CStone Pharmaceuticals

基石藥業

(Incorporated in the Cayman Islands with limited liability)

(**Stock Code: 2616**)

VOLUNTARY ANNOUNCEMENT
CSTONE'S STRATEGIC PARTNER HENGRUI INITIATES A PHASE III CLINICAL TRIAL OF ANTI-CTLA-4-BASED COMBINATION THERAPY AS FIRST-LINE TREATMENT FOR ADVANCED HEPATOCELLULAR CARCINOMA

CStone Pharmaceuticals (the "**Company**" or "**CStone**") is pleased to announce that its strategic partner, Jiangsu Hengrui Pharmaceuticals Co., Ltd. ("**Hengrui**") has recently initiated a Phase III clinical study of CS1002/SHR-8068 (anti-**CTLA-4** monoclonal antibody) in combination with adebrelimab and bevacizumab for the first-line treatment of advanced hepatocellular carcinoma (HCC).

The study aims to evaluate the efficacy of CS1002/SHR-8068 in combination with adebrelimab (anti-PD-L1 monoclonal antibody) and bevacizumab (experimental group) versus sintilimab (anti-PD-1 monoclonal antibody) combined with bevacizumab (control group) in first-line treatment of advanced HCC patients, by assessing objective response rates (ORR) and overall survival (OS).

CS1002 is an investigational anti-CTLA-4 monoclonal antibody developed by CStone. CS1002 is differentiated from prior CTLA-4 targeting drug in its dosing schedules that have been tested in early development and the encouraging efficacy and safety in three indications providing proof-of-concept for CS1002 as a potential backbone for IO combinations. CTLA-4 is a transmembrane protein encoded by the CTLA-4 gene that can down-regulate the activity of T cells when binding with its ligand, B7.1/B7.2, a pathway also used by tumor cells to avoid T lymphocyte attack. Consequently, blockade of the CTLA-4 pathway can stimulate T cell activation and proliferation to induce or enhance anti-tumor immune responses. CTLA-4 provides a new immuno-therapeutic approach to a number of human cancers.

In November 2021, CStone and Hengrui entered into a strategic partnership and exclusive licensing agreement on CS1002 in the Greater China region. Under the terms of the agreement, CStone is eligible for an upfront payment and potential milestone payments up to approximately US$200 million in addition to double-digit royalties. Hengrui has obtained the exclusive rights for research, development, registration, manufacturing, and commercialization of CS1002 in Greater China. CStone retains the rights to develop

and commercialize CS1002 outside of Greater China.

In February 2024, safety and efficacy data from the first-in-human study of CS1002 as monotherapy and in combination with nofazinlimab/CS1003 (anti-PD-1 monoclonal antibody) for advanced/metastatic solid tumors was published in the journal *Cancer*. The results showed that CS1002, either as monotherapy or in combination with nofazinlimab, demonstrated good tolerability and safety. Preliminary efficacy data also provided strong clinical evidence supporting further development of CS1002-based combination therapies.

In addition to the Phase III study for HCC, in January 2024, Hengrui received an IND approval from the NMPA for evaluating CS1002/SHR-8068 in combination with adebrelimab and chemotherapy as the first-line treatment of patients with advanced or metastatic non-squamous non-small cell lung cancer.

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 15 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 CS1002/SHR-8068 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, October 2, 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.