CStone Pharmaceuticals

基石藥業

(Incorporated in the Cayman Islands with limited liability)

(**Stock Code: 2616**)

VOLUNTARY ANNOUNCEMENT
CSTONE SUBMITS CLINICAL TRIAL APPLICATION IN AUSTRALIA FOR CS5001 (ROR1 ADC) IN COMBINATION WITH FIRST-LINE STANDARD-OF-CARE FOR DLBCL

CStone Pharmaceuticals (the "**Company**" or "**CStone**") is pleased to announce the submission of a Phase Ib clinical trial application in Australia for CS5001, its ROR1-targeting antibody-drug-conjugate (ADC), in combination with first-line standard-of-care (SoC) for diffuse large B-cell lymphoma (DLBCL). CS5001 is also being evaluated as both a monotherapy and in combination with PD-L1 inhibitor for advanced solid tumors in an ongoing global multi-center clinical trial.

Key Highlights:

- Phase Ib trial to evaluate CS5001 in combination with R-CHOP (rituximab, cyclophosphamide, doxorubicin, vincristine and prednisone) as a first-line treatment for DLBCL, aiming to reshape the standard-of-care landscape.

- CS5001 is also being investigated globally in a multi-center Phase Ib clinical trial for multiple solid tumor types.

Building on the promising data from CS5001 monotherapy in later-line aggressive and indolent lymphomas, this Phase Ib trial aims to expand the therapeutic potential of ROR1 ADC across all DLBCL stages and solid tumors. The study will explore:

- CS5001 in combination with R-CHOP: First-line treatment for DLBCL patients who have not received prior systemic therapy;
- CS5001 in combination with second-line SoC: For patients with relapsed or refractory DLBCL;
- CS5001 monotherapy: Targeting ROR1-expressing solid tumors;
- CS5001 in combination with sugemalimab: Combination therapy for advanced solid tumors.

Dr. Jason Yang, CEO, President of R&D, and Executive Director at CStone, stated: "We are thrilled to

reach another key clinical milestone for CS5001. The existing data underscore its broad potential in both lymphomas and solid tumors. Notably, a ROR1 ADC combined with R-CHP has demonstrated an impressive complete response (CR) rate in a Phase II trial for first-line DLBCL. As we advance from late-line monotherapy to frontline combination therapy, we are optimistic that CS5001 will provide significant clinical benefits to DLBCL patients and establish itself as a first-line treatment option. Meanwhile, we continue to explore CS5001's potential in solid tumors and eagerly anticipate further positive outcomes."

The global multi-center Phase Ib trial for CS5001 is actively enrolling patients across the United States, Australia, and China. Recruitment is ongoing for monotherapy cohorts targeting aggressive and indolent advanced lymphomas, which could potentially expand into a Phase II single-arm registrational study. Additional cohorts, including the first-line DLBCL combination therapy and solid tumor monotherapy and combination therapy arms, will be initiated soon.

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 the 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. These indicate that CS5001 has great development potential and precision treatment prospect in both hematologic tumors and malignant solid tumors. Additionally, CS5001 utilizes site-specific conjugation for a precise drug antibody ratio (DAR) 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. CS5001 was originally generated by collaboration of LCB and ABL Bio, both leading biotech companies in South Korea. Under 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.

CS5001 has demonstrated encouraging safety and robust anti-tumor activity in the Phase 1a dose escalation trials across 10 dose levels.

- At the tentative recommended Phase 2 dose (RP2D) of DL8 (125 μg/kg), CS5001 achieved objective response rates (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.
- CS5001 was well tolerated in heavily pre-treated patients with advanced B-cell lymphomas and solid tumors.

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 16 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, March 6, 2025

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, Mr. Hongbin Sun and Ms. Yip Betty Ho as independent non-executive directors.