CStone Pharmaceuticals

基石藥業

(Incorporated in the Cayman Islands with limited liability)

(**Stock Code: 2616**)

VOLUNTARY ANNOUNCEMENT

CSTONE ANNOUNCES FIRST PATIENT DOSED IN THE PHASE III TRIAL OF CS1001 IN COMBINATIONATION WITH CHEMOTHERAPY IN FIRST-LINE ESOPHAGEAL SQUAMOUS CELL CARCINOMA

CStone Pharmaceuticals (the "**Company**" or "**CStone**") announces that the first patient has been dosed in the Phase III GEMSTONE-304 clinical study of the Company's anti-PD-L1 antibody CS1001 in combination therapy as first-line treatment in patients with advanced esophageal squamous cell carcinoma ("**ESCC**"). The GEMSTONE-304 trial is a multicenter clinical study designed to evaluate the efficacy and safety of CS1001 in combination with 5-fluorouracil plus cisplatin ("**FP**") doublet chemotherapy in the first-line treatment of unresectable locally advanced, relapsed, or metastatic ESCC.

Epidemiological data indicate that approximately 90% of all esophageal cancer cases in China are ESCC, and approximately 70% of ESCC cases were locally advanced or metastatic at the time of diagnosis. The platinum-based doublet chemotherapy is the current standard of care first-line treatment for patients with advanced ESCC, but it has limited efficacy. Existing data on this first-line treatment for advanced ESCC suggest an objective response rate ("**ORR**") of approximately 35%, a median progression-free survival of less than six months, and a median overall survival of less than one year. There are no alternative treatments for these ESCC patients.

CS1001 is an investigational anti-PD-L1 antibody developed by CStone. Results released at the 2019 Chinese Society of Clinical Oncology Annual Meeting have shown that, as of July 1, 2019, the Phase Ib clinical trial of CS1001 in combination with the FP chemotherapy regimen in first-line treatment of ESCC achieved an ORR of 77.8% with durable response as well as favorable overall safety and tolerability.

Dr. Frank Ningjun Jiang, chairman, executive director and chief executive officer of CStone, commented: "Esophageal cancer is one of the tumor types that are particularly prevalent in China, accounting for over 50% of the occurrences of the world's new esophageal cancer cases and related deaths. However, the current treatment of ESCC in China has not achieved breakthroughs for years, and there are long-term and urgent unmet needs from the clinical patients. I am glad that we have dosed the first patient in the GEMSTONE-304 trial. I hope CS1001 will continue to demonstrate its clinical potential in its development programs, and will soon become a new treatment option for ESCC patients in China."

Dr. Jason Yang, chief medical officer of CStone, commented: "Early symptoms of esophageal cancer are relatively silent; as a result, esophageal cancer patients are commonly diagnosed at advanced stages for which there are very limited treatment options. Furthermore, no immunotherapy has currently been approved for the first-line treatment of ESCC. Recent published results from the Phase Ib trial of CS1001 have already demonstrated promising preliminary antitumor efficacy in advanced ESCC. We will continue accelerate this Phase III trial of CS1001 with our best effort. Should this clinical program lead to successful outcomes, it will be a major breakthrough for advanced ESCC patients who are in urgent need of effective therapies."

About CS1001

CS1001 is an investigational monoclonal antibody directed against PD-L1 being developed by CStone. Authorized by a company based in the United States, 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 I dose-escalation study in China, in which CS1001 showed good tolerability and produced sustained clinical benefits during Phase Ia and Ib stages of the study in multiple indications.

CS1001 is being investigated in a number of ongoing clinical trials, including one Phase I bridging study in the United States. In China, its clinical program includes one multi-arm Phase Ib study, two pivotal Phase II studies and three Phase III studies for several types of tumors.

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 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 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, January 7, 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.