CStone Pharmaceuticals

基石藥業

(Incorporated in the Cayman Islands with limited liability)

(**Stock Code: 2616**)

VOLUNTARY ANNOUNCEMENT
CSTONE ANNOUNCES FIRST PATIENT ENROLLED IN THE GLOBAL MULTICENTER PHASE IB CLINICAL TRIAL OF CS5001 (ROR1 ADC)

CStone Pharmaceuticals (the "**Company**" or "**CStone**") is pleased to announce the enrollment of the first patient in the global multicenter Phase Ib clinical trial of CS5001, an anti-ROR1 ADC and a key asset in the Company's Pipeline 2.0.

Key Highlights:

- CS5001 is so far the first known ROR1 ADC to demonstrate clinical anti-tumor activity in both solid tumors and lymphomas and positioned top two globally in clinical development.
- Clinical data indicates a higher objective response rate (ORR) of CS5001 as a monotherapy for both aggressive and indolent advanced lymphomas compared to competitors, potential for faster-to-market registration, and capacity of reshaping the frontline combination treatment landscape.
- The global multicenter Phase I trial of CS5001 is currently in progress in the USA, Australia, and China, with Phase Ib dose optimization already initiated and potentially to be further expanded into a Phase II single-arm registrational study.

CS5001 has demonstrated encouraging safety and robust anti-tumor activity in the Phase Ia dose escalation trials across 10 dose levels. CS5001 was well tolerated in heavily pre-treated patients with advanced B-cell lymphomas and solid tumors, with no dose-limiting toxicity (DLT) observed up to dose level 10 (DL10). At the tentative recommended Phase II dose (RP2D) of DL8 (125 μg/kg), CS5001 achieved ORRs of 70% in advanced B-cell lymphoma and 100% in Hodgkin lymphoma. Encouraging efficacy signals were also observed in advanced solid tumors, including non-small cell lung cancer and pancreatic cancer.

Dr. Jason Yang, CEO, President of R&D, and Executive Director at CStone, commented, "The clinical data of CS5001 have been presented at multiple international academic meetings this year, raising widespread attention within the industry. Based on the latest clinical data, CS5001 as a monotherapy has demonstrated a higher ORR in both aggressive and indolent advanced lymphomas compared to

competitors, with consistent efficacy trends as patient numbers grow. This reinforces our confidence in its potential for faster-to-market registration and capacity of reshaping the frontline combination treatment landscape.

We are delighted to see CS5001 advance to the Phase Ib dose-optimization and expansion trial. This study also holds the potential to evolve into a Phase II single-arm registrational trial for relapsed/refractory diffuse large B cell lymphoma (DLBCL). We will also explore the safety and efficacy of CS5001 as a monotherapy or in combination with the frontline standard of care (SOC) across multiple lymphomas and solid tumors. Our goal is to bring innovative treatments like CS5001 to global cancer patients, offering them improved survival benefits and new hope."

About CS5001 (ROR1 ADC)

CS5001 is a clinical-stage antibody-drug conjugate ("ADC") targeting ROR1 (receptor tyrosine kinase-like orphan receptor 1). CS5001 has been uniquely designed with 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 address toxicity associated with traditional PBD payloads, leading to a better safety profile. CS5001 has demonstrated complete tumor suppression in several preclinical cancer models and demonstrated favorable serum half-life and pharmacokinetic characteristics. CS5001 is a promising candidate drug with precision treatment potential in both hematologic tumors and malignant solid tumors. Additionally, CS5001 utilizes site-specific conjugation for a precise drug antibody ratio of which enables homogeneous production and large-scale manufacturing.

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

The first-in-human data for CS5001 in patients with advanced solid tumors and lymphomas was presented at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting. Additionally, the latest clinical data on CS5001 as a monotherapy in patients with advanced lymphomas has recently been presented at the 66th American Society of Hematology (ASH) Annual Meeting.

About CStone

CStone (HKEX: 2616), established in late 2015, is an innovation-driven biopharmaceutical company focused on the research and development of anti-cancer therapies. Dedicated to addressing patients' unmet medical needs in China and globally, the Company has made significant strides since its inception. To date, the Company has successfully launched 4 innovative drugs and secured approvals for 16 new drug applications (NDAs) covering 9 indications. The Company's pipeline is balanced by 17 promising candidates, featuring potentially first-in-class or best-in-class antibody-drug conjugates (ADCs), multispecific antibodies, immunotherapies and precision medicines. CStone also prides itself on a management team with comprehensive experiences and capabilities that span the entire drug development spectrum, from preclinical and translational research to clinical development, drug manufacturing, business development, and commercialization.

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

Cautionary Statement required by Rule 18A.05 of the Listing Rules: THE COMPANY CANNOT GUARANTEE THAT WE MAY BE ABLE TO ULTIMATELY DEVELOP AND MARKET CS5001 SUCCESSFULLY. Shareholders of the Company and potential investors are advised to exercise due care when dealing in the shares of the Company.

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 realized 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, December 19, 2024

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.