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CStone Pharmaceuticals

基石藥業

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 2616)

VOLUNTARY ANNOUNCEMENT

FIRST PATIENT DOSED IN PHASE III GEMSTONE-303 STUDY FOR CS1001 IN COMBINATION WITH CHEMOTHERAPY IN FIRST-LINE GASTRIC ADENOCARCINOMA AND GASTRO-ESOPHAGEAL JUNCTION ADENOCARCINOMA

CStone Pharmaceuticals (the “**Company**” or “**CStone**”) announces that the first patient has been successfully enrolled and dosed in a Phase III clinical trial assessing CS1001, China’s first fully human, full-length anti-PD-L1 antibody, in combination with chemotherapy for the treatment of gastric adenocarcinoma (GC) or gastro-esophageal junction (“**GEJ**”) adenocarcinoma. The multi-center, placebo-controlled clinical trial, GEMSTONE-303 will evaluate efficacy and safety of CS1001 plus oxaliplatin and capecitabine (XELOX) chemotherapy as first-line treatment in patients with unresectable, locally advanced, or metastatic gastric adenocarcinoma or GEJ adenocarcinoma.

According to data from the Chinese National Cancer Center, gastric cancer is the second most common cause of cancer-related death after lung cancer. In 2015, gastric cancer accounted for approximately 679,100 new cancer cases in China, and approximately 498,000 patients died from the disease. Gastric adenocarcinoma comprises in excess of 90% of malignant neoplasms of the stomach, while incidence of GEJ has been rising in recent years. Currently chemotherapy is still the primary treatment option for both gastric adenocarcinoma and GEJ, while the only available biologic drug therapy for the indication is restricted to HER2-positive cases, which make up only 12% to 13% of total patient numbers.

Dr. Frank Ningjun Jiang, Chairman, executive director and CEO of CStone, commented, “We are pleased to get this Phase III clinical study under way with the first patient enrolled and dosed. For the past few decades, gastric cancer incident rate and mortality rate have decreased in most areas of the world; however, in China the number of cases of gastric cancer keeps increasing and both gastric adenocarcinoma and GEJ still represent major healthcare problems with serious unmet medical needs. We hope CS1001 can prove successful in this registration study and provide an important new treatment option for Chinese gastric cancer patients.”

Dr. Jianxin Yang, CStone’s Chief Medical Officer, commented: “Around 40% to 60% of patients with gastric adenocarcinoma are diagnosed at the advanced stage, for which treatment options are limited. Current clinical studies have shown that anti-PD-1/PD-L1 drugs when paired with chemotherapy are highly efficacious in multiple cancer types including gastric cancer. We expect that CS1001 in combination with oxaliplatin and capecitabine will generate significantly better efficacy than chemotherapy alone in patients with gastric cancer.”

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 in safety over similar drugs.

CS1001 has completed a Phase I dose-escalation clinical study in China, in which CS1001 showed good tolerance and produced sustained clinical benefit during the Phase Ia stage of study. Currently, two registrational Phase II clinical studies and three registrational Phase III clinical studies have been initiated in China.

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 with a strategic emphasis on immuno-oncology combination therapies. Currently, 4 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

Shanghai, People's Republic of China, April 16, 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. Xiaomeng Tong, 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.