**CStone Pharmaceuticals**
**基石藥業**
*(Incorporated in the Cayman Islands with limited liability)*
**(Stock Code: 2616)**

# VOLUNTARY ANNOUNCEMENT
# NMPA IND APPROVAL FOR CS5007 (EGFR/HER3 BISPECIFIC ADC) IN CHINA

This announcement is made by CStone Pharmaceuticals (the "**Company**," together with its subsidiaries, collectively referred to as the "**Group**" or "**CStone**") on a voluntary basis for the purpose of keeping the shareholders of the Company and potential investors abreast of the latest business development of the Group.

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CStone today announced that the Investigational New Drug (IND) application for CS5007, one of its Pipeline 2.0 core assets and an EGFR/HER3 bispecific antibody-drug conjugate (ADC), has been rapidly approved by the China National Medical Products Administration (NMPA) through approval pathway for innovative drug clinical trials, with the entire process completed in just 23 working days. This milestone reflects the clinical and regulatory teams' deep policy expertise, proactive alignment with authorities and forward-looking strategic planning under the current regulatory framework. It also constitutes regulatory endorsement of the molecule's early R&D data and clinical development plan, laying a solid foundation for subsequent trials. The global multicenter Phase I clinical study of CS5007 was initiated in Australia in June 2026, with the first patient successfully enrolled, and to be conducted in parallel in China.

Dr. Jason Yang, CEO, President of R&D, and Executive Director at CStone, commented, "The IND approval for CS5007 in China marks another important milestone in the execution of our Pipeline 2.0 strategy. Following the initiation of its global Phase I study in Australia in June 2026, the China NMPA approval further demonstrates the efficiency of CStone's integrated global development model, enabling the parallel advancement of innovative programs across multiple regions. It also reinforces the strength and sustainability of our proprietary ADC platform as a proven engine for innovation. Leveraging our in-house R&D capabilities and globally integrated development strategy, we will continue to advance multiple next-generation ADC programs worldwide, unlock the full value of our pipeline, and bring innovative treatment options to patients around the world."

Dr. Qingmei Shi, Chief Medical Officer of CStone, added, "EGFR and HER3 are frequently co-expressed across a broad range of epithelial-derived solid tumors, and HER3-mediated compensatory signaling has been recognized as a key driver of resistance to EGFR-targeted therapies, representing a significant unmet medical need. As a differentiated EGFR/HER3 bispecific ADC, CS5007 features a rationally designed, unique molecular construct that simultaneously targets both pathways. It is designed to overcome acquired resistance to EGFR-targeted therapies while delivering anti-tumor activity with a favorable safety profile. With Phase I clinical studies approved in both Australia and China, we are accelerating the global multicenter clinical development of CS5007 to comprehensively evaluate its safety, tolerability, pharmacokinetic and pharmacodynamic (PK/PD) characteristics, and preliminary antitumor activity. We look forward to advancing this innovative ADC candidate and exploring its potential of being a new treatment option for patients worldwide."

**About the global multicenter Phase I clinical trial of CS5007**

This global, multicenter Phase I clinical trial of CS5007 is a first-in-human study comprising dose-escalation and dose-expansion cohorts evaluating CS5007 monotherapy in patients with advanced solid tumors whose disease has progressed following standard therapies, who are ineligible for standard treatment, or for whom no effective treatment options are available. The study is designed to evaluate the safety, tolerability, PK/PD characteristics, and preliminary antitumor activity of CS5007, and to establish the recommended Phase II dose (RP2D). Approximately 310 patients are expected to be enrolled. The trial is being conducted concurrently in Australia and China to accelerate its global development.

**About CStone**

CStone (HKEX: 2616), established in late 2015, is an innovation-driven biopharmaceutical company focused on the research and development of therapies for oncology, immunology, inflammation, and other key disease areas. 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 21 new drug applications covering 9 indications. The Company's pipeline is balanced by 16 promising candidates, featuring 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 Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited:** THE COMPANY CANNOT GUARANTEE THAT WE MAY BE ABLE TO ULTIMATELY DEVELOP AND MARKET CS5007 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, August 21, 2026

*As at the date of this announcement, the Board comprises Dr. Wei Li as Chairman and non-executive director, Dr. Jianxin Yang as executive director, Mr. Kenneth Walton Hitchner III and Mr. Edward Hu as non-executive directors, and Mr. Kenneth Howard Jarrett, Ms. Fang Xie and Ms. Catherine Yen as independent non-executive directors.*