CStone Pharmaceuticals

基石藥業

(Incorporated in the Cayman Islands with limited liability)

(**Stock Code: 2616**)

VOLUNTARY ANNOUNCEMENT
CSTONE ANNOUNCED TWO KEY PHASE III REGISTRATIONAL CLINICAL TRIALS OF SUGEMALIMAB COMPLETED PATIENT ENROLLMENT

CStone Pharmaceuticals (the "**Company**" or "**CStone**") is pleased to announce that two key phase III registrational clinical trials of sugemalimab, a fully human, full-length anti-PD-L1 antibody developed in-house, have completed patient enrollment. The two trials are GEMSTONE-303, where sugemalimab in combination with standard of care chemotherapy is used as first-line treatment of unresectable locally advanced or metastatic gastric adenocarcinoma /gastro-esophageal junction (GEJ) adenocarcinoma, and GEMSTONE-304, where sugemalimab in combination with standard of care chemotherapy is used as first-line treatment of unresectable locally advanced, recurrent, or metastatic esophageal squamous cell carcinoma ("**ESCC**").

Key Highlight

- Both trials investigate first-line treatment with sugemalimab combined with chemotherapy in patients with metastatic gastric adenocarcinoma /gastro-esophageal junction (GEJ) adenocarcinoma or ESCC.
- A significant milestone in our pipeline development just after sugemalimab was approved in December 2021 for first-line treatment of stage IV non-small cell lung cancer ("**NSCLC**") in China, we submitted a new drug application ("**NDA**") to the National Medical Product Administration ("**NMPA**") for the treatment of stage III NSCLC and a pivotal phase 2 trial on sugemalimab met primary endpoint of objective response rate in patients with relapsed or refractory extranodal natural killer/T-cell lymphoma ("**R/R ENKTL**")

Dr. Jason Yang, Chief Medical Officer of CStone, said, "We are very glad that the two phase III registrational clinical trials for gastric and esophageal cancers have completed patient enrollment. This represents a significant milestone in our pipeline development just after sugemalimab was approved for first-line treatment of stage IV NSCLC in China in December 2021 and we submitted an NDA to the NMPA for the treatment of stage III NSCLC in September 2021, and a pivotal phase II trial on sugemalimab met primary endpoint of objective response rate in patients with R/R ENKTL in January

2022. I greatly appreciate all researchers, patients and their families for their contributions to the trials. As with lung cancer, the incidence and mortality rates of gastric/esophageal cancer rank among the highest in the world, especially in China, and huge unmet needs remain for patients. Should the results of the GEMSTONE-303 and 304 studies meet their primary endpoints, we look forward to providing patients with additional treatment options as quickly as possible."

Gastric/esophageal cancer is one of the most common cancers globally. According to the GLOBOCAN 2020 data, there were more than 1 million new cases of gastric cancer worldwide and 769,000 deaths in 2020. The incidence and mortality of gastric cancer ranked 5th and 4th respectively among all common cancers worldwide. There were more than 600,000 new cases of esophageal cancer, and 544,000 deaths in 2020, with the incidence and mortality ranking 8th and 6th, respectively, globally. The incidence of gastric adenocarcinoma accounted for more than 90% of gastric malignancies, and the incidence of GEJ adenocarcinoma has been on the rise in recent years. Epidemiological data indicated that around 90% of all esophageal cancer cases in China are ESCC, and ESCC cases were commonly locally advanced or metastatic at the time of diagnosis and miss the opportunities of curative treatments.

The GEMSTONE-303 study is a multi-center, placebo-controlled phase III registrational clinical trial designed to evaluate the efficacy and safety of sugemalimab plus capecitabine and oxaliplatin (CAPOX) as the first-line treatment in patients with unresectable locally advanced or metastatic gastric adenocarcinoma or GEJ adenocarcinoma. In a phase Ib study in this patient population, sugemalimab in combination with CAPOX demonstrated an objective response rate of 62.1% (18/29), and a disease control rate ("**DCR**") of 82.8%, with durable responses in patients.

The GEMSTONE-304 study is a multi-center, placebo-controlled phase 3 registrational clinical trial designed to evaluate the efficacy and safety of sugemalimab in combination with 5-fluorouracil plus cisplatin (FP) as first-line treatment in patients with unresectable locally advanced, recurrent, or metastatic ESCC. In a phase Ib trial in this population, sugemalimab in combination with FP achieved an ORR of 67.6% (25/37) and a DCR of 89.2%, along with durable responses in first-line ESCC patients.

About sugemalimab

Sugemalimab is an investigational anti-PD-L1 monoclonal antibody discovered by CStone. Sugemalimab using the OmniRat® transgenic animal platform, which can generate fully human antibodies in one stop, under license from Ligand Corporation of the US. As a fully human, full-length anti-PD-L1 immunoglobulin G-4 (IgG4) monoclonal antibody, sugemalimab offers potentially reduced risks of immunogenicity and toxicity in patients, a unique advantage over similar drugs.

Currently, the NMPA of China has approved sugemalimab in combination with chemotherapy for the treatment of treatment-naïve patients with stage IV NSCLC. In addition, sugemalimab is being investigated in a number of ongoing clinical trials, including one Phase II registrational study for lymphoma and three Phase III registrational studies in stage III NSCLC, gastric cancer, and esophageal cancer, respectively.

CStone formed a strategic collaboration agreement with Pfizer Inc. (NYSE: PFE) that includes the development and commercialization of sugemalimab in mainland China, and a framework to bring additional oncology medicines to the Greater China market.

About CStone

CStone is a biopharmaceutical company focused on researching, 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, CStone has received five drug approvals in Greater China, including three in Mainland China, one in Hong Kong, and one in Taiwan. CStone's vision is to become globally recognized as a world-renowned 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, the People's Republic of China, January 18, 2022

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. Kenneth Walton Hitchner III, Mr. Yanling Cao, Mr. Xianghong Lin and Mr. Edward Hu as non-executive Directors, and Dr. Paul Herbert Chew, Mr. Ting Yuk Anthony Wu and Mr. Hongbin Sun as independent non-executive Directors.