CStone Pharmaceuticals

基石藥業

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 2616)

VOLUNTARY ANNOUNCEMENT
CSTONE ANNOUNCES FIRST PATIENT ENROLLMENT IN CHINA FOR THE MULTI-REGIONAL PHASE 1 TRIAL OF CS5001, A POTENTIAL BEST-IN-CLASS ROR1-TARGETING ADC

CStone Pharmaceuticals (the "**Company**" or "**CStone**") is pleased to announce that the enrollment of the first patient in China in CS5001-101, a multi-regional Phase 1 clinical trial of the ROR1-targeting ADC, CS5001, that has been ongoing in the U.S. and Australia.

Key Highlights

- The multi-regional Phase 1 clinical trial of CS5001 has been advancing through dose escalation in the U.S. and Australia with good safety and tolerability demonstrated.
- The joining of China investigational centers to this trial will further accelerate the global development of this potential best-in-class ROR1 ADC.
- As one of the most advanced ROR1 ADCs in clinical development, CS5001 has therapeutic potential for various hematological and solid malignancies.
- This marks another important milestone for CStone's Pipeline 2.0 strategy.

The CS5001-101 study is designed to evaluate the safety, tolerability, pharmacokinetics, and preliminary anti-tumor activity of CS5001 in advanced lymphomas and solid tumors. The trial has been advancing through dose escalation with multiple dose levels in the U.S. and Australia with good safety and tolerability demonstrated.

CS5001 has many distinctive features, including proprietary site-specific conjugation, tumor-cleavable linker, and prodrug technology. CS5001 demonstrated a best-in-class potential in mantle cell lymphoma and triple negative breast cancer xenograft models compared to a benchmark ROR1 ADC. In addition, CS5001 demonstrated a bystander effect in in vitro co-culture systems, suggesting

that solid tumors with heterogeneous/low expression of ROR1 may also benefit. Preclinical data of CS5001 was presented in a late-breaking abstract (LBA) session at the 33rd International Conference on Molecular Targets and Cancer Therapeutics in 2021. The translational data on CS5001 have recently been reported in an oral presentation at the 13th World Antibody Drug Conjugate Conference (World ADC London).

"We are excited to announce the enrollment of the first patient in China in this multi-regional phase 1 clinical trial of CS5001" said Dr. Jason Yang, Chief Executive Officer and executive director of CStone. "This marks another milestone in our Pipeline 2.0 strategy. With the addition of the China investigational centers， the pace of this important program will be further accelerated. We will rapidly promote the global development of CS5001 in all aspects and look forward to bringing more quality treatment options to patients soon."

"CS5001 is one of the most clinically advanced ROR1 ADCs globally and there many reasons to believe that it has potential to be best-in-class" said Dr. Archie Tse, Chief Scientific Officer of CStone. "It consists of a fully human antibody backbone conjugated site-specifically to prodrugs of pyrrolobenzodiazepine (PBD) via a proprietary tumor-cleavable linker, all of which aim to widen the therapeutic window of the ADC. Results from the preclinical studies of CS5001 already showed its therapeutic potential in ROR1-expressing hematological and solid malignancies."

About CS5001 (ROR1 ADC)

CS5001 is now a clinical-stage antibody-drug conjugate (ADC) targeting ROR1 (receptor tyrosine kinase-like orphan receptor 1). CS5001 has uniquely designed and LCB's proprietary tumor-cleavable linker and pyrrolobenzodiazepine (PBD) prodrug. Only after reaching the tumor, the linker and prodrug are cleaved to release the PBD toxin, resulting in lethal DNA cross-links in cancer cells. The use of the linker plus PBD prodrug effectively helps addressing the toxicity problem associated with traditional PBD payloads, leading to a better safety profile. Additionally, CS5001 utilizes site-specific conjugation for a precise drug antibody ratio, which enables homogeneous production and large-scale manufacturing.

In October 2020, CStone signed a licensing agreement with LegoChem Biosciences, Inc. (LCB) for the development and commercialization of CS5001 which was originally generated by collaboration of LCB and ABL Bio, both South Korea-based leading biotech companies. Under the agreement, CStone obtains the exclusive global right to develop and commercialize CS5001 outside the Republic of Korea.

About CStone

CStone is a biopharmaceutical company focused on research, development and commercialization of 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 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 seven NDA approvals for four drugs. CStone's vision is to bring innovative oncology therapies to cancer patients worldwide.

For more information about CStone, please visit: www.cstonepharma.com.

Forward Looking Statement

There is no assurance that any forward-looking statements regarding the business development of the Group in this announcement or any of the matters set out herein are attainable, will actually occur or will be realised or are complete or accurate. The financial and other data relating to the Group as disclosed in this announcement has also not been audited or reviewed by its auditors. Shareholders

and/or potential investors of the Company are advised to exercise caution when dealing in the securities of the Company and not to place any excessive reliance on the information disclosed herein. Any shareholder or potential investor who is in doubt is advised to seek advice from professional advisors.

By Order of the Board
CStone Pharmaceuticals
Dr. Wei Li
Chairman

Suzhou, the People's Republic of China, April 24, 2023

As at the date of this announcement, the board of directors of the Company comprises Dr. Wei Li as Chairman and non-executive director, Dr. Jianxin Yang as executive director, Mr. Kenneth Walton Hitchner III, 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.