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

VOLUNTARY ANNOUNCEMENT
CSTONE UPDATED CLINICAL PROGRESS AND KEY PHASE I/II DATA FOR CS2009 (PD-1/VEGF/CTLA-4 TRISPECIFIC ANTIBODY)

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 encouraging clinical progress for CS2009, a novel PD-1/VEGF/CTLA-4 trispecific antibody self-developed by the Company.

Key Highlights:

- Excellent Safety Profile: As of mid-March 2026, 113 heavily pretreated patients with solid tumors have been enrolled in the Phase I trial of CS2009, with a median follow-up of approximately 6 months. The more mature data continue to show a favorable safety profile, with 23% incidence of Grade ≥3 Treatment-Related Adverse Events (TRAEs). No excessive toxicities that typically occurred in combination therapies containing CTLA-4 and PD-(L)1 were observed, and the incidence of Grade ≥3 VEGF-related AEs was low.

- Compelling Efficacy in Lung Cancer: CS2009 monotherapy demonstrates potentially transformative Phase I/II efficacy in Non-Small Cell Lung Cancer (NSCLC). In first-line NSCLC (PD-L1 tumor proportion score [TPS]≥50%), the overall response rate (ORR) reached 90%, with a disease control rate (DCR) of 100%. In immuno-oncology (IO)-pretreated, AGA negative second-/later-line NSCLC, ORR reached 25%.

- Broad Antitumor Potential: Including in "Cold Tumors": CS2009 monotherapy also demonstrates potent antitumor activity in later-line "cold" tumors that are not sensitive to PD-(L)1 mAb. An ORR of 40% was observed in patients with non-clear cell renal cell carcinoma (nccRCC), and an ORR of 33.3% in soft tissue sarcoma (STS), demonstrating its broad-spectrum therapeutic potential across multiple tumor types.

- Accelerated Global Phase III Development Plan: The Company plans to initiate the first wave of Phase III global multi-regional clinical trials (MRCT) for CS2009 by the end of 2026, targeting indications including NSCLC, colorectal cancer (CRC), and small cell lung cancer (SCLC).

- Data Presentation Plan: Updated Phase I and Phase II clinical data for CS2009 are expected to be disclosed at the 2026 American Society of Clinical Oncology (ASCO) Annual Meeting and/or the European Society for Medical Oncology (ESMO) Congress.

Rapid Patient Enrollment with Phase I/II Data Supporting Favorable Safety and Efficacy

The global multi-center Phase I/II clinical trial for CS2009 is actively ongoing in Australia and China, and its Investigational New Drug (IND) application for Phase II has been approved by the U.S. Food and Drug Administration (FDA). As of mid-March 2026, a total of 113 patients with advanced solid tumors have been enrolled in Phase I, with a median follow-up of approximately six months. 85 patients have been enrolled in Phase II.

1. Phase I Data Reinforces an Excellent Safety Profile:

- CS2009 demonstrates a favorable safety and tolerability profile across all six dose levels evaluated, with no dose-limiting toxicities (DLTs) observed and the maximum tolerated dose (MTD) not reached.

- The incidence of Grade ≥3 TRAEs was 23%; Grade ≥3 immune-related adverse events (irAEs) was 12.4%; and Grade ≥3 VEGF-related TRAEs was 4.4%. No excessive toxicities that typically occurred in combination therapies containing CTLA-4 and PD-(L)1 were observed.

n (%)	All DLs (N=113)	DL1-3 1/3/10 mg/kg, Q3W (n=21)	DL4 20 mg/kg, Q3W (n=33)	DL5 30 mg/kg, Q3W (n=49)	DL6 45 mg/kg, Q3W (n=10)
No. of patients with ≥1 following event					
Treatment-emergent adverse event (TEAE)	102 (90.3%)	21 (100.0%)	30 (90.9%)	42 (85.7%)	9 (90.0%)
Grade ≥3 TEAE	48 (42.5%)	11 (52.4%)	15 (45.5%)	18 (36.7%)	4 (40.0%)
Treatment-related TEAE (TRAE)	88 (77.9%)	18 (85.7%)	25 (75.8%)	36 (73.5%)	9 (90.0%)
Grade ≥3 TRAE	**26 (23.0%)**	6 (28.6%)	7 (21.2%)	11 (22.4%)	2 (20.0%)
Serious TEAE	47 (41.6%)	9 (42.9%)	14 (42.4%)	20 (40.8%)	4 (40.0%)
Treatment-related serious TEAE	25 (22.1%)	2 (9.5%)	8 (24.2%)	11 (22.4%)	4 (40.0%)
Immune-related TEAE	45 (39.8%)	9 (42.9%)	18 (54.5%)	16 (32.7%)	2 (20.0%)
Grade ≥3 immune-related TEAE	**14 (12.4%)**	3 (14.3%)	6 (18.2%)	5 (10.2%)	0
VEGF-related TRAE	23 (20.4%)	4 (19.0%)	11 (33.3%)	7 (14.3%)	1 (10.0%)
Grade ≥3 VEGF-related TRAE	**5 (4.4%)**	2 (9.5%)	1 (3.0%)	2 (4.1%)	0
Infusion-related reaction	4 (3.5%)	0	1 (3.0%)	1 (2.0%)	2 (20.0%)
TEAE leading to drug withdraw	9 (8.0%)	1 (4.8%)	3 (9.1%)	5 (10.2%)	0

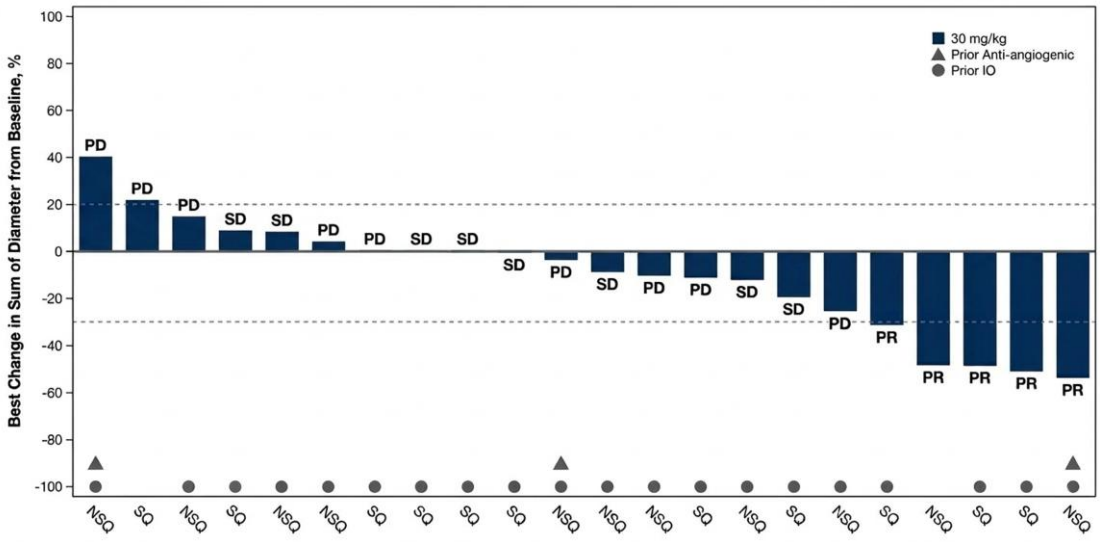
*Abbreviations: DL=Dose Level; Q3W=once every 3 weeks; TEAE=Treatment-Emergent Adverse Event; TRAE=Treatment-Related Adverse Event; irAE=Immune-Related Adverse Event

2. Broad Antitumor Activity Observed in IO-Pretreated Tumors and "Cold Tumors":

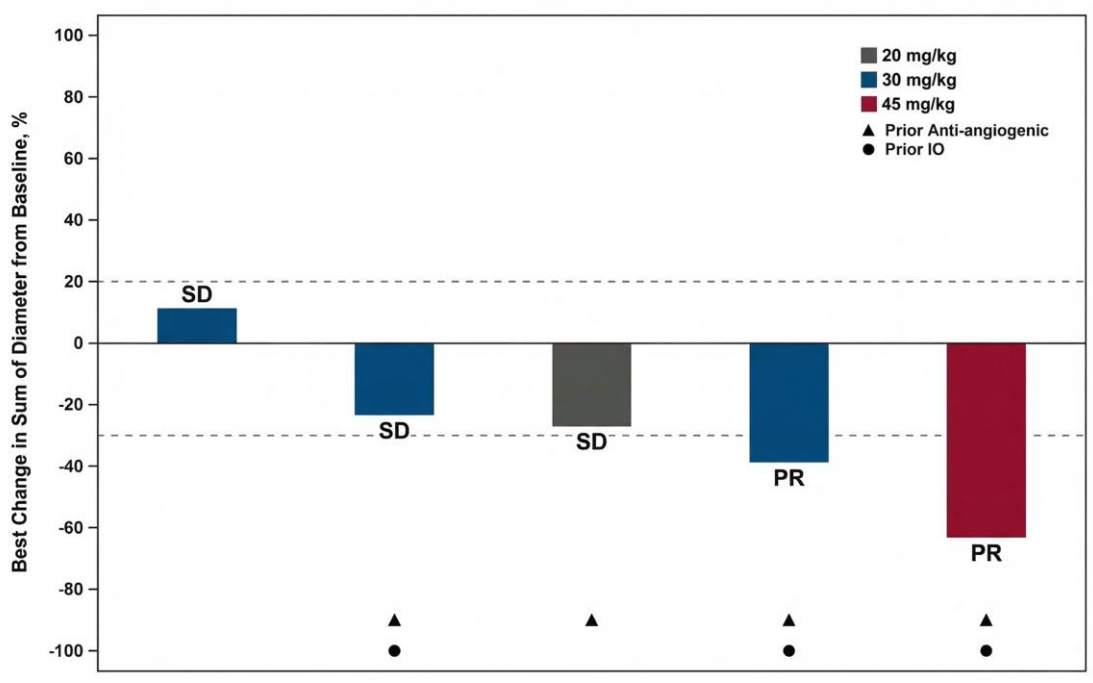
Antitumor activity was observed across all dose levels, with robust efficacy signals in multiple tumor types.

- At the 30 mg/kg, Q3W, CS2009 monotherapy achieved an ORR of 25% (6/24) and a DCR of 58.3% (14/24)

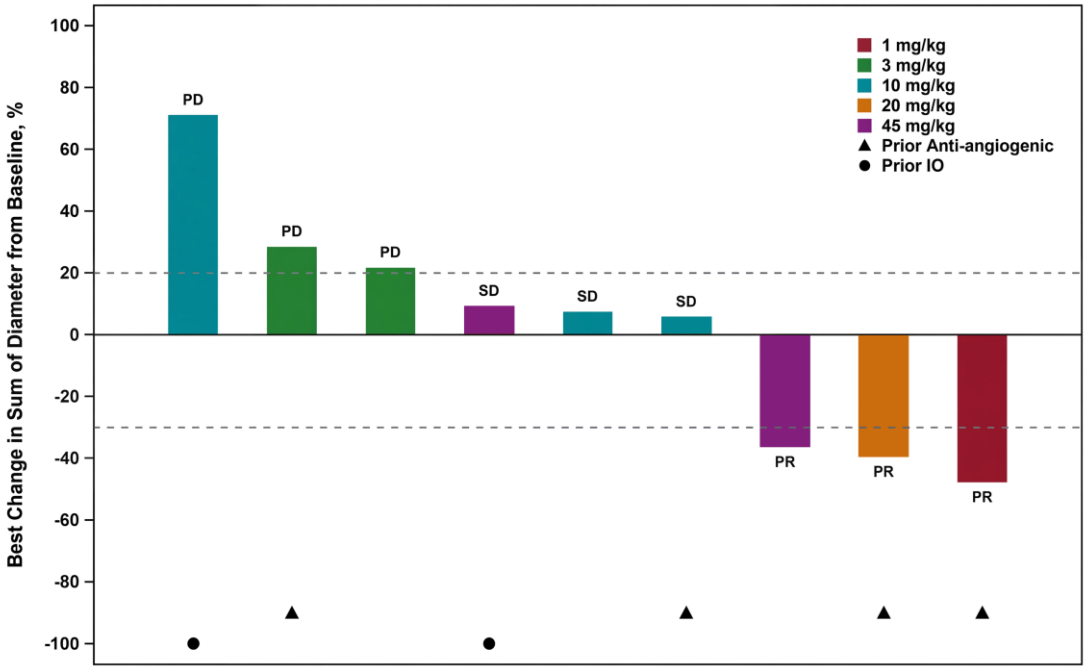
in IO-pretreated, AGA-negative second-/later-line NSCLC patients.



- Across dose levels, CS2009 monotherapy resulted in an ORR of 40% and a DCR of 100% in patients with nccRCC (n=5):



- Across dose levels, CS2009 monotherapy resulted in an ORR of 33.3% and a DCR of 66.7% in patients with STS (n=9):

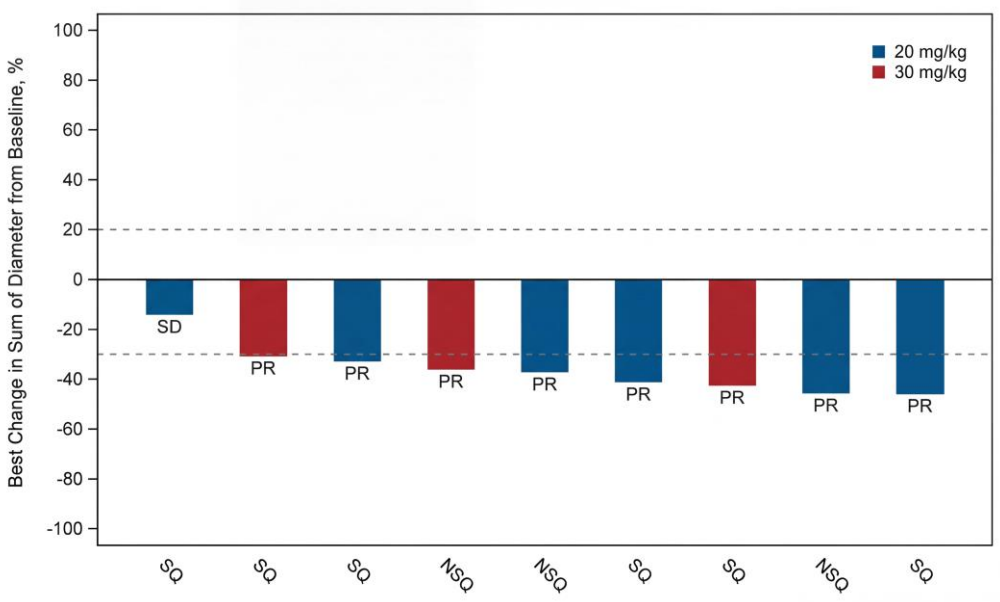


Initial Phase II Data demonstrated transformative efficacy potential and excellent tolerability in combination with standard cares of chemotherapy in 1L NSCLC and 1L CRC

The global multi-center Phase II clinical trial employs a multi-cohort parallel expansion design to evaluate the efficacy and safety of CS2009 monotherapy and combination therapy across 15 cohorts in 9 solid tumor types, including NSCLC, colorectal cancer (CRC), extensive-stage small cell lung cancer (ES-SCLC), cervical cancer (CC), gastric or gastroesophageal junction cancer (GC/GEJC), esophageal squamous cell carcinoma (ESCC), platinum-resistant ovarian cancer (PROC), triple-negative breast cancer (TNBC), and hepatocellular carcinoma (HCC).

1. Monotherapy Shows Striking Efficacy in first-line NSCLC:

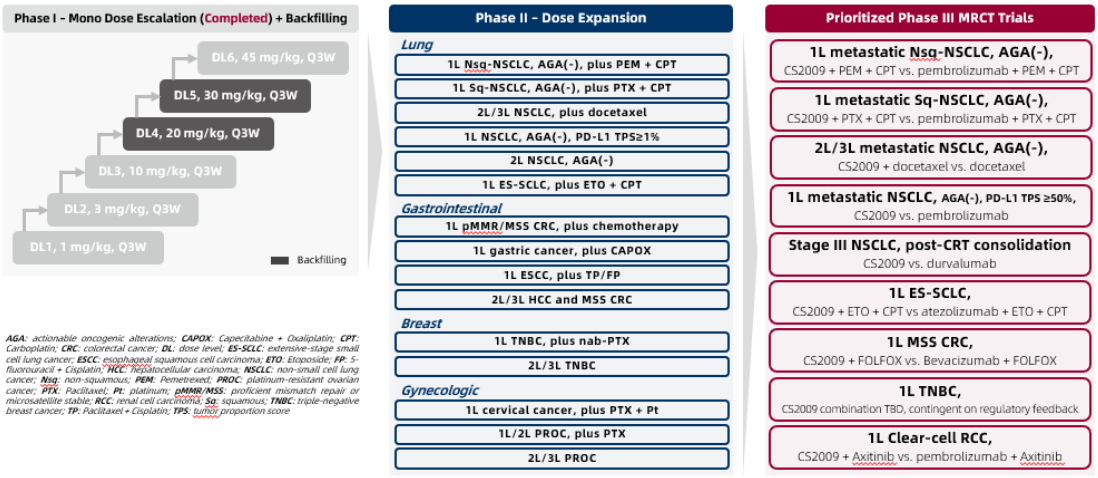
CS2009 monotherapy (20 mg/30 mg, Q3W) achieved an ORR of 90% (9/10) and a DCR of 100% (10/10) in first-line NSCLC patients with PD-L1 TPS≥50% (n=9).



2. Combination Therapies Demonstrate Favorable Tolerability and Promising Efficacy:

Safety data from multiple cohorts of CS2009 combined with standard chemotherapy showed that the combinations were well-tolerated across tumor types, with CS2009 without increasing the incidence or severity of chemotherapy-related adverse events. Initial potent antitumor activity were observed in combo treatment in first-line NSCLC and first-line CRC.

Efficient and Clearly-Defined Global Development Strategy



CStone plans to initiate the first set of Phase III global MRCTs for CS2009 by the end of 2026, focusing on indications including NSCLC, colorectal cancer, and small cell lung cancer.

Additional Phase I and Phase II clinical data for CS2009 are expected to be presented at the 2026 ASCO and/or ESMO Annual Meetings.

About CS2009 (PD-1/VEGF/CTLA-4 Trispecific Antibody)

CS2009, an innovative trispecific antibody designed and developed by CStone, with the potential to be first- or best-in-class. It combines three clinically validated targets—PD-1, VEGFA, and CTLA-4—and exerts multidimensional antitumor effects through synergistic actions. Specifically, anti-PD-1 activity reverses T cell exhaustion, anti-CTLA-4 activity promotes T cell activation and proliferation, while anti-VEGFA activity blocks tumor angiogenesis and improves the tumor micro-environment (TME). In the TME, anti-PD-1 and anti-CTLA-4 activities are significantly enhanced by crosslinking with VEGFA. Meanwhile, CS2009 preferentially blocks PD-1 and CTLA-4 on double-positive tumor-infiltrating T cells while minimizing interference with CTLA-4 regulation in peripheral T cells.

About CStone Pharmaceuticals

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 CS2009 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 26, 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.