage over similar drugs.

CS1001 has completed a Phase 1 dose-escalation study in China, in which CS1001 showed good tolerability and produced sustained clinical benefits during the Phase 1a stage of the study.

CS1001 is being investigated in a number of ongoing clinical trials, including one Phase 1 bridging study in the United States. In China, its clinical program includes one multi-arm Phase 1b study, two pivotal Phase 2 studies, and three Phase 3 studies for several tumor types. CS1001 has not been approved for marketing in any market.

About Regorafenib (Stivarga®)

Regorafenib is an oral multi-kinase inhibitor that potently blocks multiple protein kinases involved in tumor angiogenesis (VEGFR1, -2, -3, TIE2), oncogenesis (KIT, RET, RAF-1, BRAF), metastasis (VEGFR3, PDGFR, FGFR) and tumor immunity (CSF1R).

Regorafenib is approved under the brand name Stivarga® in more than 90 countries worldwide, including the United States, countries of the European Union, China and Japan for the treatment of metastatic colorectal cancer and metastatic gastrointestinal stromal tumors. The product is also approved in more than 80 countries including the United States, Japan, countries of the European Union as well as China for the second-line treatment of advanced hepatocellular.

Regorafenib is a compound developed by Bayer. In 2011, Bayer entered into an agreement with Onyx Pharmaceuticals, Inc. ("**Onyx**"), a biopharmaceutical company, under which Onyx receives a patent royalty on all global net sales of regorafenib in oncology.

About CStone

CStone is a biopharmaceutical company focused on developing and commercializing innovative immuno-oncology and precision medicine 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, five late-stage candidates are at or near 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, June 10, 2019

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.