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CStone Pharmaceuticals

基石藥業

(Incorporated in the Cayman Islands with limited liability) (Stock Code: 2616)

VOLUNTARY ANNOUNCEMENT CSTONE TO PRESENT LATEST CLINICAL DATA ON CS5001 FOR LYMPHOMA AT THE 66TH AMERICAN SOCIETY OF HEMATOLOGY (ASH) ANNUAL MEETING

CStone Pharmaceuticals (the "**Company**" or "**CStone**") is pleased to announce that the latest clinical data on CS5001, an anti-ROR1 ADC and one of the leading assets in CStone Pipeline 2.0, for lymphoma will be presented at the 66th American Society of Hematology (ASH) Annual Meeting. The ASH Annual Meeting will be held in San Diego, California, USA, from December 7 to December 10, 2024, with both in-person and virtual sessions.

- Presentation Type: Poster
- Abstract Title: Safety and Efficacy in Patients with Advanced Lymphomas from a Global Phase Ia/Ib, First-in-Human Study of CS5001, a Novel Anti-ROR1 ADC
- Publication Number: 1739
- Presentation Time: Saturday, December 7, 2024, 5:30-7:30 PM PST
- Location: San Diego Convention Center, Halls G-H

CS5001 is so far the first anti-ROR1 ADC known to show clinical anti-tumor activity in both solid tumors and lymphomas. Preliminary data from the first-in-human study presented by the Company at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting demonstrated that CS5001 is welltolerated and exhibits encouraging anti-tumor activity across various dose levels in patients with heavily pre-treated advanced solid tumors and lymphomas.

At the ASH Annual Meeting, CStone will present updated safety and efficacy data from this ongoing firstin-human CS5001 study focused on advanced B-cell lymphomas. As of the abstract data cutoff, CS5001 achieved an objective response rate (ORR) of 43.5% among all evaluable patients with advanced B-cell lymphoma across all dose levels. Starting from the initial effective dose, the Hodgkin lymphoma and the non-Hodgkin lymphoma subgroups achieved an ORR of 60.0% and 50.0%, respectively. Updated data following abstract data cutoff, including more patients with lymphoma enrolled at the preliminary recommended phase II dose (RP2D) levels, will be detailed in the poster session at the ASH Annual Meeting.

The global multicenter Phase I trial of CS5001 is actively enrolling in the United States, Australia, and China for Phase Ia dose-escalation. A Phase Ib dose-expansion study with potential for registration across multiple tumor types is expected to be initiated shortly.

About CS5001 (ROR1 ADC)

CS5001 is a clinical-stage antibody-drug conjugate ("ADC") targeting ROR1 (receptor tyrosine kinaselike 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 the toxicity problem 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 signed a licensing agreement with LigaChem 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 (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 18 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: <u>www.cstonepharma.com</u>.

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, November 6, 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.