CStone Pharmaceuticals

基石藥業

(Incorporated in the Cayman Islands with limited liability)

(**Stock Code: 2616**)

VOLUNTARY ANNOUNCEMENT

CSTONE PRESENTS DATA FROM CS1001-101 CLINICAL TRIAL AT ASCO 2019 MEETING

CStone Pharmaceuticals (the "**Company**" or "**CStone**") presented the updated data from the CS1001-101 clinical trial at the 2019 American Society for Clinical Oncology ("**ASCO**") Annual Meeting in a poster presentation. CS1001-101 is a Phase 1a/1b open-label, multiple-dose, dose-escalation and expansion study assessing the safety, tolerability, pharmacokinetics and anti-tumor efficacy of CS1001 in patients with advanced solid tumors or lymphomas. The trial shows that CS1001 is well-tolerated with an expected pharmacokinetics profile and durable anti-tumor activities are observed in a number of tumor types.

As of November 30, 2018, in the Phase 1a study, a total of 29 patients were enrolled and were administered with CS1001 at escalating doses from 3 mg/kg, to 10 mg/kg, 20 mg/kg, 40 mg/kg and 1200 mg flat dose. The median treatment duration for all patients was 126 days (range: 21-408 days or more), and 9 patients remained on treatment as of data cutoff. Of the 29 patients enrolled, 7 patients showed partial response with an overall response rate (ORR) of 24% (6 patients are still on treatment). These data demonstrated that CS1001 is efficacious in a variety of solid tumors and lymphomas.

Professor Lin Shen, vice president of Peking University Cancer Hospital, who is the principal investigator in this CS1001 phase 1 study, commented: "I am pleased that the latest clinical data in this phase 1 trial continues to show that CS1001 is well-tolerated, and its safety profile is comparable with other PD-L1s. CS1001 has demonstrated encouraging anti-tumor activities across different tumor types in the phase 1a and 1b studies with durable responses."

Dr. Frank Ningjun Jiang, chairman, executive director and chief executive officer of CStone, commented: “CS1001 is a fully human, full-length anti-PD-L1 monoclonal antibody that can potentially reduce the risk of immunogenicity and its associated toxicities in patients. CS1001 is one of CStone’s three immunotherapy backbone assets. We have built well-designed clinical development plans to evaluate this drug candidate both as monotherapy and in combination therapies for the treatment of lung cancer, gastric cancer, and other advanced tumors."

Dr. Jason Jianxin Yang, CStone’s chief medical officer, noted: “We are pleased to present CS1001’s latest clinical data that further proves its safety and efficacy. These data support the continued development of CS1001 in registrational studies. Currently, CS1001 is being evaluated in two Phase 2 and three Phase 3 registrational clinical studies in multiple tumor types and over 500 patients have been enrolled in 7 global clinical trials. We look forward to bringing this immunotherapy molecule to market as soon as possible, allowing more patients to be able to benefit from it.”

At this year’s ASCO meeting, CStone also presented a ‘Trial-in-Progress’ poster for the ongoing GEMSTONE-301 clinical study. This is a randomized, double-blind, placebo-controlled Phase 3 study evaluating CS1001 as a consolidation therapy in subjects with locally advanced/unresectable (stage III) non-small cell lung cancer (NSCLC) who have not progressed after prior concurrent/sequential chemoradiotherapy.

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 U.S. 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.

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

Suzhou, People's Republic of China, June 2, 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.