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

VOLUNTARY ANNOUNCEMENT
ASCO 2026 | CSTONE PRESENTS LATEST CS2009 (PD-1/VEGF/CTLA-4 TRISPECIFIC ANTIBODY) CLINICAL DATA

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 multiple key clinical updates for its core asset CS2009 (a PD-1/VEGF/CTLA-4 trispecific antibody) were presented in two posters at the American Society of Clinical Oncology (ASCO) Annual Meeting, covering Phase I/II clinical data in first-line and later-line Non-Small Cell Lung Cancer (NSCLC) and Colorectal Cancer (CRC) patients, as well as mature Phase I data from longer follow-up in patients with advanced solid tumors.

Key Highlights:

- First-line NSCLC – Compelling Activity Across All PD-L1 Subgroups

  In first-line NSCLC patients with high PD-L1 expression (TPS ≥50%), CS2009 monotherapy achieved an objective response rate (ORR) of 81.3% and a disease control rate (DCR) of 100.0%, with consistent benefit across squamous (ORR: 87.5%) and non-squamous (ORR: 75.0%) histologies. In the PD-L1-negative/low population (TPS ≤5%) squamous NSCLC cohort, CS2009 in combination with chemotherapy achieved an ORR of 75.0% and a DCR of 100.0%; notably, PD-L1-negative patients within this cohort achieved an ORR of 100.0%; the current efficacy readout remains immature due to the short follow-up for most patients in this cohort.

- Later-line NSCLC – Potential to Overcome Immunotherapy Resistance

In heavily pretreated later-line NSCLC, CS2009 demonstrated encouraging antitumor activity, with most patients experiencing sustained tumor shrinkage. Across all dose levels, the 6-month duration of response (DOR) rate reached 85.7%. In the second-/third-line combination cohort, CS2009 achieved an ORR of 66.7% and a DCR of 100.0%. In the 30 mg/kg monotherapy cohort, patients whose disease had progressed following prior immunotherapy (IO) plus platinum-based chemotherapy —— a setting with significant unmet medical need—achieved an ORR of 30.8% and a DCR of 84.6%.

- "Cold Tumors" – Meaningful Activity in Immunotherapy-Refractory Settings

  In "cold tumors" with limited immunotherapy responsiveness, CS2009 monotherapy produced a 25.0% ORR and an 87.5% DCR in heavily pretreated proficient mismatch repair/microsatellite stable metastatic colorectal cancer (pMMR/MSS mCRC). A 66.7% ORR and 100.0% DCR were observed when CS2009 was combined with XELOX in first-line mCRC. The current efficacy readout remains immature due to the short follow-up for most patients in these two CRC cohorts. Additional monotherapy activity was seen in soft tissue sarcoma (STS) and non clear cell renal cell carcinoma (nccRCC) (ORR: 33.3% each), reinforcing CS2009's potential to remodel the tumor microenvironment.

- Updated Safety Data – Favorable Profile Confirmed with Longer Follow-up

  With extended follow-up since initial presentation at European Society for Medical Oncology (ESMO) Congress 2025, updated Phase I safety data further confirmed the well-tolerated profile of CS2009. Importantly, no excessive toxicities typically associated with CTLA-4/PD-(L)1 combinations observed. Among heavily pretreated patients with advanced solid tumors, Grade ≥3 treatment related adverse events (TRAE) occurred in 24.6% of patients, immune related adverse events (irAE) in 12.7% , and TRAE possibly related to anti-VEGF in 5.1%. This favorable safety profile was consistently maintained across both monotherapy and chemotherapy combination cohorts in first-line NSCLC.

- Next Step – Phase III Registrational MRCT Planned by Year-End

  The ongoing global Phase I/II trial has enrolled nearly 300 patients across China and Australia, with U.S. Investigational New Drug (IND) clearance now obtained. CStone plans to initiate the first Phase III global multi regional registrational trial (MRCT) for CS2009 by the end of 2026.

Dr. Jason Yang, CEO, President of R&D, and Executive Director at CStone, commented, "As the clinical evidence continues to mature, CS2009 has advanced beyond early mechanistic validation and preliminary efficacy exploration to deliver a compelling proof of concept (POC). We are encouraged by its consistently favorable safety profile, both as a monotherapy and in combination with chemotherapy, alongside broad antitumor activity across multiple treatment settings. CS2009 has demonstrated promising potential to address key challenges in cancer immunotherapy, including overcoming immunotherapy resistance and extending clinical benefit to tumor types that have historically shown limited responsiveness to immunotherapy. Robust antitumor activity has been observed across multiple cohorts, including both first-line and later-line NSCLC, as well as first-line and later-line pMMR/MSS mCRC. These data further validate the strength of CS2009's triple-target synergistic mechanism and support its potential to serve as a next-generation immunotherapy backbone. Importantly, the findings provide a strong foundation for our planned global Phase III registrational MRCT and reinforce our confidence that CS2009 could ultimately offer transformative treatment options for patients with lung cancer, CRC, and a broad range of solid tumors."

Key Highlights of the Poster Presentations：

Non-Small Cell Lung Cancer (NSCLC)

In the ongoing Phase I/II study, CS2009 was evaluated as monotherapy or in combination with chemotherapy in advanced NSCLC patients without actionable oncogenic alterations. A total of 108 patients were enrolled across four groups:

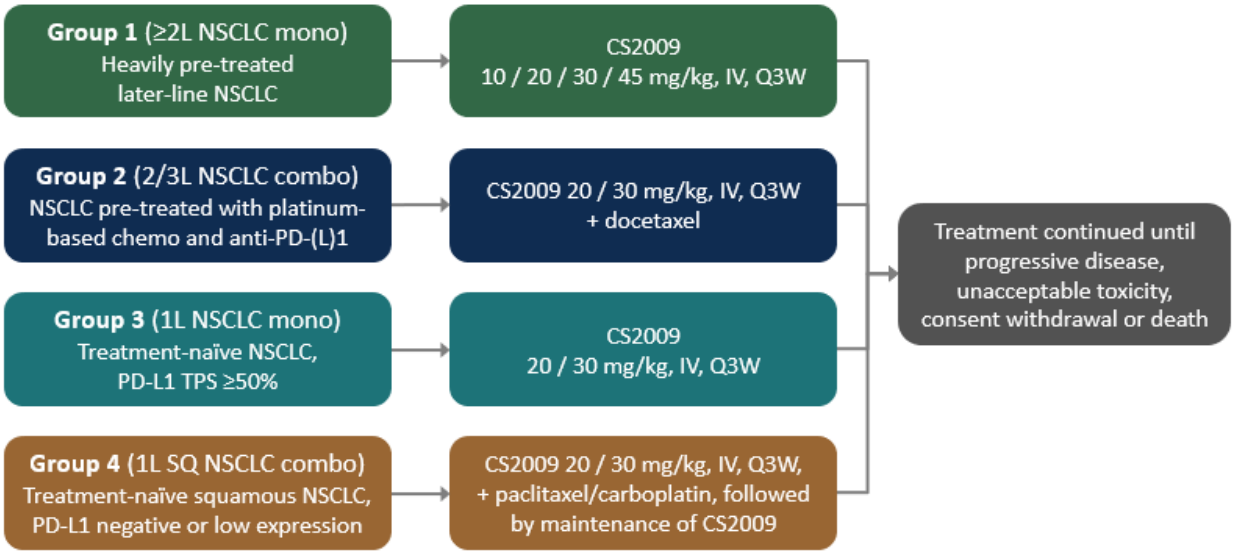
(1) Group 1 (≥2L NSCLC monotherapy), n=57: CS2009 was dosed at 10–45 mg/kg, once every 3 weeks (Q3W);

(2) Group 2 (2/3L NSCLC combination therapy), n=9: CS2009 was dosed at 20 or 30 mg/kg, Q3W plus docetaxel;

(3) Group 3 (1L NSCLC monotherapy), n=23: CS2009 was dosed at 20 or 30 mg/kg, Q3W;

(4) Group 4 (1L squamous NSCLC combination therapy), n=19: CS2009 was dosed at 20 or 30 mg/kg, Q3W plus paclitaxel/carboplatin, followed by CS2009 maintenance therapy.

Study Design



1. Baseline Patient Characteristics

In Group 1 (≥2L NSCLC monotherapy), 61.4% had received one prior line of therapy, 21.1% two lines, and 17.5% three or more lines. In Group 2 (2/3L NSCLC combination therapy), all patients had received one prior line of therapy.

Baseline Characteristics (Safety Analysis Set)

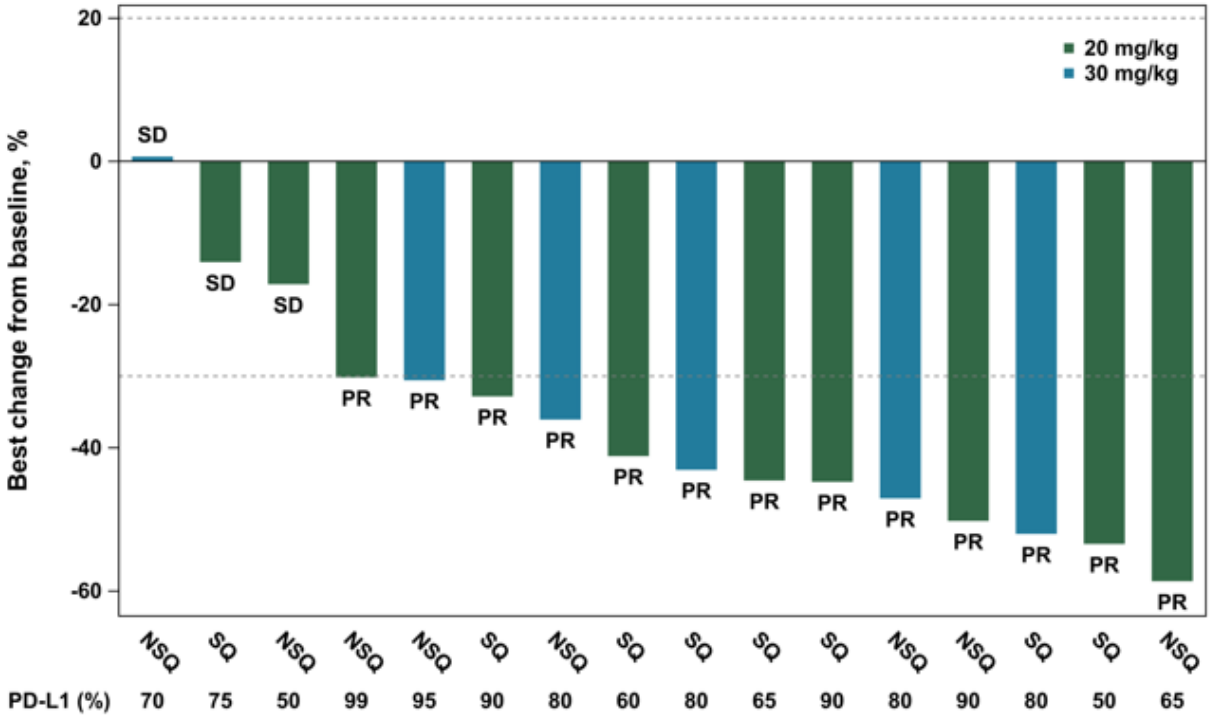
Characteristics	Group 1 ≥2L NSCLC mono (n=57)	Group 2 2/3L NSCLC combo (n=9)	Group 3 1L NSCLC mono (n=23)	Group 4 1L SQ NSCLC combo (n=19)
Age, median (range), years	67.0 (37-78)	62.0 (44-74)	69.0 (48-82)	70.0 (38-74)
Male, n (%)	43 (75.4)	8 (88.9)	21 (91.3)	15 (78.9)
Race, n (%)				
Asian	42 (73.7)	8 (88.9)	23 (100)	19 (100)
White	14 (24.6)	1 (11.1)	0	0
Other	1 (1.8)	0	0	0
ECOG PS, n (%)				
0	13 (22.8)	1 (11.1)	4 (17.4)	5 (26.3)
1	44 (77.2)	8 (88.9)	19 (82.6)	14 (73.7)
Histology type, n (%)				
Squamous	25 (43.9)	6 (66.7)	11 (47.8)	19 (100)
Non-squamous	32 (56.1)	3 (33.3)	12 (52.2)	0

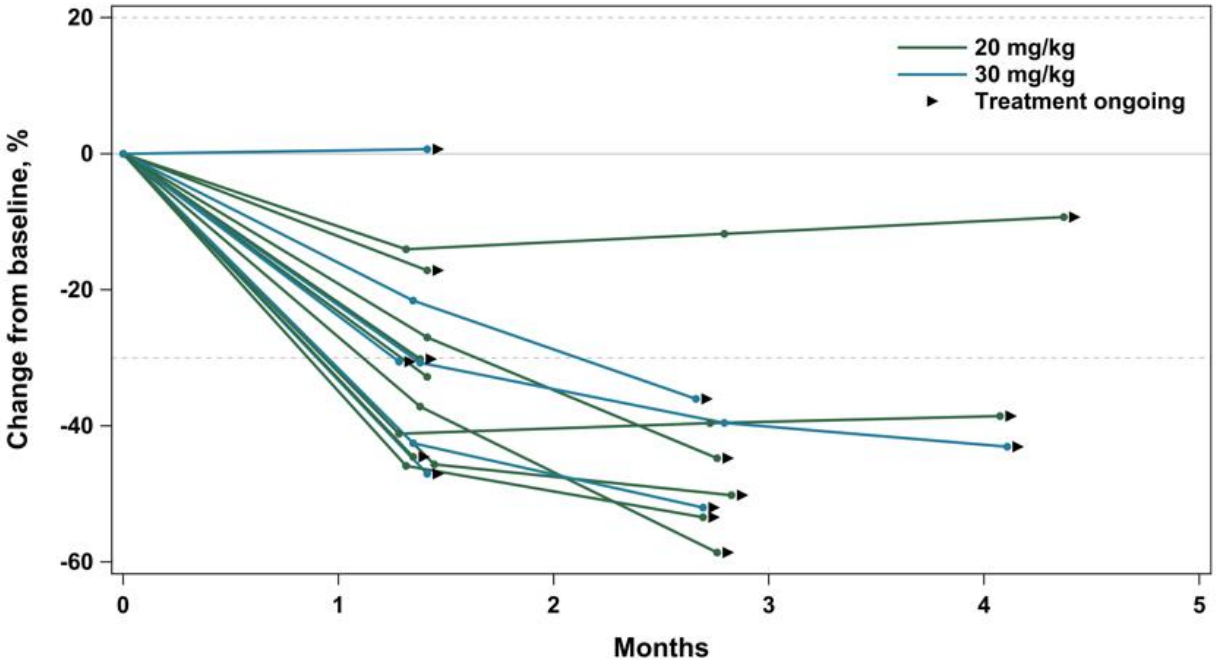
2. Robust Efficacy*

(1) Group 3 (1L NSCLC monotherapy, PD-L1 high expression TPS ≥50%, n=16):

- ORR was 81.3% (13/16) with a DCR of 100.0% (16/16); response rates were comparable in squamous (ORR: 87.5%, 7/8) and non-squamous (ORR: 75.0%, 6/8) histologies.

Change from Baseline in Target Lesions in Group 3



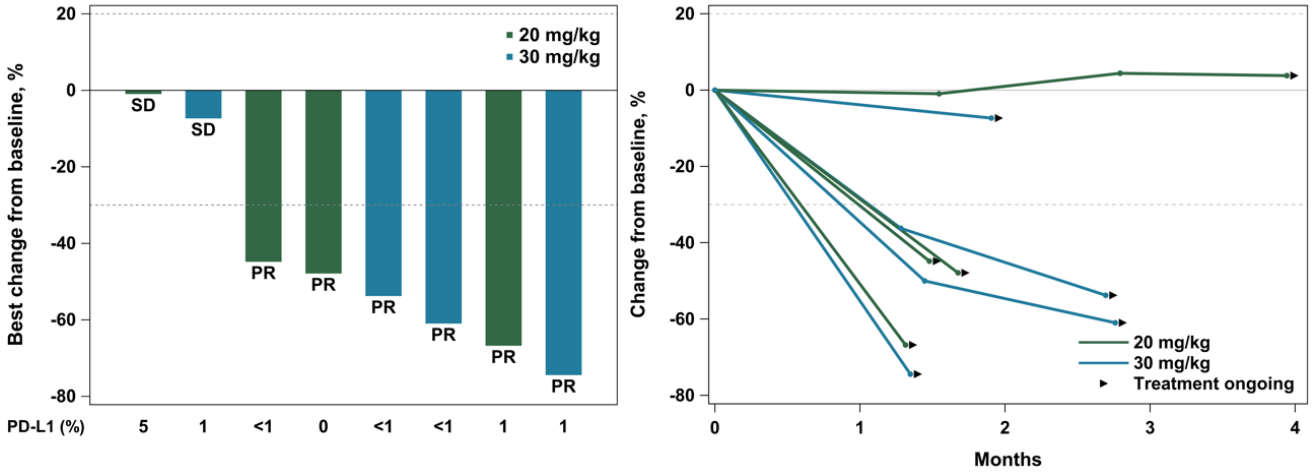


**Note: Efficacy analyses were performed only in patients who received at least one post-baseline tumor assessment. The number of such patients is less than or equal to the total number of patients enrolled in the group.*

(2) Group 4 (1L squamous NSCLC combination therapy, PD-L1 negative or low expression TPS ≤5%, n=8):

- ORR was 75.0% (6/8) and DCR 100.0% (8/8); notably, the ORR in the PD-L1 TPS<1% subgroup reached 100.0% (4/4).

Change from Baseline in Target Lesions in Group 4



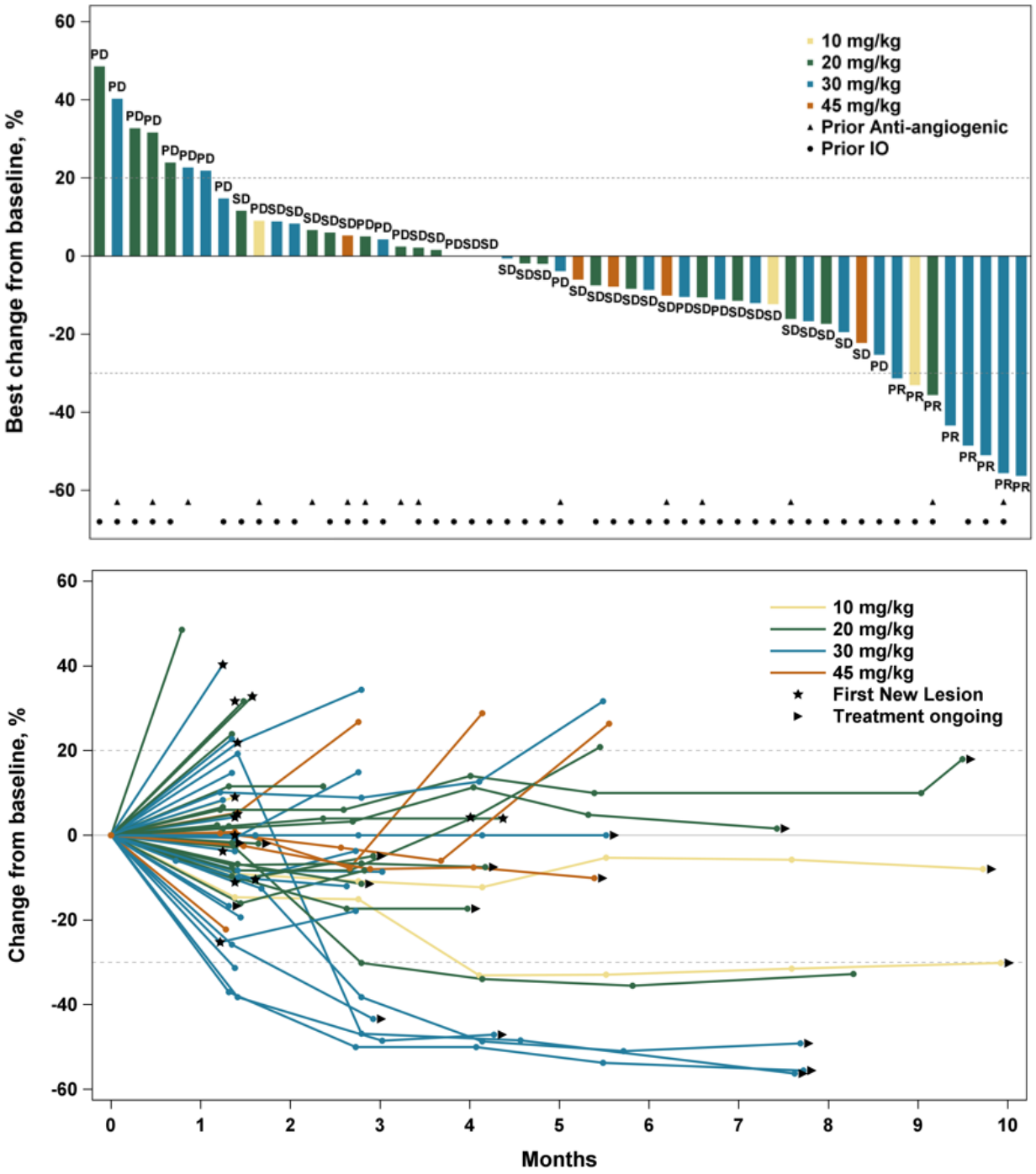
**Note: Efficacy analyses were performed only in patients who received at least one post-baseline tumor assessment. The number of such patients is less than or equal to the total number of patients enrolled in the group.*

(3) Group 1 (≥2L NSCLC monotherapy, most IO pretreated, n=54):

- Across dose levels: Most patients showed sustained tumor shrinkage; median DOR was not reached, and the 6-month DOR rate was 85.7%.
- At 30 mg/kg: ORR was 24.0% (6/25) and DCR 60.0% (15/25); median DOR was not reached, with a

6-month DOR rate of 80.0%. For patients who had received only prior immunotherapy plus platinum-doublet chemotherapy (n=13), ORR rose to 30.8% (4/13) and DCR to 84.6% (11/13).

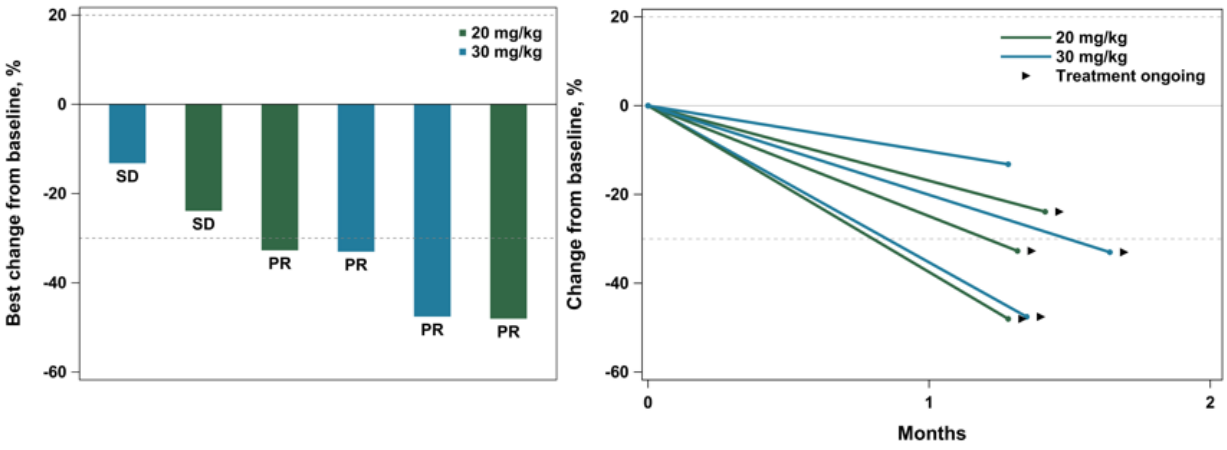
Change from Baseline in Target Lesions in Group 1



(4) Group 2 (2/3L NSCLC combination therapy, n=6):

- ORR was 66.7% (4/6), and DCR was 100% (6/6).

Change from Baseline in Target Lesions in Group 2



**Note: Efficacy analyses were performed only in patients who received at least one post-baseline tumor assessment. The number of such patients is less than or equal to the total number of patients enrolled in the group.*

3. Favorable Safety and Tolerability

(1) Group 1 (≥2L NSCLC monotherapy): The incidence of Grade ≥3 TRAE, irAE, and TRAE possibly related to anti-VEGF therapy were 19.3%, 12.3%, and 5.3%, respectively;

(2) Group 2 (2/3L NSCLC combination therapy): The incidence of Grade ≥3 TRAE was 44.4%, with no Grade ≥3 irAE or TRAE possibly related to anti-VEGF therapy observed;

(3) Group 3 (1L NSCLC monotherapy): The incidence of Grade ≥3 TRAE was only 4.3%, with no TRAE possibly related to anti-VEGF therapy observed;

(4) Group 4 (1L squamous NSCLC combination therapy): The incidence of Grade ≥3 TRAE and irAE were 26.3% and 10.5%, with no TRAE possibly related to anti-VEGF therapy observed.

Safety Summary (Safety Analysis Set)

n (%)	Group 1 ≥2L NSCLC mono (n=57)	Group 2 2/3L NSCLC combo (n=9)	Group 3 1L NSCLC mono (n=23)	Group 4 1L SQ NSCLC combo (n=19)
TEAE	54 (94.7)	4 (44.4)	17 (73.9)	13 (68.4)
Grade ≥3 TEAE	22 (38.6)	4 (44.4)	6 (26.1)	6 (31.6)
Treatment-related TEAE (TRAE)	46 (80.7)	4 (44.4)*	14 (60.9)	13 (68.4)*
Grade ≥3 TRAE	11 (19.3)	4 (44.4)*	1 (4.3)	5 (26.3)*
Immune-related TEAE (irAE)	27 (47.4)	0	2 (8.7)	5 (26.3)
Grade ≥3 irAE	7 (12.3)	0	0	2 (10.5)
TRAE possibly related to anti-VEGF	15 (26.3)	0*	2 (8.7)	1 (5.3)*
Grade ≥3 TRAE possibly related to anti-VEGF	3 (5.3)	0*	0	0*
TRAE leading to CS2009 discontinuation	6 (10.5)	1 (11.1)	0	0

Note: Safety data for Groups 2/3/4 remain preliminary due to limited follow-up.
*TRAE related to any treatment—either CS2009 or chemo.

Metastatic Colorectal Cancer (mCRC)

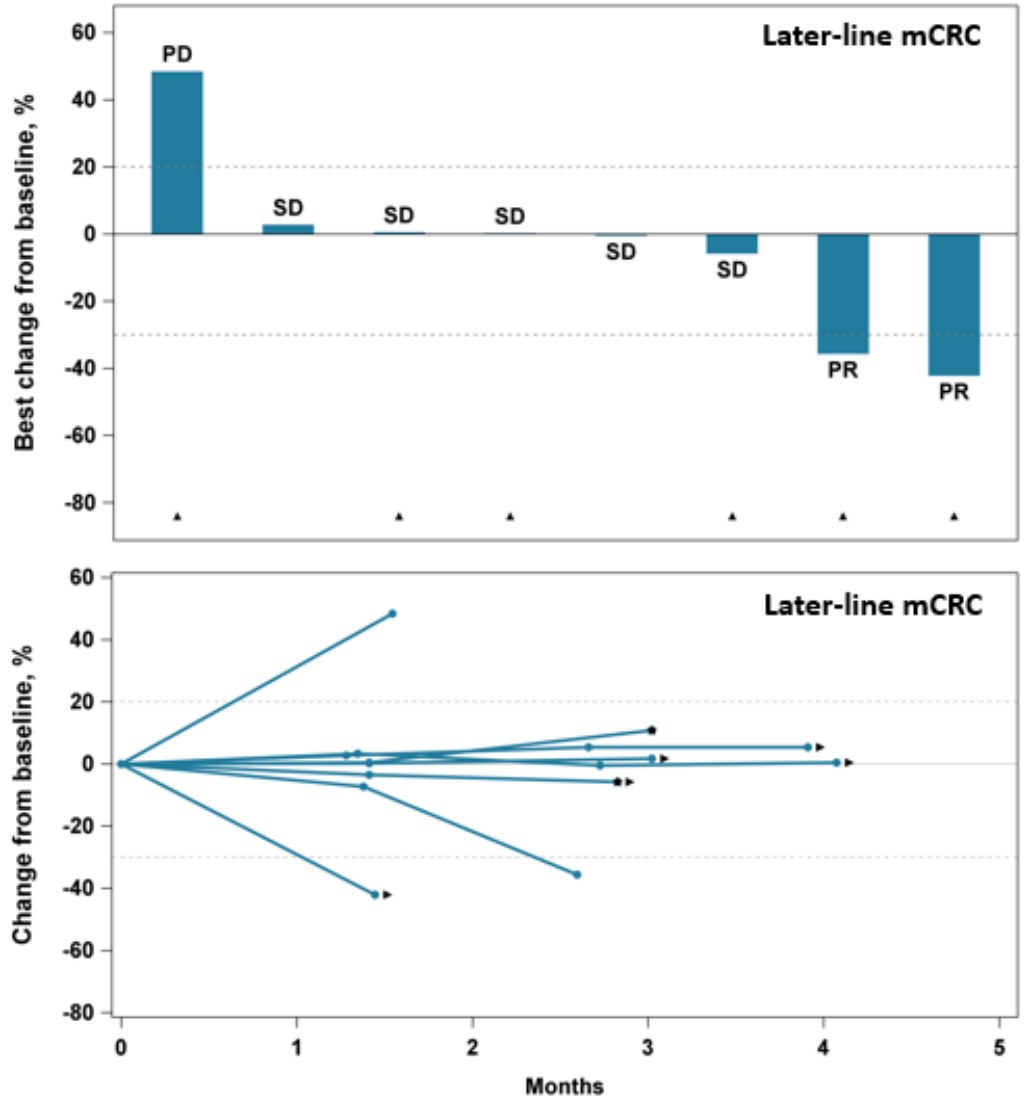
1. Later line mCRC Monotherapy Cohort: 14 heavily pretreated patients with mCRC, mostly pMMR/MSS,

received CS2009 30 mg/kg monotherapy. Among efficacy-evaluable patients (n=8), ORR was 25.0% (2/8) and DCR was 87.5% (7/8).

Baseline Characteristics in mCRC (Safety Analysis Set)

Characteristics	Later-line (n=14)	Characteristics	Later-line (n=14)
Age, years		**MSI/MMR status**, n (%)	
median (range),	61 (40-74)	pMMR/MSS	12 (85.7)
Male, n (%)	9 (64.3)	Unknown	2 (14.3)
ECOG PS, n (%)		**Liver metastases**, n (%)	8 (57.1)
1	12 (85.7)	**Prior therapy**, n (%)	
Location, n (%)		1	5 (35.7)
Left colon or rectum	11 (78.6)	2	5 (35.7)
Right colon	3 (21.4)	≥3	4 (28.6)

Change from Baseline in Target Lesions in mCRC



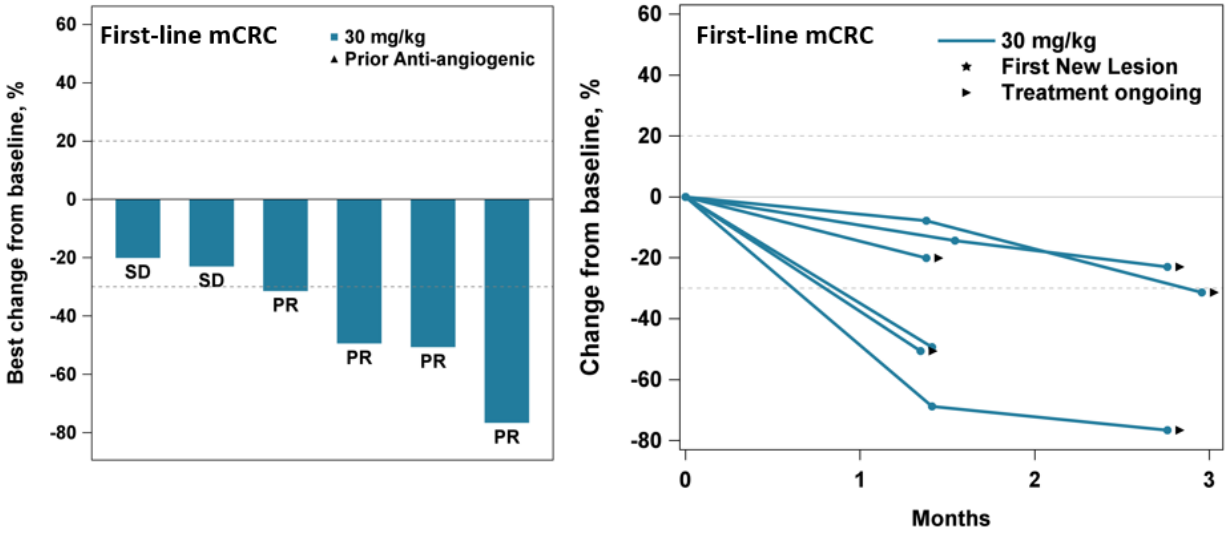
**Note: Efficacy analyses were performed only in patients who received at least one post-baseline tumor assessment. The number of such patients is less than or equal to the total number of patients enrolled in the group.*

2. 1L mCRC Combination Therapy Cohort: 14 treatment-naïve mCRC patients, mostly pMMR/MSS, received CS2009 30 mg/kg plus XELOX. Safety data showed Grade ≥3 TRAE in 14.3%, irAE in 7.1%, and TRAE possibly related to anti-VEGF in 14.3% (all grade 1–2, isolated events). In patients with at least one post-baseline tumor assessment (n=6), ORR reached 66.7% (4/6) and DCR was 100.0% (6/6).

Baseline Characteristics in mCRC (Safety Analysis Set)

Characteristics	First-line (n=14)	Characteristics	First-line (n=14)
Age, years		**MSI/MMR status**, n (%)	
median (range),	62.5 (35-75)	pMMR/MSS	13 (92.9)
Male, n (%)	11 (78.6)	Unknown	1 (7.1)
ECOG PS, n (%)		**Liver metastases**, n (%)	9 (64.3)
1	14 (100)	**Prior therapy**, n (%)	
Location, n (%)		1	-
Left colon or rectum	11 (78.6)	2	-
Right colon	3 (21.4)	≥3	-

Change from Baseline in Target Lesions in mCRC



**Note: Efficacy analyses were performed only in patients who received at least one post-baseline tumor assessment. The number of such patients is less than or equal to the total number of patients enrolled in the group.*

Phase I Dose Escalation in Advanced Solid Tumors: Safety, Efficacy, and Pharmacokinetics/Pharmacodynamics (PK/PD) Characteristics

1. Baseline Patient Characteristics

A total of 118 heavily pretreated patients with advanced solid tumors were enrolled in the dose-escalation

phase across six dose levels (1–45 mg/kg). Among them, 50.8% had prior immunotherapy and 45.8% prior anti-angiogenic therapy.

Baseline Characteristics in Phase 1 (Safety Analysis Set)

Characteristics	Total (N=118)	Characteristics	Total (N=118)	Characteristics	Total (N=118)
Age, years		**Sex**, n (%)		**Prior therapy**, n (%)	
median (range)	61 (19-80)	Female	51 (43.2)	1	46 (39.0)
Race, n (%)		Male	67 (56.8)	2	32 (27.1)
Asian	67 (56.8)	**ECOG PS**, n (%)		≥3	37 (31.4)
White	48 (40.7)	1	77 (65.3)		
Other	3 (2.5)	0	41 (34.7)		

2. Favorable Safety and Tolerability

(1) Dose escalation of CS2009 has been completed, with no Dose-Limiting Toxicities (DLTs) observed and Maximum Tolerated Dose (MTD) not reached;

(2) The incidence of Grade ≥3 TRAE, irAE, and TRAE possibly related to anti-VEGF therapy were 24.6%, 12.7%, and 5.1%, respectively. The incidence of infusion-related reactions was 4.2%, all grade 1-2 and manageable.

Safety Summary in Phase 1 (Safety Analysis Set)

n (%)	1-10 mg/kg (n=21)	20 mg/kg (n=33)	30 mg/kg (n=54)	45 mg/kg (n=10)	All DLs (N=118)
TEAE	21 (100)	31 (93.9)	45 (83.3)	10 (100)	107 (90.7)
Grade ≥3 TEAE	10 (47.6)	15 (45.5)	20 (37.0)	5 (50.0)	50 (42.4)
Treatment-related TEAE (TRAE)	18 (85.7)	27 (81.8)	39 (72.2)	10 (100)	94 (79.7)
Grade ≥3 TRAE	6 (28.6)	7 (21.2)	13 (24.1)	3 (30.0)	29 (24.6)
Immune-related TEAE	9 (42.9)	18 (54.5)	16 (29.6)	3 (30.0)	46 (39.0)
Grade ≥3 immune-related TEAE	3 (14.3)	6 (18.2)	5 (9.3)	1 (10.0)	15 (12.7)
Infusion-related reaction	1 (4.8)	1 (3.0)	1 (1.9)	2 (20.0)	5 (4.2)
TRAE possibly related to anti-VEGF	5 (23.8)	11 (33.3)	9 (16.7)	2 (20.0)	27 (22.9)
Grade ≥3 TRAE possibly related to anti-VEGF	2 (9.5)	1 (3.0)	3 (5.6)	0	6 (5.1)
TRAE leading to drug discontinuation	1 (4.8)	3 (9.1)	5 (9.3)	0	9 (7.6)

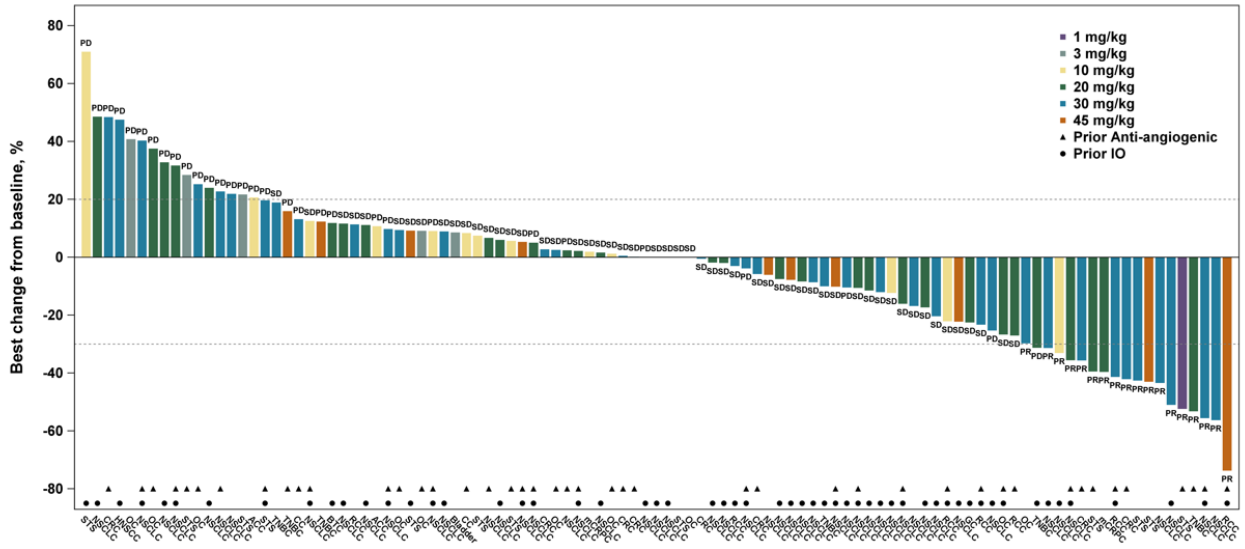
3. Overall Phase I Efficacy as Expected; Meaningful Signal in “cold tumors”

(1) In the overall efficacy-evaluable population (n=104), ORR was 17.3% (18/104) and DCR was 70.2% (73/104); median DOR was not reached, and the 6-month DOR rate was 77.4%. At 20 mg/kg and 30 mg/kg, ORRs were 13.3% (4/30) and 22.7% (10/44), respectively, with DCRs around 70%.

Best Overall Response in Phase 1

n (%)	1-10 mg/kg (n=20)	20 mg/kg (n=30)	30 mg/kg (n=44)	45 mg/kg (n=10)	All DLs (N=104)
Overall response rate (ORR)	**2 (10.0)**	**4 (13.3)**	**10 (22.7)**	**2 (20.0)**	**18 (17.3)**
Partial Response (PR)	2 (10.0)	4 (13.3)	10 (22.7)	2 (20.0)	18 (17.3)
Stable Disease (SD)	11 (55.0)	17 (56.7)	21 (47.7)	6 (60.0)	55 (52.9)
Progressive Disease (PD)	7 (35.0)	9 (30.0)	13 (29.5)	2 (20.0)	31 (29.8)
Disease control rate (DCR)	**13 (65.0)**	**21 (70.0)**	**31 (70.5)**	**8 (80.0)**	**73 (70.2)**

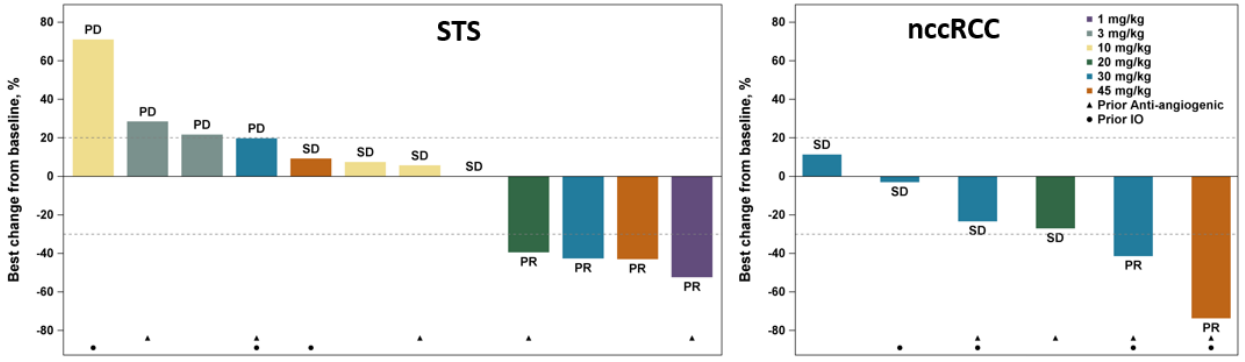
Change from Baseline in Target Lesions in Phase 1

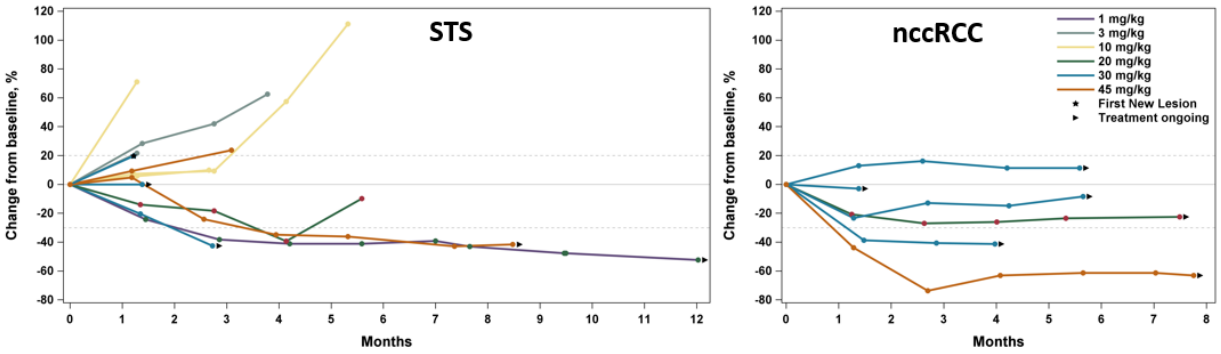


(2) In addition to CRC, CS2009 monotherapy has also demonstrated encouraging antitumor activity in later-line 'cold tumors' that are insensitive to PD-(L)1, such as STS and nccRCC:

- STS (n=12): ORR 33.3% (4/12), DCR 66.7% (8/12);
- nccRCC (n=6): ORR 33.3% (2/6), DCR 100.0% (6/6).

Change from Baseline in Target Lesions in STS and nccRCC

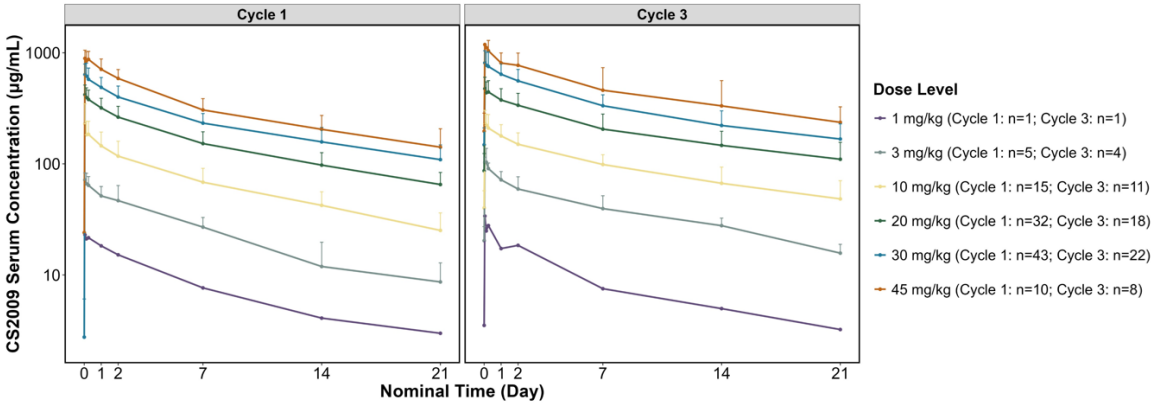




4. Excellent PK/PD Characteristics

(1) CS2009 demonstrated linear PK with a half-life of 6–9 days, supporting Q3W dosing. No significant accumulation was observed at Cycle 3. The incidence of anti-drug antibody (ADA) positivity was extremely low at only 0.7% (1/139).

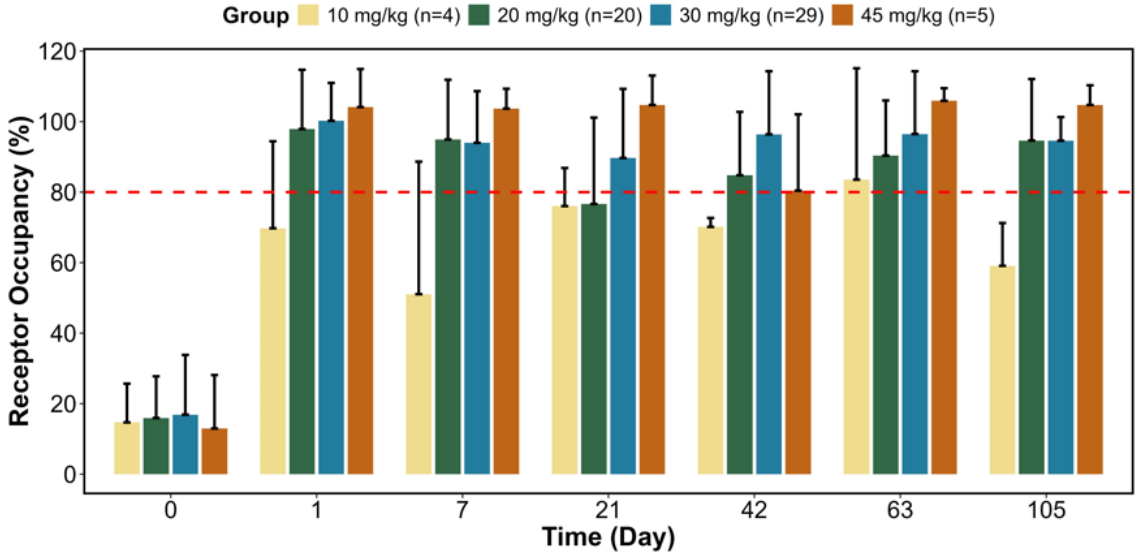
Mean (+SD) Concentration-time Profile of CS2009



(2) PD profile demonstrated saturated receptor occupancy and robust T-cell activation/proliferation confirming PD-1/CTLA-4 blockade and deep and sustained VEGFA neutralization.

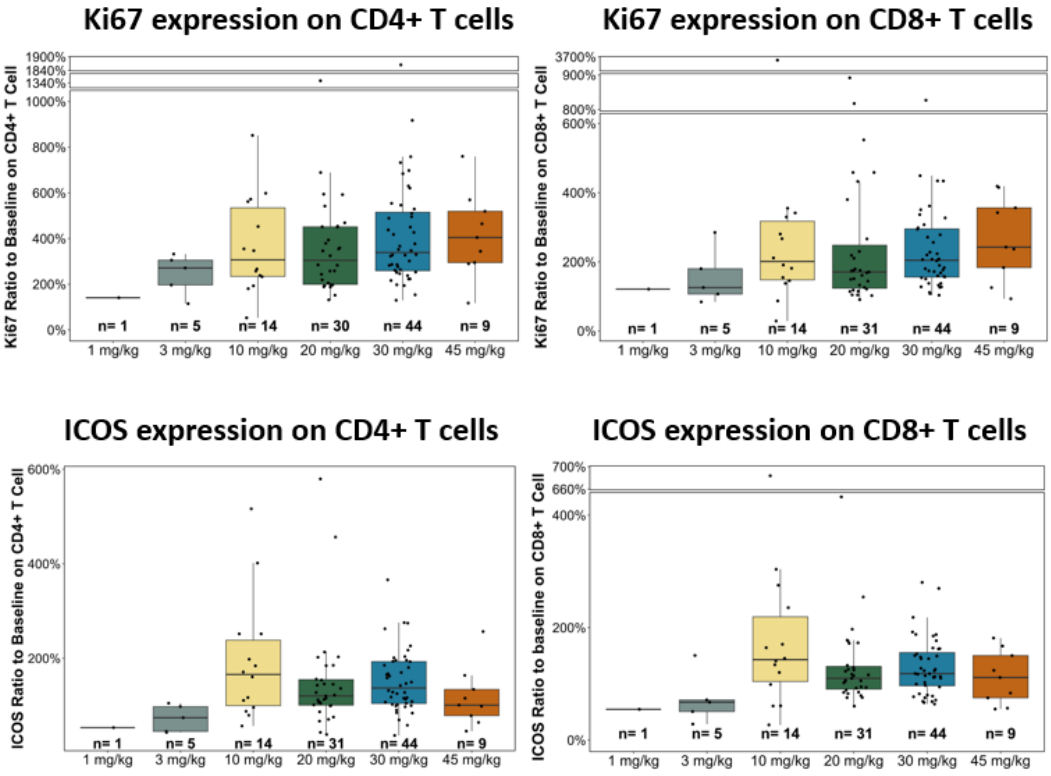
- Receptor occupancy (RO) of PD-1/CTLA-4 on peripheral T cells reached saturation throughout the dosing interval at doses ≥20 mg/kg.

Receptor Occupancy of PD-1/CTLA-4



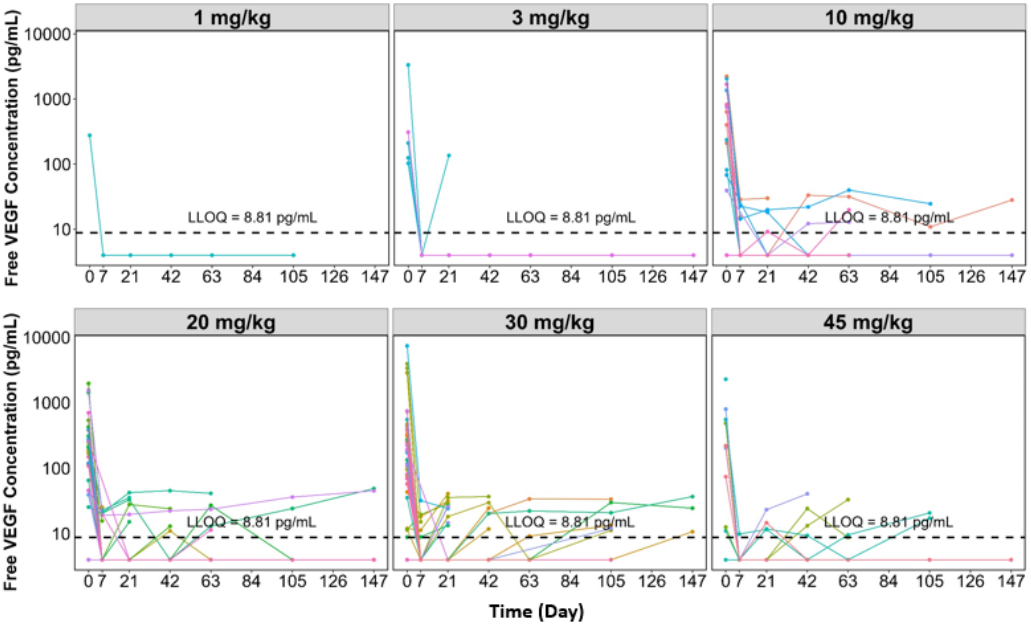
- On cycle 1 day 8, CS2009 induced notable, dose-dependent upregulation of Ki67 (proliferation due to PD-1 and CTLA-4 blockade) and ICOS (activation due to CTLA-4 blockade) expression on both CD4+ and CD8+ T cells, collectively demonstrating effective PD-1 and CTLA-4 inhibition by CS2009.

Ki67 and ICOS change on CD4+ and CD8+ T Cells on Cycle 1 Day 8



- Serum-free VEGFA reduced deeply and rapidly across all dose levels, and the effect sustained throughout dose intervals.

Individual Serum-free VEGFA Concentrations by Dose Level



Concentrations below the LLOQ were plotted as 0.5 × LLOQ for visualization

CStone will continue Phase II dose expansion in selected tumor types for dose optimization and to generate data as monotherapy or in combinations, supporting registrational trials in NSCLC, CRC and other indications. The first Phase III global MRCT is expected to be initiated by the end of 2026.

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 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, June 1, 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.