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CStone Pharmaceuticals

基石藥業

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

VOLUNTARY ANNOUNCEMENT

CSTONE ANNOUNCES THE INITIATION OF GLOBAL PHASE I TRIAL OF CS5007 (EGFR/HER3 BISPECIFIC ADC)

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 its potential investors abreast of the latest business development of the Group.

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CStone today announced that the global multicenter Phase I clinical trial of its Pipeline 2.0 core candidate CS5007 (an EGFR/HER3 bispecific antibody-drug conjugate [ADC]) has received ethics approval from the Australian Human Research Ethics Committee (HREC). This milestone not only marks the initiation of global clinical development of CS5007 but also underscores that the Company’s Pipeline 2.0 strategy is accelerating into delivery, with follow-on heavyweight assets advancing into the clinic and poised to reinforce confidence in CStone’s mid- to long-term growth.

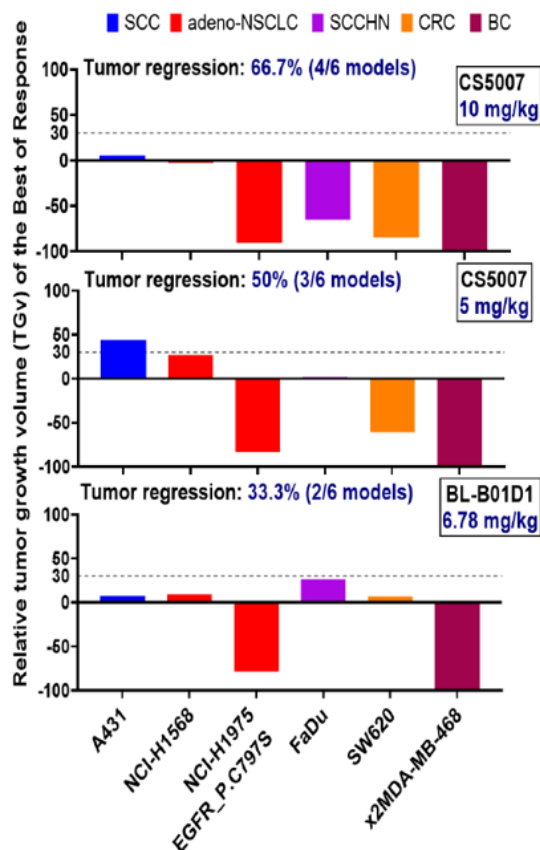
Dr. Jason Yang, CEO, President of R&D, and Executive Director at CStone, commented, “The initiation of the global Phase I trial of CS5007 represents another important milestone in our Pipeline 2.0. It once again validates the innovative depth and global competitiveness of our proprietary ADC platform and sends a clear signal: CStone’s next-generation innovative pipeline is rapidly transitioning from technology accumulation into clinical execution, with follow-on assets accelerating and building strong momentum. Amid near-term capital market volatility, the Company is steadily carving out a differentiated position through our robust proprietary platform, well-prioritized pipeline, and clear path to globalization. With its differentiated EGFR/HER3 bispecific design and compelling preclinical data, CS5007 aims to directly address two core challenges in the treatment of advanced solid tumors: drug resistance and tumor heterogeneity. We believe CS5007 has the potential to become a best-in-class innovative ADC in this setting. Moving forward, CStone will remain focused on clinical value, accelerate the global development of our innovative pipeline, and stay fully committed to delivering transformative therapies to patients while creating long-term returns for investors.”

Dr. Qingmei Shi, Chief Medical Officer of CStone, added, "CS5007 stands out as a highly representative and important oncology asset within CStone's Pipeline 2.0. By simultaneously targeting both the EGFR and HER3 signaling pathways, CS5007 has the potential to overcome the limitations of conventional single-target therapies, achieving more comprehensive and sustained pathway inhibition, which in turn could translate into deeper and more durable antitumor activity across a broad range of solid tumors. Notably, CS5007 employs a highly potent, clinically validated topoisomerase I inhibitor payload and has demonstrated a significant bystander effect, which may further broaden its therapeutic potential to tumors with heterogeneous antigen expression. The encouraging preclinical efficacy and safety profile of CS5007 provides a strong scientific foundation for the upcoming clinical program. With the initiation of this global first-in-human Phase I study, we will systematically evaluate the safety, pharmacokinetic/pharmacodynamic (PK/PD) profile, and preliminary antitumor activity of CS5007 in patients with advanced solid tumors, generating robust data to guide future development decisions."

CStone's Proprietary ADC Platform Enables Best-in-Class Potential

Built on CStone's in-house proprietary ADC technology platform, CS5007 comprises an anti-EGFR/HER3 human IgG1 bispecific antibody, CStone's proprietary hydrophilic CSL20 linker and the clinically validated topoisomerase I inhibitor exatecan as the payload. This design ensures an excellent combination of plasma stability, precise tumor-targeted payload release, and a manageable safety profile, effectively reducing the risk of off-target toxicity. As a bispecific ADC, CS5007 is designed to simultaneously target and block both the EGFR and HER3 pathways, offering a mechanistic solution to the common challenge of resistance seen with single-target EGFR therapies.

In April 2026, preclinical data presented by CStone at the American Association for Cancer Research (AACR) Annual Meeting further demonstrated that CS5007 possesses broad-spectrum antitumor activity, inhibiting tumor growth in cell line-derived xenograft (CDX) models derived from multiple tumor types, including non-small cell lung cancer (NSCLC), colorectal cancer (CRC), breast cancer (BC), squamous cell carcinoma of the head and neck (SCCHN), and squamous cell carcinoma (SCC). Moreover, clear efficacy signals were observed in challenging models including osimertinib-resistant and EGFR-low-expressing tumors.



Notes: 1) BL-B01D1 is a biosimilar synthesized by MCE. 2) The dose of BL-B01D1 (6.78 mg/kg) was determined as the dose level providing molar-equivalent payload carried by 10 mg/kg CS5007. With the exception of FaDu model, BL-B01D1 was given 5 mg/kg single dose. 3) Relative tumor growth volume (TGv, %) was calculated according to the following equation: $TGv (\%) = 100 \times (T_i - T_0)/T_0$, and if not, $TGv (\%) = 100 \times (T_i - T_0)/(V_i - V_0)$. 4) The presented data is the summarized best of response after the 1st cycle treatment (7 days).

About the global multicenter Phase I clinical trial of CS5007

The newly initiated global multicenter Phase I clinical trial 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, pharmacokinetics, and preliminary antitumor activity of CS5007, while establishing 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 its 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, June 12, 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.