**CStone Pharmaceuticals**

**基石藥業**

*(Incorporated in the Cayman Islands with limited liability)*

(**Stock Code: 2616**)

## VOLUNTARY ANNOUNCEMENT

# CSTONE PRESENTS POOLED SAFETY DATA FROM THE PHASE 1B TRIAL OF CS1001, DEMONSTRATING PROMISING OVERALL SAFETY AND TOLERABILITY AT ESMO 2019

CStone Pharmaceuticals (the "**Company**" or "**CStone**") announces that the Company has released pooled safety data from the Phase Ib (GEMSTONE-101) study of the Company's anti-PD-L1 antibody CS1001 in a poster presentation at the European Society of Medical Oncology 2019 Congress ("**ESMO 2019**"), demonstrating the promising safety and tolerability profile of CS1001. The poster also presented results from the four cohorts of the Phase Ib trial that included esophageal squamous cell carcinoma, microsatellite instability high/deficient mismatch repair (MSI-H/dMMR) tumors, gastric cancer or gastroesophageal junction cancer, and cholangiocarcinoma or gallbladder cancer.

Dr. Frank Ningjun Jiang, chairman, executive director and chief executive officer of CStone, commented: "CS1001 is an investigational anti-PD-L1 monoclonal antibody developed by CStone, and one of our three backbone immunotherapy drug candidates. I am pleased that following the data release at Chinese Society of Clinical Oncology 2019, we have presented additional promising trial data at ESMO 2019. CS1001 is currently being investigated in multiple tumor types in China. We hope CS1001 will deliver more encouraging results in future studies."

CStone's chief medical officer, Dr. Jason Yang, noted: "Being a fully human, full-length anti-PD-L1 monoclonal antibody, CS1001 has the potential to reduce the risk of immunogenicity and associated toxicity in patients. In the pooled safety data from the Phase Ib study released at ESMO 2019, CS1001 was shown to be safe and well tolerated, without any unexpected adverse event reported. Based on the benign safety profile and promising efficacy data, we will continue to explore CS1001's potential in both monotherapy and combination therapies, thereby to benefit more cancer patients as soon as possible."

**Overview of the GEMSTONE-101 Study**

The GEMSTONE-101 study is a Phase Ia/Ib, open-label, multi-dose, dose-escalation and dose-expansion study designed to evaluate the safety, tolerability, pharmacokinetics, and antitumor efficacy of CS1001 in advanced solid tumors or lymphoma in China.

- Phase Ia of the study is a dose-escalation study designed to evaluate the safety, pharmacokinetics and determine the recommended dose for the subsequent studies.
- Phase Ib of the study is a dose-expansion study aimed at assessing CS1001's antitumor activities and tolerability in cohorts of selected tumor types.

**Pooled safety data from the GEMSTONE-101 Ib study**

- As of July 1, 2019, 192 patients were enrolled in the Phase Ib study across multiple cohorts of various tumor types.
- Median duration of CS1001 treatment was 112 days (range: 3 to 377).
- The majority of patients reported treatment-emergent adverse events (TEAEs, regardless of treatment-related or not); 95.9% of patients in the CS1001 monotherapy cohorts and 99.0% of patient in the CS1001 plus chemotherapy combination cohorts reported TEAEs. 38.4% of patients in the monotherapy cohorts reported Grades 3 to 5 TEAEs, and 70.1% of patients in the CS1001 plus chemotherapy combination therapy cohorts reported Grades 3 to 5 TEAEs.
- The incidence of serious adverse events ("**SAEs**") nearly doubled in the CS1001 plus chemotherapy combination cohorts compared to the monotherapy cohorts. 40.2% of patients in the chemotherapy combination cohort developed reported SAEs, while 20.5% of those in the monotherapy cohort reported SAEs.

**Promising antitumor activities that were demonstrated in the four cohorts of the GEMSTONE-101 Ib study**

- CS1001 in combination with CF chemotherapy as first-line treatment of esophageal squamous cell carcinoma has demonstrated durable response, with an objective response rate ("**ORR**") of 77.8% (14/18) and a disease control rate ("**DCR**") of 88.9%.
- CS1001 in combination with XELOX chemotherapy as first-line treatment of gastric cancer/gastroesophageal junction cancer demonstrated durable response, with an ORR of 62.1% (18/29) and DCR of 82.8%.
- CS1001 in unresectable cholangiocarcinoma/gallbladder cancer demonstrated durable response, with an ORR of 10.3% (3/29) and a DCR of 37.9%.
- CS1001 in MSI-H/dMMR tumors demonstrated an ORR of 38.1% (8/21) and a DCR of 57.1%.

**About CS1001**

CS1001 is an investigational monoclonal antibody directed against PD-L1 being developed by CStone. Authorized 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 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 the Phase Ia stage of the study.

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 tumor types.

**About CStone**

CStone is a biopharmaceutical company focused on developing and commercializing innovative immuno-oncology and molecularly-targeted drugs to address unmet medical needs for cancer patients in China and worldwide. Since the Company's establishment in 2015, CStone has assembled a world-class management team that has a full spectrum of complementary skillsets from preclinical research to clinical development and commercialization. With combination therapies as a core strategy, the Company has built a rich oncology pipeline of 15 oncology drug candidates. Currently, five late-stage drug 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 and differentiated 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, September 30, 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.*