CStone Pharmaceuticals

基石藥業

(Incorporated in the Cayman Islands with limited liability)

(**Stock Code: 2616**)

VOLUNTARY ANNOUNCEMENT

CSTONE ANNOUNCES THE PHASE IB DATA AND PROGRESS WITH THE PIVOTAL TRIAL OF CS1001 IN NON-SMALL CELL LUNG CANCER

CStone Pharmaceuticals (the "**Company**" or "**CStone**") announced that it will release updated results regarding the CS1001-101 study of the Company's anti-PD-L1 monoclonal antibody, CS1001, in an abstract at the 2020 Annual Meeting of American Society of Clinical Oncology ("**ASCO"**).

The key updates include:

- The updated data on the use of CS1001 in combination with platinum-based chemotherapy in first-line advanced non-small cell lung cancer ("**NSCLC**") demonstrated objective response rates ("**ORR**") of 47.6% in non-squamous NSCLC cohort and 75% in squamous NSCLC cohort;

- CS1001 demonstrated a benign safety profile and there were no discontinuations due to treatment-related adverse events ("**TRAEs**").

Dr. Jason Yang, chief medical officer of CStone, commented: "We are pleased that CS1001 in combination with platinum-based chemotherapy has demonstrated promising anti-tumor activity and good safety, which supports the exploration of CS1001 in combination with chemotherapy in first-line treatment of advanced NSCLC. CStone has completed subject enrollment for the Phase III study of CS1001, in which CS1001 will be used in combination with platinum-based chemotherapy for first-line treatment of advanced NSCLC. The top-line data from the Phase III trial are expected to be published in the coming months. It is worth mentioning that this trial is the first Phase III study in China targeting first-line NSCLC treatment with both squamous and

non-squamous sub-populations involved; with the improvements in the ORR and progression-free survival data at Phase Ib, we are confident in and look forward to the Phase III results."

About the CS1001-101 study

The CS1001-101 study is a Phase I study designed to evaluate the safety, tolerability, pharmacokinetics, and anti-tumor activity of CS1001 in patients with advanced solid tumors or lymphomas. The results of CS1001-101 study to be released at the annual meeting of ASCO this year are efficacy data from the Phase Ib cohort study, which is a proof-of-concept study aiming to assess the efficacy and safety of CS1001 in combination with platinum-based chemotherapy for first-line treatment of NSCLC.

Phase Ib Study Results

21 and 20 patients were enrolled in the non-squamous and squamous NSCLC cohorts, respectively.

Efficacy data

- As of July 1, 2019, ten patients from each of the two cohorts had reached partial response, resulting in an ORR of 47.6% for the non-squamous NSCLC cohort, and 58.8% for the squamous NSCLC cohort. The median duration of response ("**mDoR**") and median progression-free survival ("**mPFS**") endpoints were not reached due to the short median follow-up duration prior to the data cutoff (non-squamous NSCLC: 5.4 months; squamous NSCLC: 3.9 months);

- Updated efficacy data collected during the most recent follow-up period (the median follow-up duration as of February 19, 2020: non-squamous NSCLC: 13.4 months; squamous NSCLC: 11.3 months) are shown in the table below.

	ORR (%)	mPFS (months), 95% CI	mDoR (months), 95% CI
Non-squamous NSCLC cohort of the CS1001 Phase Ib study (N=21)	**47.6**	**6.5 (4.40, 11.7)**	**8.7 (1.77, -)**
Squamous NSCLC cohort of the CS1001 Phase Ib study (N=20)	**75.0**	**8.4 (8.18, -)**	**6.4 (6.24, -)**

Safety data

- As of the data cutoff on July 1, 2019, 18 patients (85.7%) in the non-squamous NSCLC cohort reported CS1001-related adverse events ("**AE**"), and six patients (28.6%) reported TRAEs of Grade 3 or higher. five patients reported immune-related AEs ("**irAEs**"), with the most common irAEs being elevated alanine aminotransferase levels (N=4, Grade $\leqslant$2) and elevated aspartate aminotransferase levels (N=3, Grade $\leqslant$2);

- In the squamous NSCLC cohort, 18 patients (90.0%) reported TRAEs, of which five patients (25%) had TRAEs of Grade 3 or higher. IrAEs occurred in three patients with rash (N=2, Grade ≤2) being the most common irAE;

- There were no TRAEs leading to study withdrawal.

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, May 26, 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.