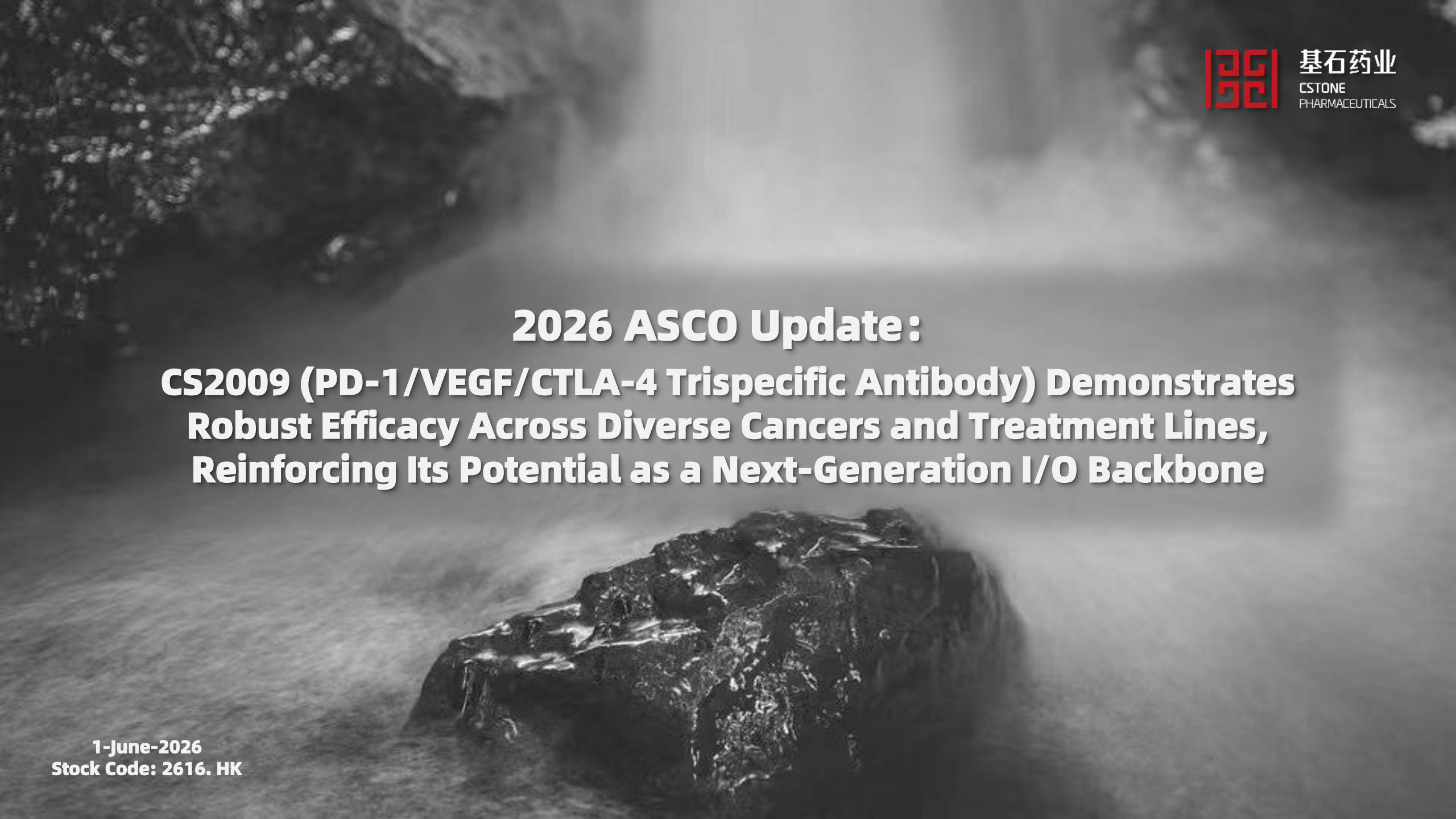
基石药业
CSTONE
PHARMACEUTICALS

# 2026 ASCO Update：

## CS2009 (PD-1/VEGF/CTLA-4 Trispecific Antibody) Demonstrates Robust Efficacy Across Diverse Cancers and Treatment Lines, Reinforcing Its Potential as a Next-Generation I/O Backbone



1-June-2026
Stock Code: 2616. HK

# Agenda


1. CS2009 Differentiation: Above & Beyond Bispecifics
2. Development Strategy for Next-Gen I/O Backbone
3. Phase I Update in Advanced Solid Tumors
4. Promising Clinical Efficacy in "Cold Tumors" – pMMR/MSS CRC, STS, and nccRCC
5. Solidified Clinical Efficacy in NSCLC
6. Commercial Potential: Multi-Billion I/O Market

*pMMR/MSS: proficient mismatch repair or microsatellite stable; STS: soft tissue sarcoma; nccRCC: non-clear-cell renal cell carcinoma*

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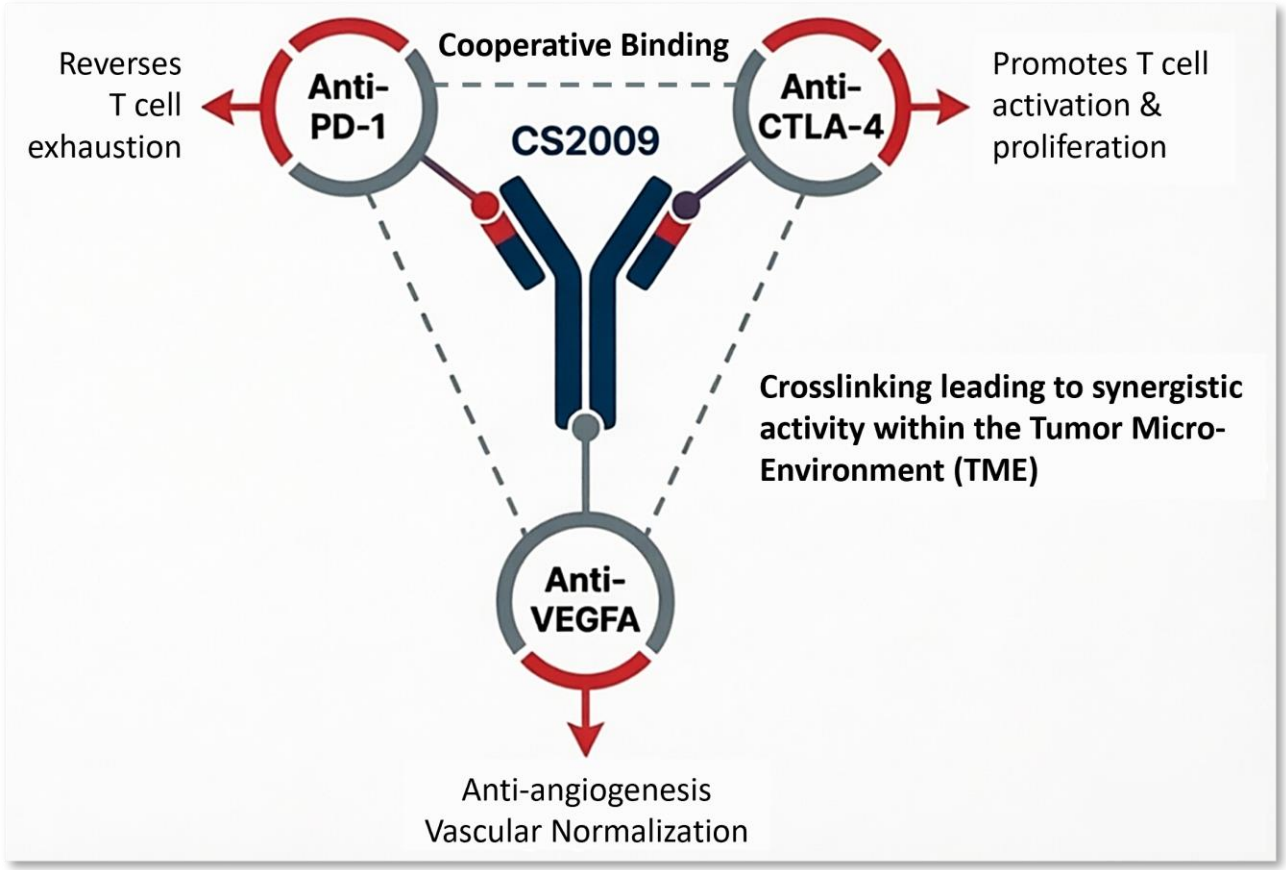
# CS2009: Potential FIC/BIC Next-Generation I/O Backbone




This diagram provides a schematic illustration of CS2009 and does not represent its true structural details.

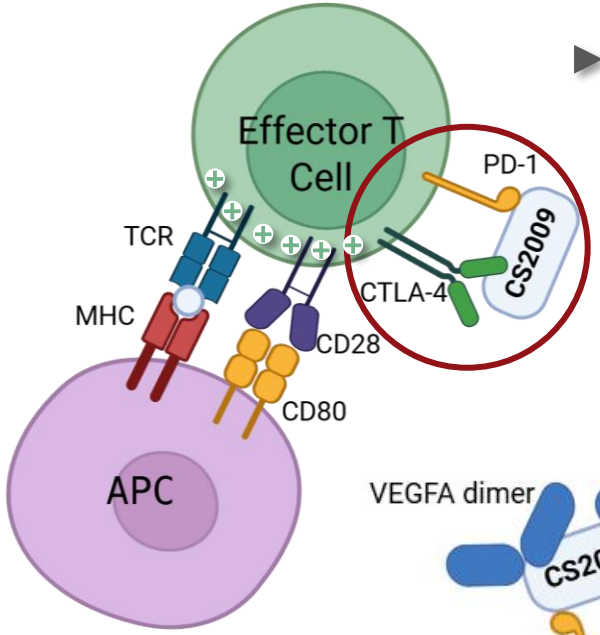
## Key Differentiation

- **First-in-class/Best-in-class Potential:**
  Potential next-generation I/O backbone that simultaneously targets PD-1/VEGF/CTLA-4
- **Better Efficacy with Durable OS Expected:**
  Multidimensional synergistic antitumor activities within the TME by blocking and cross-linking three clinically validated targets simultaneously
- **Well-tolerated by Sparing CTLA-4 Toxicity:**
  Preferential blocking of PD-1 and CTLA-4 on double-positive tumor-infiltrating T cells to minimize interference with CTLA-4 regulation in peripheral T cells, reducing systemic toxicity.

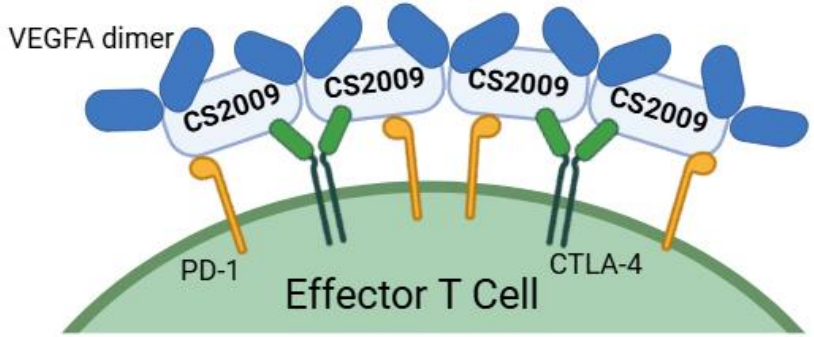
*I/O: immuno-oncology*

# **Innovative MOA**: Multi-target engagement and synergistic interactions among anti-PD-1, CTLA-4, and VEGFA arms enhance CS2009's activities in TME, while sparing peripheral CTLA4-single-positive T cells, potentially leading to significant improvement of its therapeutic window

## *Tumor Microenvironment (TME)*



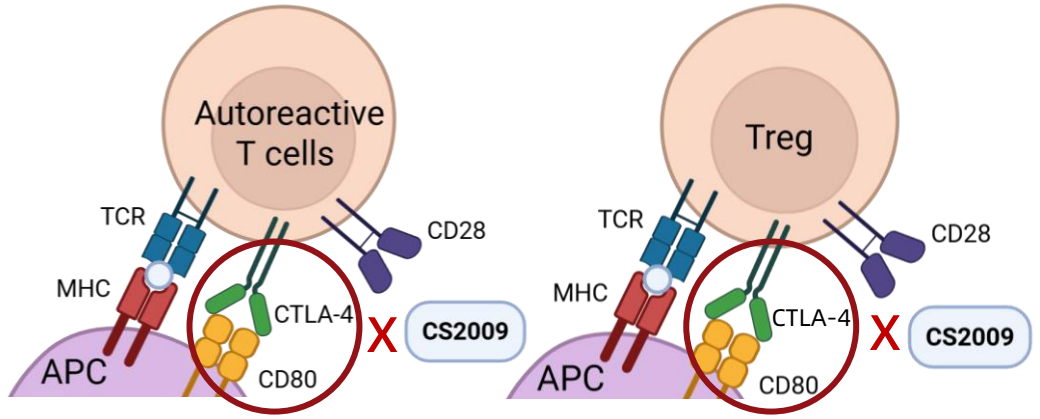

▶ **Within the TME,** CS2009 **preferentially binds PD-1 and CTLA-4 on double-positive tumor-infiltrating lymphocytes (TILs)** via avidity-driven concurrent engagement of both checkpoints, enhancing its binding affinity and checkpoint inhibitory (CPI) activity to reinvigorate TILs

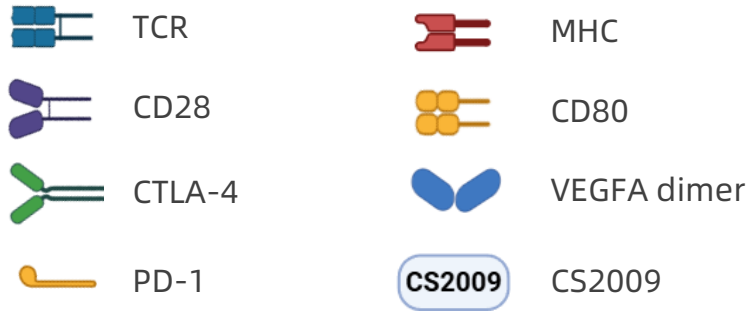



▼ **Within the TME,** CS2009 forms clusters after crosslinking with VEGFA dimers, which **strengthens its binding affinity to PD-1/ CTLA-4-expressing T cells** and further amplifies its CPI activity

## *Peripheral*

**In the peripheral,** CS2009's **monovalent** CTLA-4 arm is **unable to block CTLA-4/CD80 interactions** due to low affinity, thereby sparing CTLA-4 single-positive T cells from over-activation, thus reducing systemic autoimmune toxicity




*TME: tumor microenviroment*

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# CS2009: A Next-Gen I/O Backbone Development Strategy

Replacing & Expanding Beyond Current PD-1/L1 Standard of Care (SOC)

## PD-1/L1 Fully Established SOC (IO-based Regimens)

- **1L metastatic NSCLC:** Pembrolizumab + Platinum-based Chemo
- **Locally advanced NSCLC, post-CRT:** Durvalumab consolidation
- **Resectable NSCLC (Neoadjuvant/Adjuvant):** Nivolumab + Platinum-based Chemo
- **ES-SCLC:** Atezolizumab + Etoposide + Carboplatin
- **LS-SCLC:** Durvalumab consolidation
- **1L HCC:** Atezolizumab + Bevacizumab
- **1L HNSCC:** Pembrolizumab + Chemo
- **1L Advanced ccRCC:** Pembrolizumab + Axitinib
- **Unresectable/Metastatic Melanoma:** Pembrolizumab

## PD-1/L1 Partially Established SOC (CPS-Dependent)

- **1L TNBC:** **CPS ≥10**: Pembrolizumab + Chemo; **CPS <10**: Chemo
- **1L GC/GEJ:** **CPS ≥1**: Pembrolizumab + Chemo; **CPS <1**: Chemo
- **1L ESCC:** **CPS ≥1**: Nivolumab + Chemo; **CPS <1**: Chemo
- **2L/3L PROC:** **CPS ≥1**: Pembrolizumab + Paclitaxel +/- Bevacizumab
- **1L Cervical Cancer (recurrent/metastatic):** **CPS ≥1**: Pembrolizumab + Bevacizumab; **CPS <1**: Chemo + Bevacizumab

## PD-1/L1 Ineligible (I/O Not Yet Approved as SOC)

- **2L/3L Metastatic NSCLC (AGA-):** Docetaxel
- **1L pMMR/MSS CRC:** Bevacizumab + FOLFOX/CAPEOX/FOLFIRI
- **Non-clear-cell RCC:** TKI
- **mCRPC:** Chemo

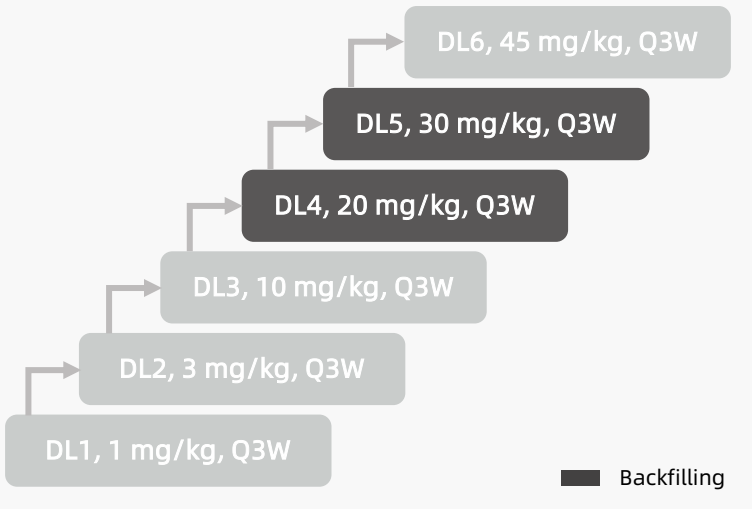
→ CS2009 Replacing PD-1/L1 in Chemo Combo

→ CS2009 Expanding into IO-Ineligible with Chemo/ADC

*AGA: actionable oncogenic alterations; CAPEOX: Capecitabine + Oxaliplatin; ccRCC: clear cell renal cell carcinoma; CPS: combined positive score; CRC: colorectal cancer; CRT: chemoradiotherapy; ES-SCLC: extensive-stage small cell lung cancer; ESCC: esophageal squamous cell carcinoma; HCC: hepatocellular carcinoma; HNSCC: head and neck squamous cell carcinoma; LS-SCLC: limited-stage small cell lung cancer; mCRPC: metastatic Castration-Resistant Prostate Cancer; NSCLC: non-small cell lung cancer; PROC: platinum-resistant ovarian cancer; pMMR/MSS: proficient mismatch repair or microsatellite stable; TNBC: triple-negative breast cancer;*

# CS2009 Clinical Development Plan: Efficient and Clearly Defined Global Development Path Forward

## Phase I – Mono Dose Escalation (Completed) + Backfilling




## Phase II – Dose Expansion

***Lung***

- 1L NSQ-NSCLC, AGA(-), plus PEM + CPT
- 1L SQ-NSCLC, AGA(-), plus PTX + CPT
- Treated NSCLC–[2L] Mono, [2/3L] plus docetaxel
- 1L NSCLC, AGA(-), PD-L1 TPS ≥1%, Mono
- 1L ES-SCLC, plus ETO + CPT

***Gastrointestinal***

- 1L pMMR/MSS CRC / pancreatic cancer, plus chemo
- 1L gastric cancer, plus CAPOX
- 1L ESCC, plus TP/FP
- HCC–[1L] Mono; [2/3L] Mono

***Breast***

- 1L TNBC, plus nab-PTX
- 2/3L TNBC, Mono

***Gynecologic***

- 1L cervical cancer, plus PTX + Pt
- PROC–[1/2L] plus PTX; [2/3L] Mono

***Kidney & Others***

- 1L RCC, Mono
- 1L MSI-H/dMMR solid tumors, Mono

## Prioritized Phase III MRCT Trials

- **1L metastatic NSQ-NSCLC, AGA(-),** CS2009 + PEM + CPT vs. pembrolizumab + PEM + CPT
- **1L metastatic SQ-NSCLC, AGA(-),** CS2009 + PTX + CPT vs. pembrolizumab + PTX + CPT
- **2/3L metastatic NSCLC, AGA(-),** CS2009 + docetaxel vs. docetaxel
- **1L metastatic NSCLC, AGA(-), PD-L1 TPS ≥50%,** CS2009 vs. pembrolizumab
- **Stage III NSCLC, post-CRT consolidation** CS2009 vs. durvalumab
- **1L ES-SCLC,** CS2009 + ETO + CPT vs. atezolizumab + ETO + CPT
- **1L MSS CRC,** CS2009 + FOLFOX vs. bevacizumab + FOLFOX
- **1L TNBC,** CS2009 combination TBD, contingent on regulatory feedback
- **1L Clear-cell RCC,** CS2009 +/- axitinib vs. pembrolizumab + axitinib
- **1L HCC,** CS2009 vs. atezolizumab + bevacizumab
- **1L MSI-H Solid Tumors,** Selected tumor types

*AGA: actionable oncogenic alterations; CAPOX: Capecitabine + Oxaliplatin; CPT: Carboplatin; CRC: colorectal cancer; DL: dose level; ES-SCLC: extensive-stage small cell lung cancer; ESCC: esophageal squamous cell carcinoma; ETO: Etoposide;* FOLFOX: folinic acid, fluorouracil and oxaliplatin; *FP: 5-fluorouracil + Cisplatin; HCC: hepatocellular carcinoma; NSCLC: non-small cell lung cancer; NSQ: non-squamous; PEM: Pemetrexed; PROC: platinum-resistant ovarian cancer; PTX: Paclitaxel; Pt: platinum; pMMR/MSS: proficient mismatch repair or microsatellite stable; Q3W: once every 3 weeks; RCC: renal cell carcinoma; SQ: squamous; TNBC: triple-negative breast cancer; TP: Paclitaxel + Cisplatin; TPS: tumor proportion score*

***R&D Milestones & Upcoming Catalysts***

- **Mar. 2025** – First patient dosed in global phase I trial
- **Sept. 2025** – First patient dosed in global phase II trial
- **Q4 2025** – Phase I data debut at ESMO
- **Feb 2026** – US IND
- **Q2 & Q4 2026** – Data presentation planned for ASCO and ESMO
- **Q4 2026** – Initiating Phase III registrational trial

# CS2009: Currently Accelerating Phase II Clinical Trial to Support Global Phase III Initiation by End of 2026

**Sept. 2025**
First patient dosed in Phase II

**Oct. 2025**
China IND approved for Phase II Combo

**Feb. 2026**
US IND approved for Phase II

**Q2/Q4 2026**
Data Disclosure Planned at ASCO and ESMO

## Phase II Clinical Design

Multi-cohort, parallel expansion study evaluating CS2009 **monotherapy and combinations** in 19 cohorts across **12 solid tumor indications** (including NSCLC, CRC, ES-SCLC, cervical cancer, G/GEJ adenocarcinoma, ESCC, pancreatic cancer, PROC, TNBC, HCC, RCC, and MSI-H solid tumors)

## Phase III MRCT Plan

- Type B meeting scheduled in **Q4 2026** to align with US FDA on trial design
- To initiate first-wave Phase III MRCTs in NSCLC, CRC, SCLC, etc., **by end of 2026**

*CRC: colorectal cancer; ESCC: esophageal squamous cell carcinoma; ES-SCLC: extensive-stage small cell lung cancer; HCC: hepatocellular carcinoma; G/GEJ: gastric and gastroesophageal junction; MRCT: multi-regional clinical trial; NSCLC: non-small cell lung cancer; OC: ovarian cancer; PROC: platinum-resistant ovarian cancer; RCC: renal cell carcinoma; STS: soft tissue sarcoma; TNBC: triple-negative breast cancer; MSI-H : microsatellite instability-high*

# Key Data Presented at 2026 ASCO Solidified CS2009's Best-in-Class Potential as Next-Generation I/O Backbone

2026 ASCO ANNUAL MEETING

*2026 ASCO* May 2026

## ▶ Phase I Update

- **Well tolerated** in **118** heavily pre-treated patients with solid tumors **after longer follow-up**
- **Encouraging ORR, high DCR, durable response**
- Linear PK; rare ADA positivity; PD data confirming MoA; sustained receptor occupancy

*2025 ESMO*
*Presented Phase I data from 72 patients*
Oct. 2025

## ▶ NSCLC

- **Well tolerated** as monotherapy and in combination across different line settings
- CS2009 monotherapy (30 mg/kg) in ≥2L NSCLC: **ORR 24.4%; 6-month DoR rate 80.0%; DCR 60.0%**
- CS2009+docetaxel in 2/3L NSCLC: **ORR 66.7%; DCR 100%**
- CS2009 monotherapy in 1L NSCLC (PD-L1 TPS ≥50%): **ORR 81.3%; DCR 100%**
- CS2009+chemo in 1L squamous NSCLC (PD-L1 negative/low): **ORR 75.0%; DCR 100%**

*Phase II*
*First patient in*
Sept. 2025

## ▶ pMMR/MSS CRC, a "Cold Tumor"

- CS2009 monotherapy in later-line mCRC: **ORR 25.0%; DCR 87.5%**
- CS2009+XELOX in 1L mCRC: **ORR 66.7%; DCR 100%**

*Phase I*
*First patient in*
March 2025

## ▶ Other "Cold Tumors"

- CS2009 monotherapy in soft tissue sarcoma (STS): **ORR 33.3%; DCR 66.7%**
- CS2009 monotherapy in non-clear-cell renal cell carcinoma (nccRCC): **ORR 33.3%; DCR 100%**

*ORR: objective response rate; DCR: disease control rate; PK: pharmacokinetics; ADA: anti-drug antibody; PD: pharmacodynamic; MoA: mechanism of action; NSCLC: non-small cell lung cancer; TPS: tumor proportion score; pMMR/MSS: proficient mismatch repair / microsatellite stable; CRC: colorectal cancer; XELOX: capecitabine plus oxaliplatin;*

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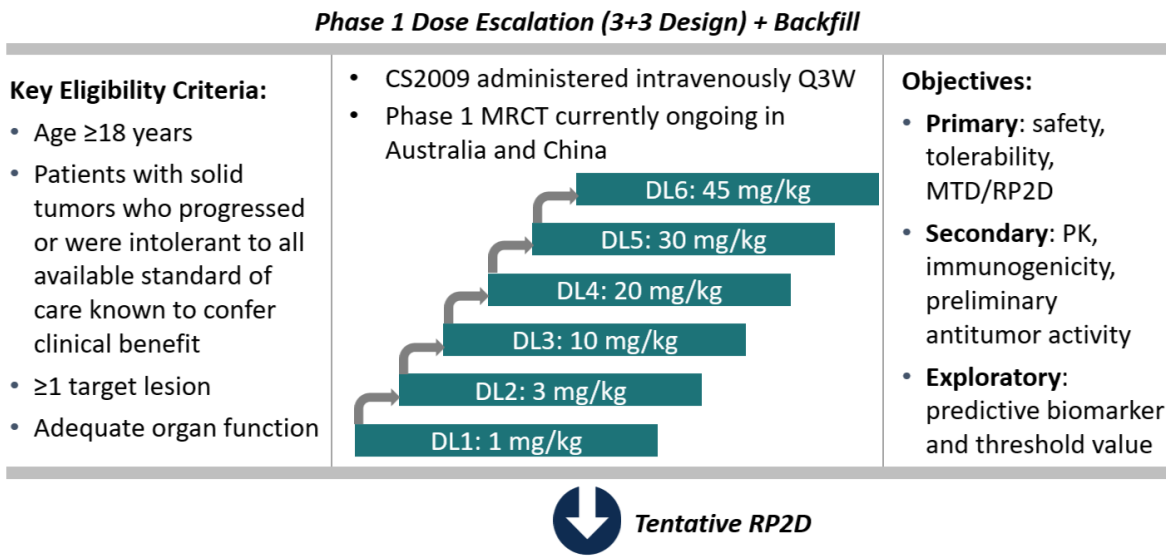
# Phase I Baseline Characteristics: 118 Patients with Advanced Solid Tumors Treated across 6 Dose Levels




| Characteristics | Total (N=118) |
|---|---|
| **Age**, years | |
| median (range) | 61 (19-80) |
| **Race**, n (%) | |
| Asian | 67 (56.8) |
| White | 48 (40.7) |
| Other | 3 (2.5) |
| **Sex**, n (%) | |
| Female | 51 (43.2) |
| Male | 67 (56.8) |
| **ECOG PS**, n (%) | |
| 1 | 77 (65.3) |
| 0 | 41 (34.7) |
| **Prior I/O therapy**, n (%) | 60 (50.8) |
| **Prior anti-angiogentic therapy**, n (%) | 54 (45.8) |
| **Prior therapy**, n (%) | |
| 1 | 46 (39.0) |
| 2 | 32 (27.1) |
| ≥3 | 37 (31.4) |

*Data cutoff date: April 13, 2026*
*DL: dose level; MTD: maximum tolerated dose;* RP2D: recommended phase 2 dose; *PK: pharmacokinetics; ECOG PS: Eastern Cooperative Oncology Group performance status;*

# Phase I Safety: Up-to-Date Phase I Data Demonstrate Compelling Safety Profile

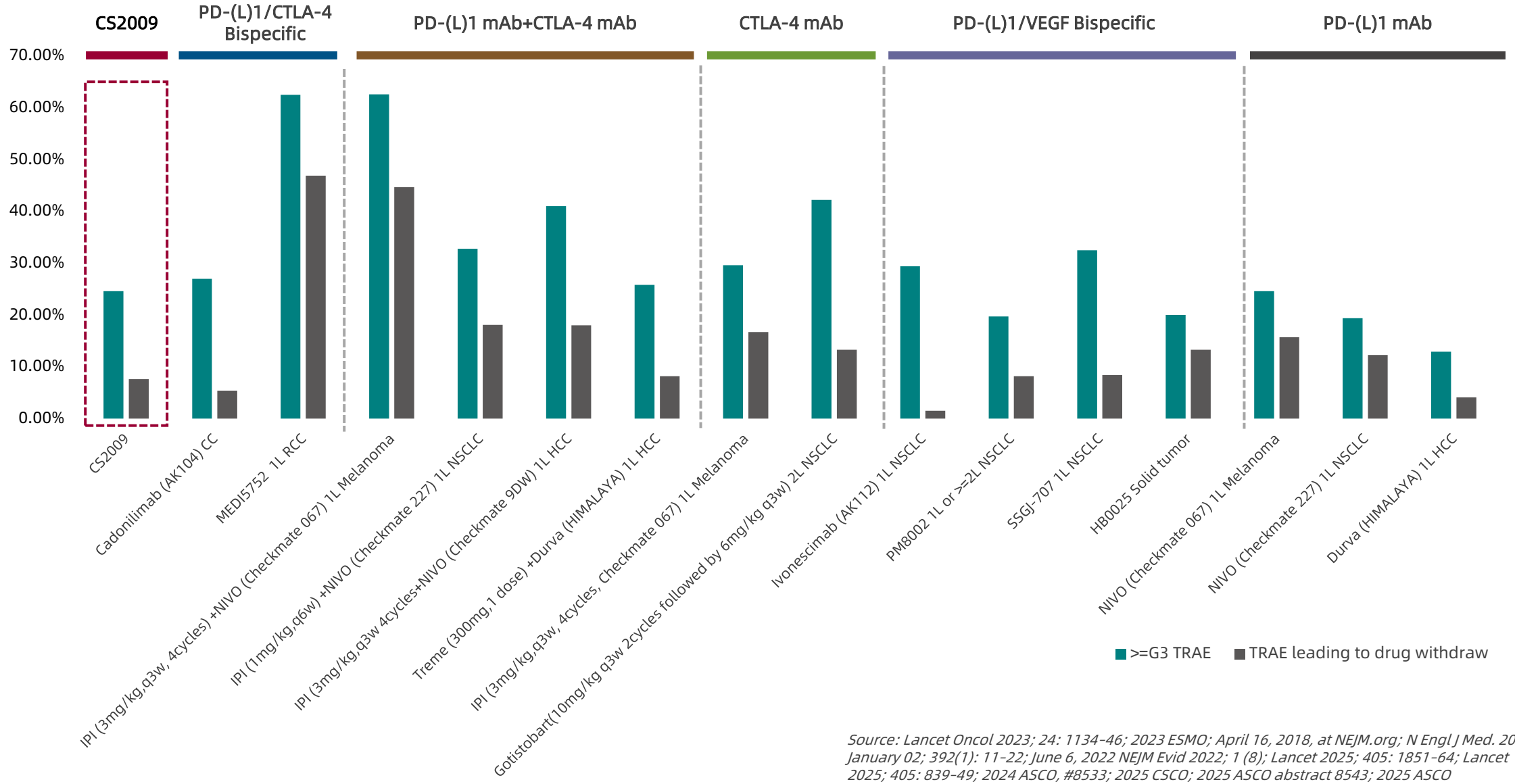
Dose escalation completed; no DLT; MTD not reached
Without excessive toxicities that typically occurred in CTLA-4- and PD-(L)1-containing combination therapies; low ≥G3 VEGF-related AEs

| 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 (irAE) | 9 (42.9) | 18 (54.5) | 16 (29.6) | 3 (30.0) | 46 (39.0) |
| • Grade ≥3 irAE | 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) |

- Most frequent (≥5%) any-grade **irAE:** hypothyroidism (6.8%), rash / AST increased / ALT increased (5.1% each)
- Most frequent (≥5%) any-grade **TRAE possibly related to anti-VEGF therapy:** proteinuria (11.9%), hypertension (8.5%)

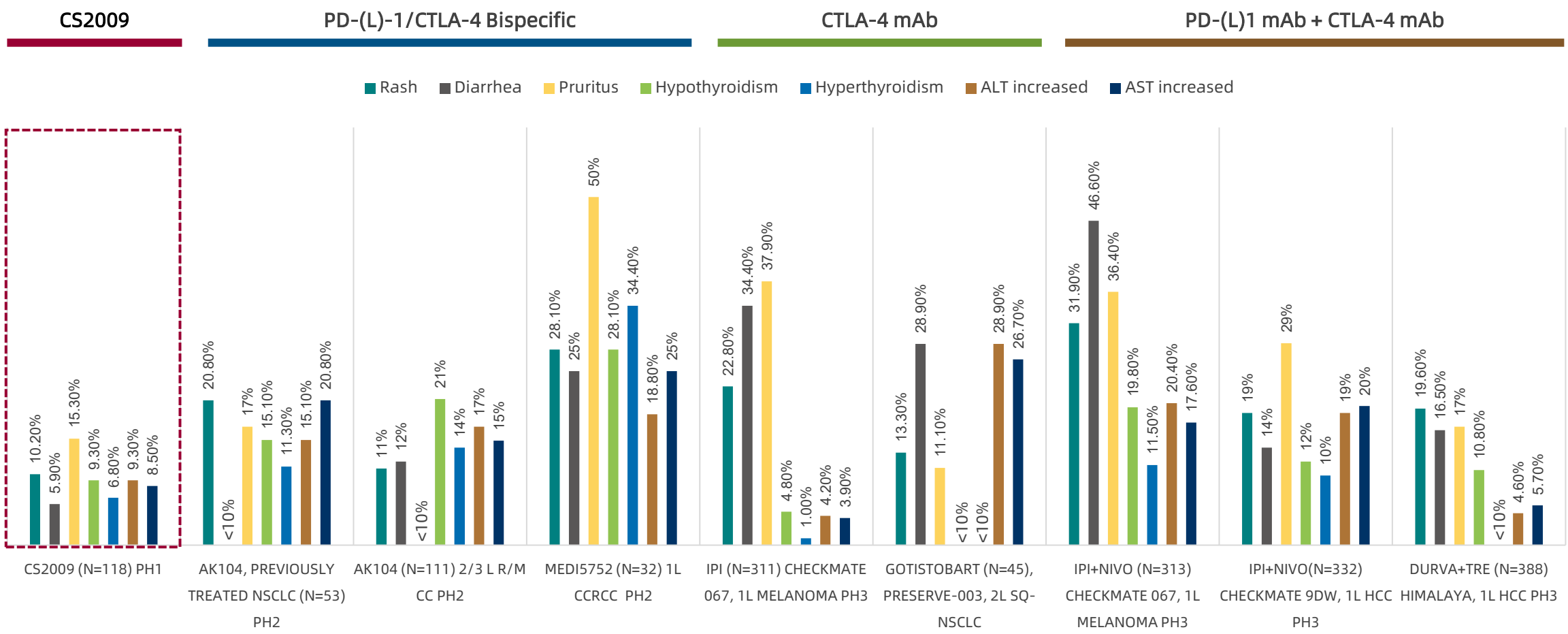
*TEAE: treatment-emergent adverse event; AST: aspartate aminotransferase; ALT: alanine aminotransferase*

# Safety Comparison (1/3): Much lower incidence of grade ≥3 TRAE and TRAE leading to treatment discontinuation vs. I/O bispecific or combination regimens




*Source: Lancet Oncol 2023; 24: 1134-46; 2023 ESMO; April 16, 2018, at NEJM.org; N Engl J Med. 2025 January 02; 392(1): 11-22; June 6, 2022 NEJM Evid 2022; 1 (8); Lancet 2025; 405: 1851-64; Lancet 2025; 405: 839-49; 2024 ASCO, #8533; 2025 CSCO; 2025 ASCO abstract 8543; 2025 ASCO*

# Safety Comparison (2/3): Much lower incidence of frequent any-grade irAE vs. PD-(L)1/ CTLA-4 bispecific or combination regimens

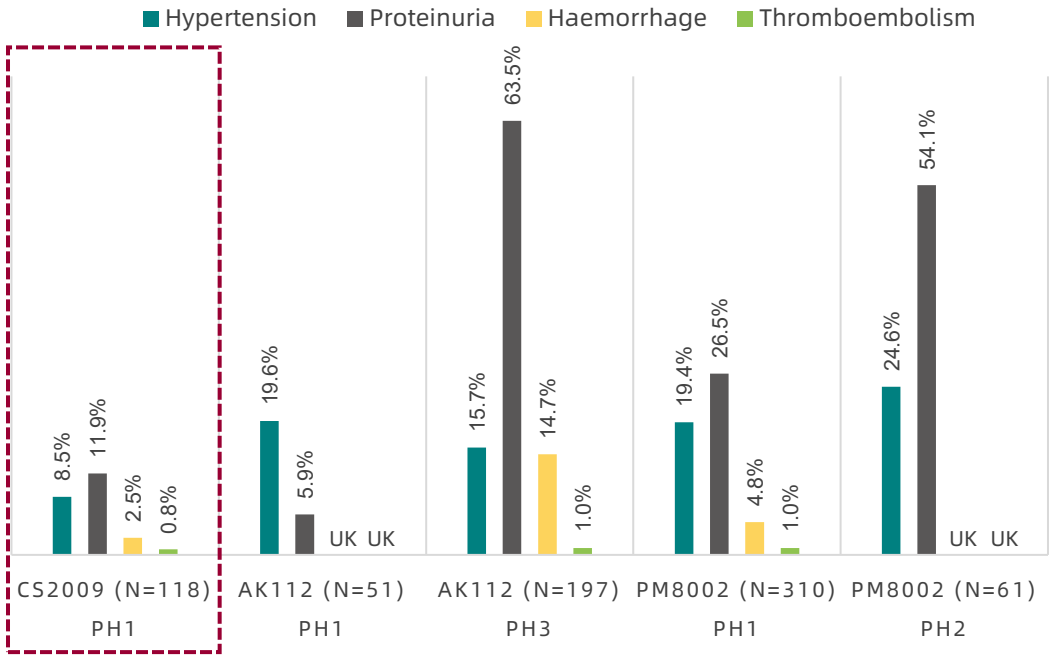



*Note: AE of <10% incidence not shown*

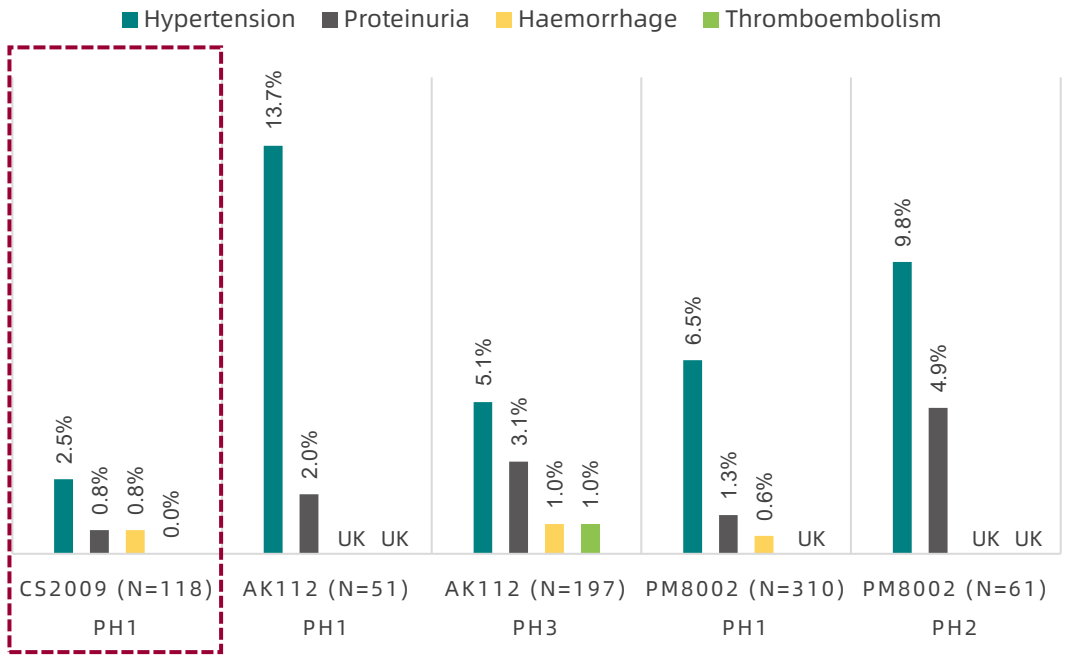
*Source: Lung Cancer 184 (2023) 107355; Lancet Oncol 2023; 24: 1134-46; 2023 ESMO; April 16, 2018, at NEJM.org; N Engl J Med. 2025 January 02; 392(1): 11-22; Lancet 2025; 405: 1851-64; June 6, 2022 NEJM Evid 2022; 1 (8); Nat Med. 2026 Mar 27*

# Safety Comparison (3/3): Much lower incidence of any-grade and grade ≥3 VEGF-related TRAE vs. PD-(L)1/VEGF bispecific

## Any-grade VEGF-related TRAE



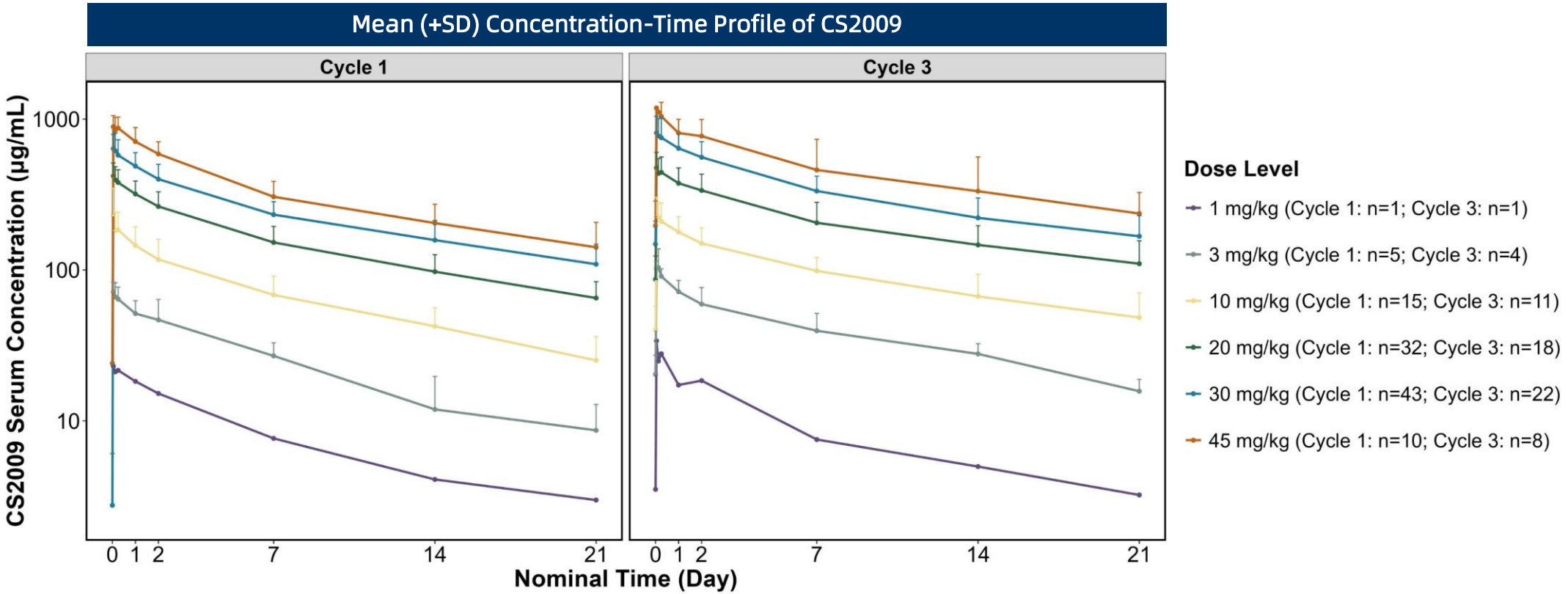

## Grade ≥3 VEGF-related TRAE




*Abbr: UK, unknown*

*Source: 2026 ASCO; J Immunother Cancer. 2024 Apr 19;12(4):e008037; Lancet 2025; 405: 839-49; 2023 ASCO, #414802; 2024 ASCO, #8533*

# CS2009 PK Profile: Dose-proportional exposure; terminal half-life of ~6-9 days; no significant accumulation after repeated doses; very low ADA-positivity incidence

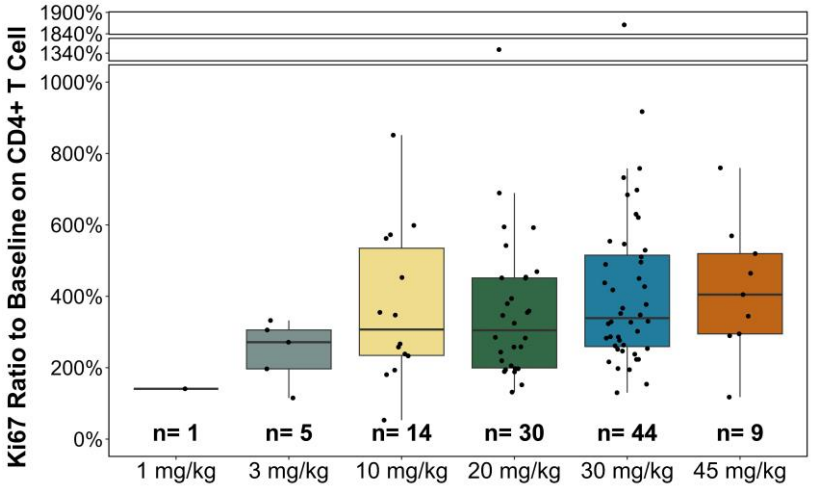



- **Dose-proportional exposure**
- **Terminal half-life:** Approximately 6-9 days
- **No significant accumulation** observed by Cycle 3
- **Immunogenicity (i.e. ADA):** Low incidence of treatment-emergent ADA positivity was observed (0.7%; 1/139 ADA-evaluable patients).

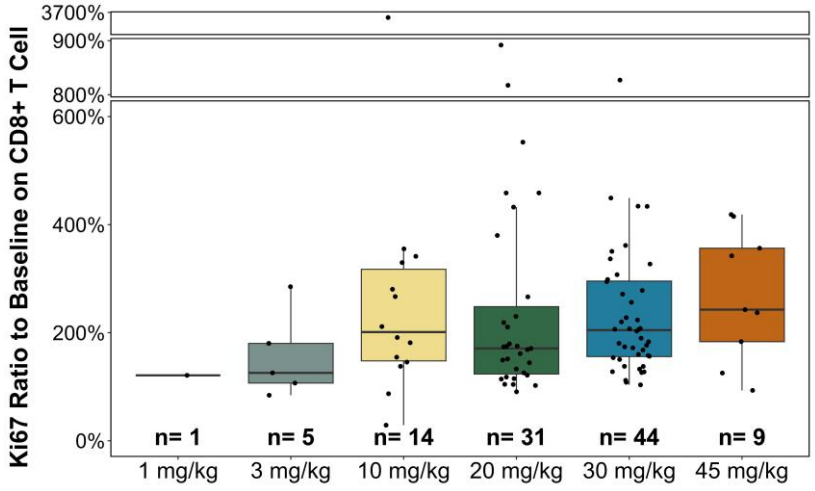
*ADA: anti-drug antibody*

# Robust T cell activation (Ki67 and ICOS up-regulation with plateau at doses ≥10 mg/kg)

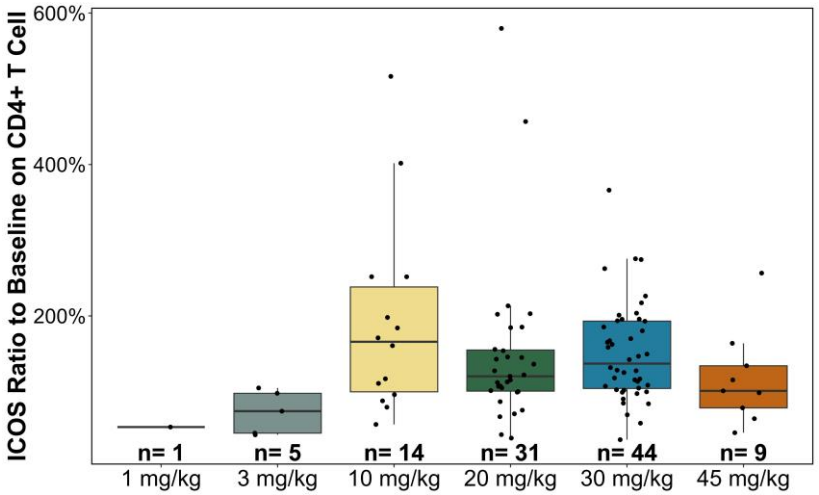
## Ki67 expression on CD4+ T cells



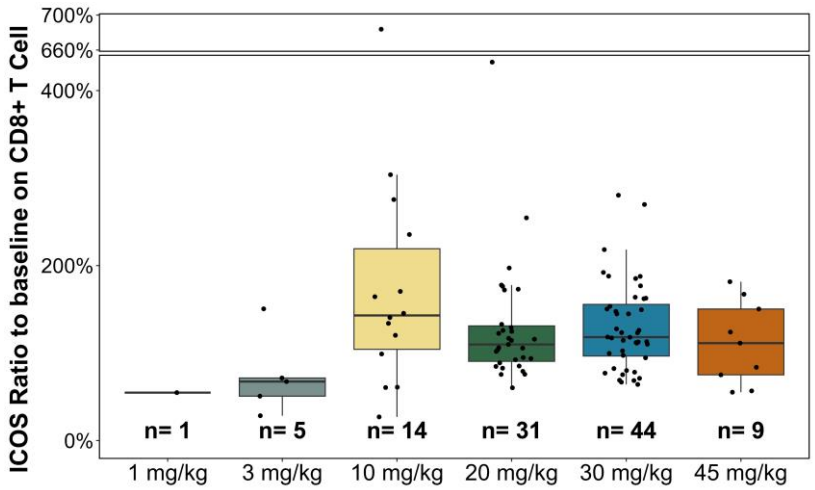

## Ki67 expression on CD8+ T cells




## ICOS expression on CD4+ T cells



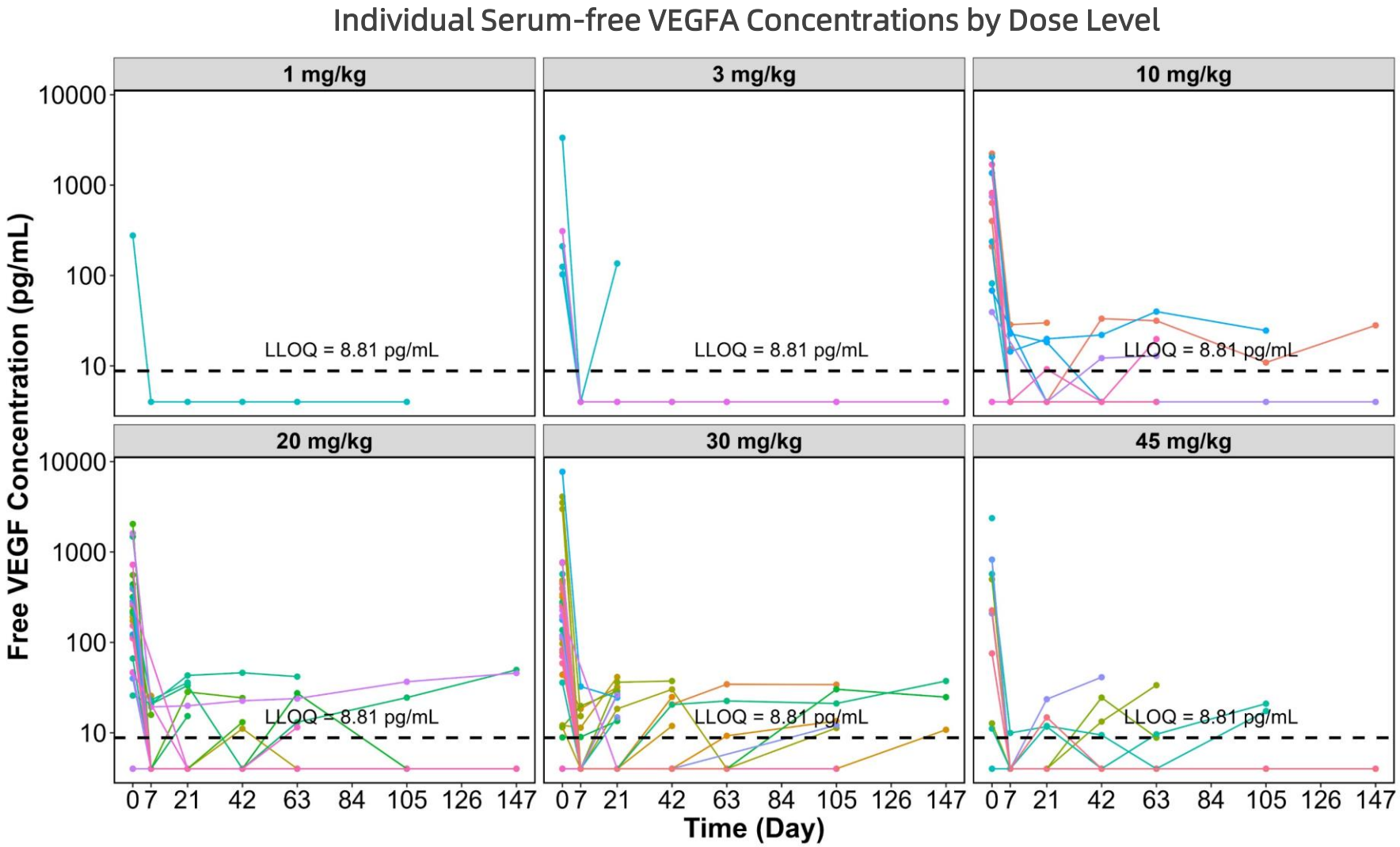

## ICOS expression on CD8+ T cells



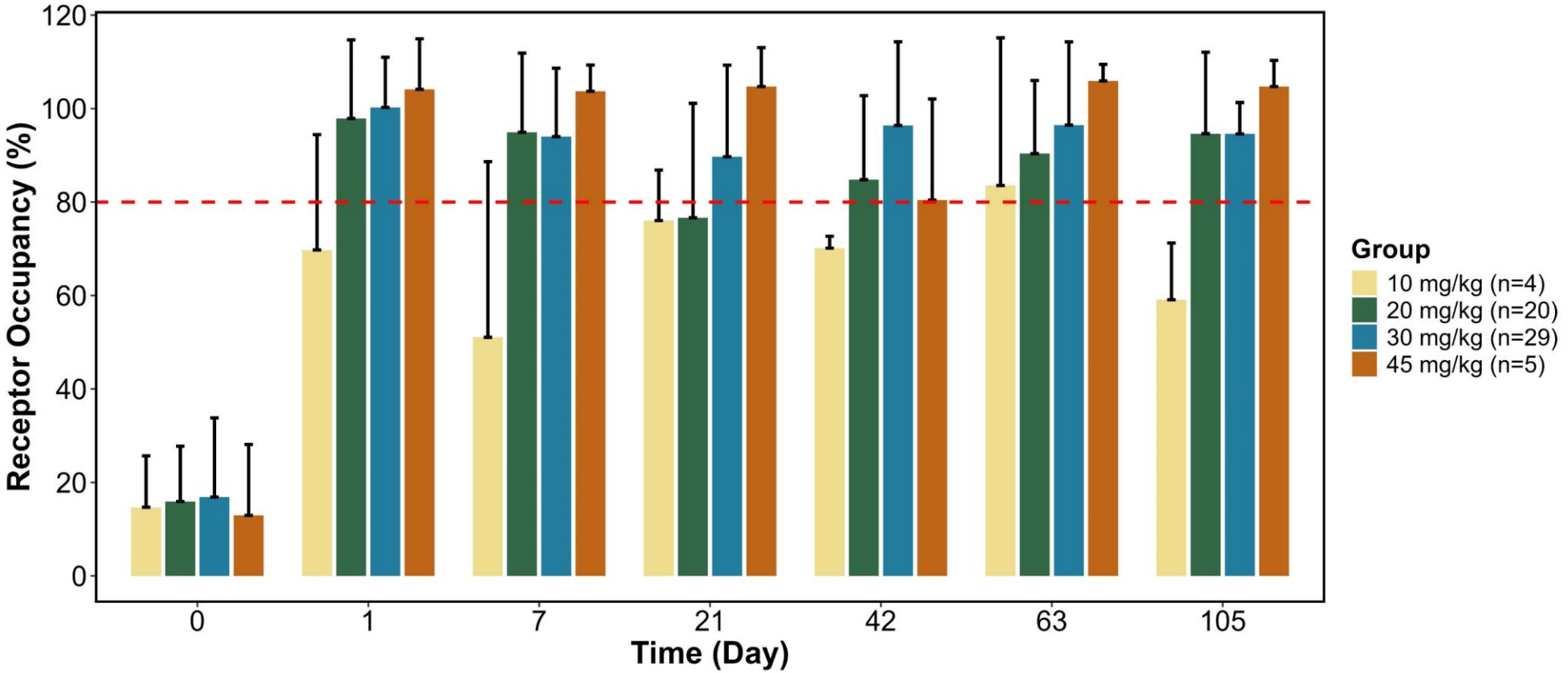

- **T-cell proliferation & activation:** On Cycle 1 Day 8, CS2009 induced notable, dose-dependent upregulation of **Ki67** (proliferation) and **ICOS** (activation) expression on both **CD4+** and **CD8+ T cells**, collectively demonstrating effective PD-1 and CTLA-4 inhibition

**CD4_Ki67_ratio** = CD4_Ki67+% (day8 / baseline)
CD4_Ki67+%= (CD45+CD3+%) × (CD3+CD4+%) × (CD3+CD4+Ki67%)

# VEGF neutralization: Serum-free VEGFA reduced deeply and rapidly across all doses, and the effect sustained throughout dose interval



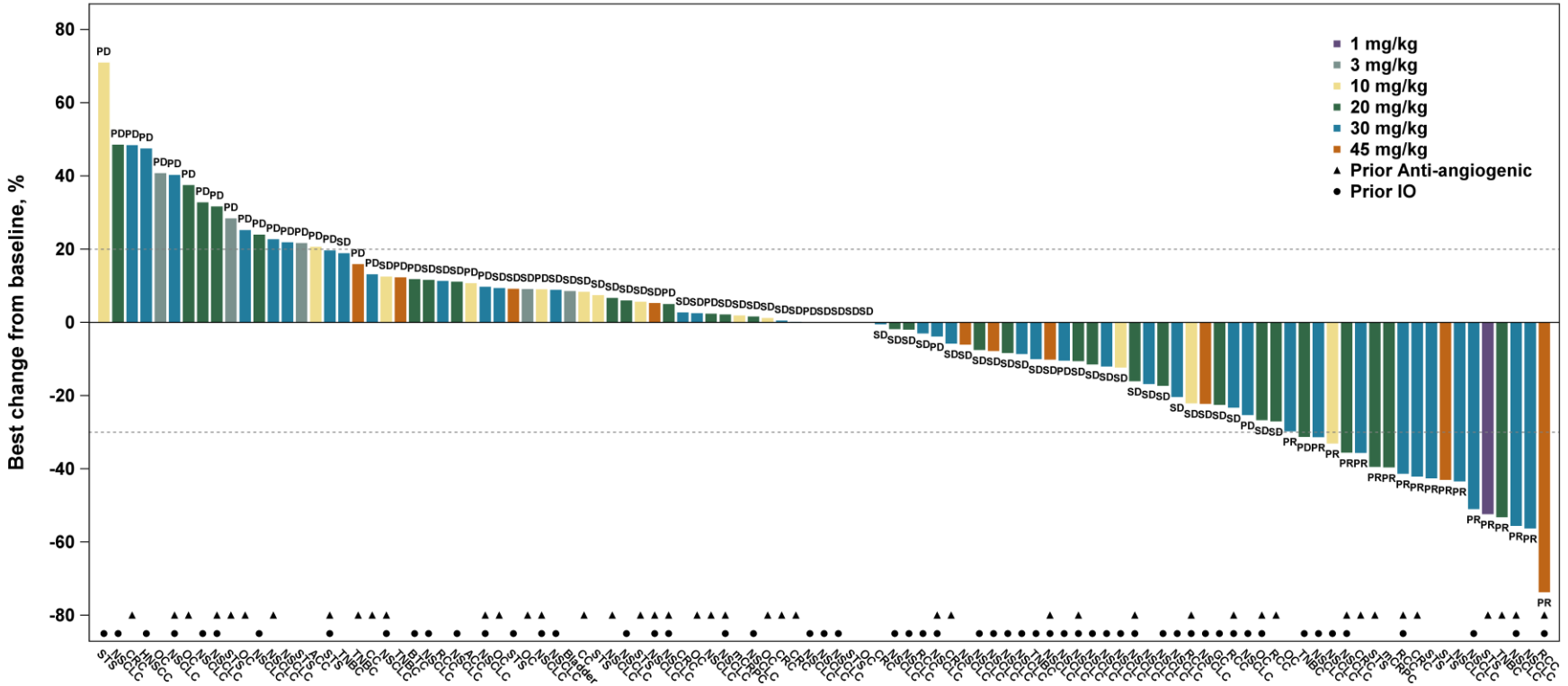
# Receptor Occupancy of PD-1/CTLA-4 on peripheral T cells reached saturation throughout dosing interval at ≥20 mg/kg



# Phase I Overall Efficacy: Response observed across all dose levels with at least 70% DCR at ≥20 mg/kg; median duration of response (DoR) not reached; 6-month DoR rate 77.4%.

Antitumor activity observed in heavily pre-treated patients with advanced solid tumors including NSCLC, CRC, mCRPC, OC, RCC, STS, TNBC, etc. (Later-line NSCLC data from phase I will be presented with 1L NSCLC in dedicated sections later)

| 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) |




*NSCLC: non-small cell lung cancer; CRC: colorectal cancer; mCRPC: metastatic castration-resistant prostate cancer; OC: ovarian cancer; RCC: renal cell carcinoma; STS: soft tissue sarcoma; TNBC: triple-negative breast cancer*

# Agenda


1. CS2009 Differentiation: Above & Beyond Bispecifics
2. Development Strategy for Next-Gen I/O Backbone
3. Phase I Update in Advanced Solid Tumors
4. **Promising Clinical Efficacy in "Cold Tumors" – pMMR/MSS CRC, STS, and nccRCC**
5. Solidified Clinical Efficacy in NSCLC
6. Commercial Potential: Multi-Billion I/O Market

*pMMR/MSS: proficient mismatch repair or microsatellite stable; STS: soft tissue sarcoma; nccRCC: non-clear-cell renal cell carcinoma*

# (1/4) CS2009 monotherapy demonstrated promising clinical efficacy in later-line metastatic CRC, mostly pMMR/MSS–a "cold tumor" not sensitive to PD-(L)1 mAb

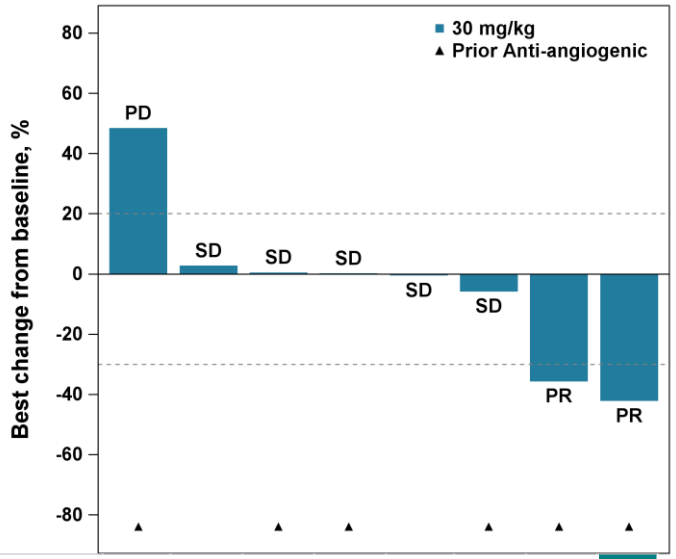
CS2009 monotherapy at 30 mg/kg, Q3W

| Baseline Characteristics | Later-line mCRC (n=14) |
|---|---|
| **Age**, years | |
| median (range) | 61 (40-74) |
| **Sex**, n (%) | |
| Female | 5 (35.7) |
| Male | 9 (64.3) |
| **Prior therapy**, n (%) | |
| 1 | 5 (35.7) |
| 2 | 5 (35.7) |
| ≥3 | 4 (28.6) |
| **ECOG PS**, n (%) | |
| 1 | 12 (85.7) |
| 0 | 2 (14.3) |
| **Location** | |
| Left colon or rectum | 11 (78.6) |
| Right colon | 3 (21.4) |
| **MSI/MMR status**, n (%) | |
| pMMR/MSS | 12 (85.7) |
| Unknown | 2 (14.3) |
| **Liver metastases**, n (%) | 8 (57.1) |

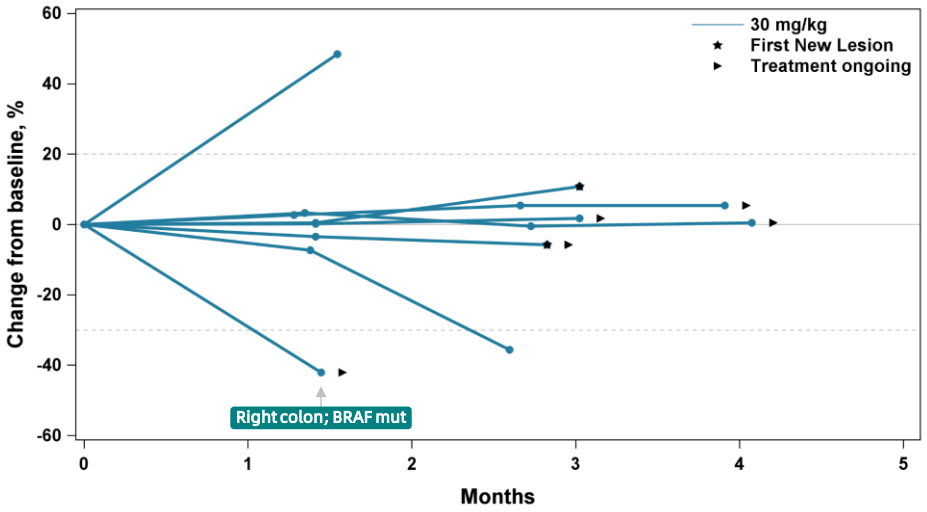
Among patients with at least one post-baseline tumor assessment (n=8),

**ORR 25.0%** (2/8)

**DCR 87.5%** (7/8)




| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| BRAF mut | n/a | n/a | n/a | n/a | n/a | n/a | n/a | yes |
| KRAS mut | n/a | n/a | n/a | n/a | n/a | n/a | n/a | no |
| Liver metastases | yes | no | yes | no | yes | yes | no | no |
| Location | right colon | rectum | rectum | rectum | left colon | rectum | rectum | right colon |




*Note: The current efficacy readout remains immature due to the short follow-up for most patients.*
*pMMR/MSS: proficient mismatch repair / microsatellite stable; mCRC: metastatic colorectal cancer; ECOG PS: Eastern Cooperative Oncology Group performance status; ORR: objective response rate; DCR: disease control rate*

# (2/4) CS2009 + chemo demonstrated promising clinical efficacy in first-line metastatic CRC

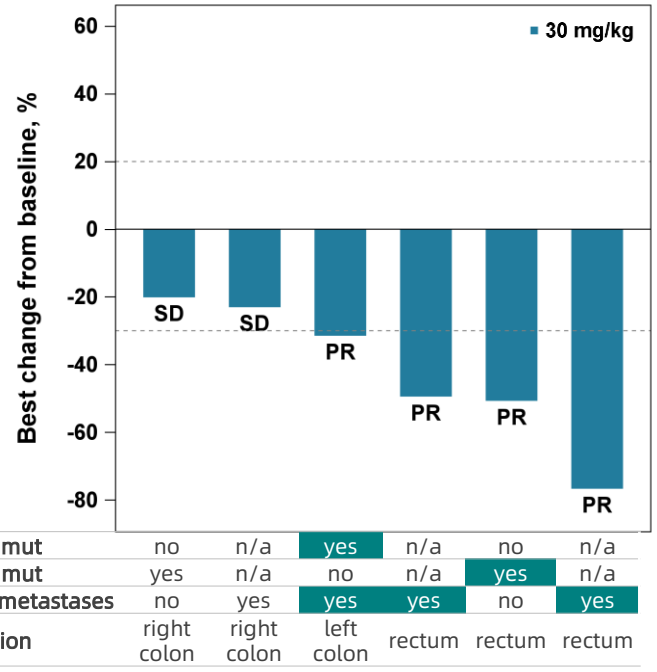
CS2009 (30 mg/kg, Q3W) + XELOX (oxaliplatin + capecitabine) for 8 cycles, followed by CS2009 + capecitabine maintenance therapy

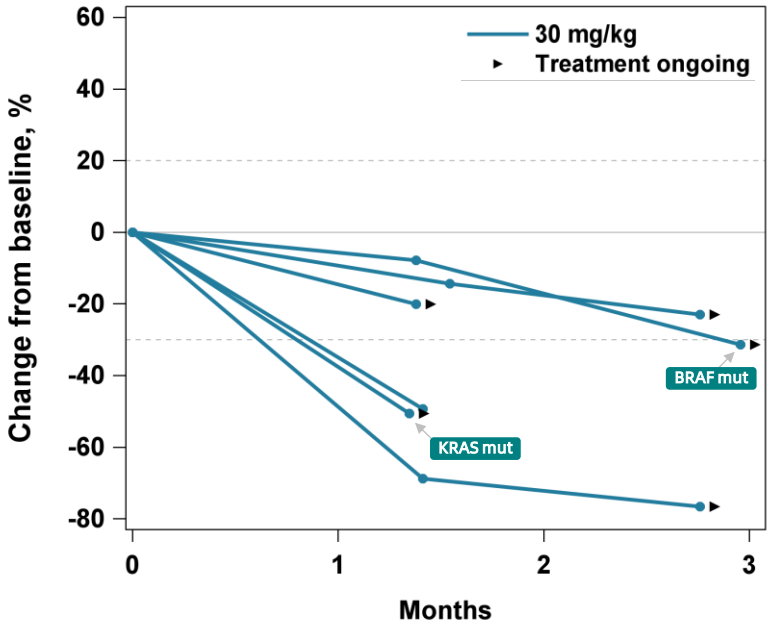
| Characteristics | First-line mCRC (n=14) |
|---|---|
| **Age**, years | |
| median (range) | 62.5 (35-75) |
| **Sex**, n (%) | |
| Female | 3 (21.4) |
| Male | 11 (78.6) |
| **ECOG PS**, n (%) | |
| 1 | 14 (100) |
| 0 | 0 |
| **Location** | |
| Left colon or rectum | 11 (78.6) |
| Right colon | 3 (21.4) |
| **MSI/MMR status**, n (%) | |
| pMMR/MSS | 13 (92.9) |
| Unknown | 1 (7.1) |
| **Liver metastases**, n (%) | 9 (64.3) |

Among patients with at least one post-baseline tumor assessment (n=6),

**ORR 66.7%** (4/6)

**DCR 100%** (6/6)




**Safety and Tolerability in First-line mCRC**

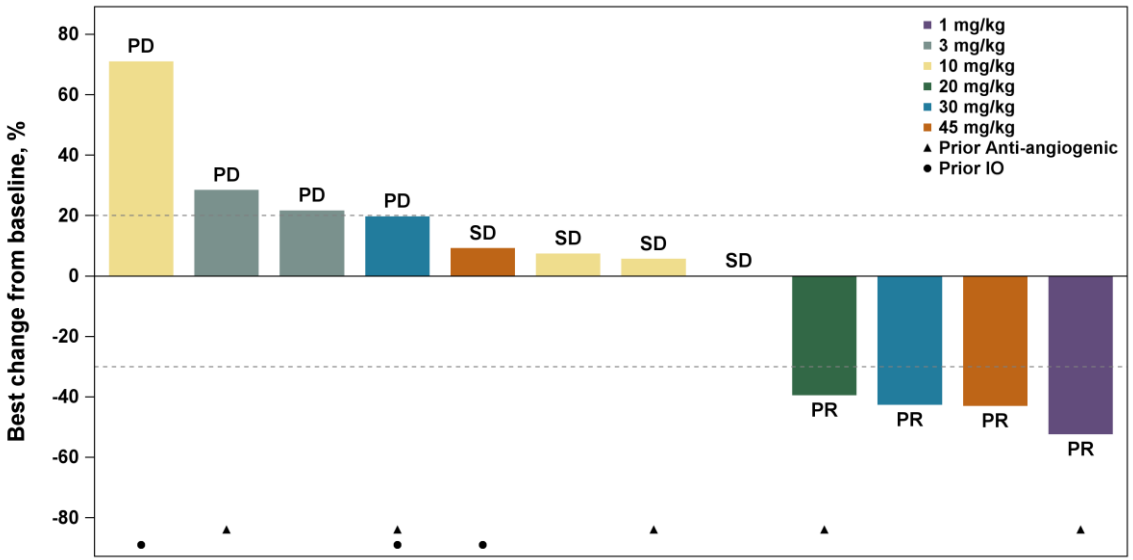
- Incidence of treatment-related TEAE (**TRAE***): *All-grade*–57.1% (8/14); *Grade ≥3*–14.3% (2/14)
- Incidence of immune-related (**irAE**): *All-grade*–14.3% (2/14), all single-case events; *Grade ≥3*–7.1% (1/14)
- Incidence of **TRAE* possibly related to anti-VEGF therapy:** 14.3% (2/14), all grade 1-2 and single-case events

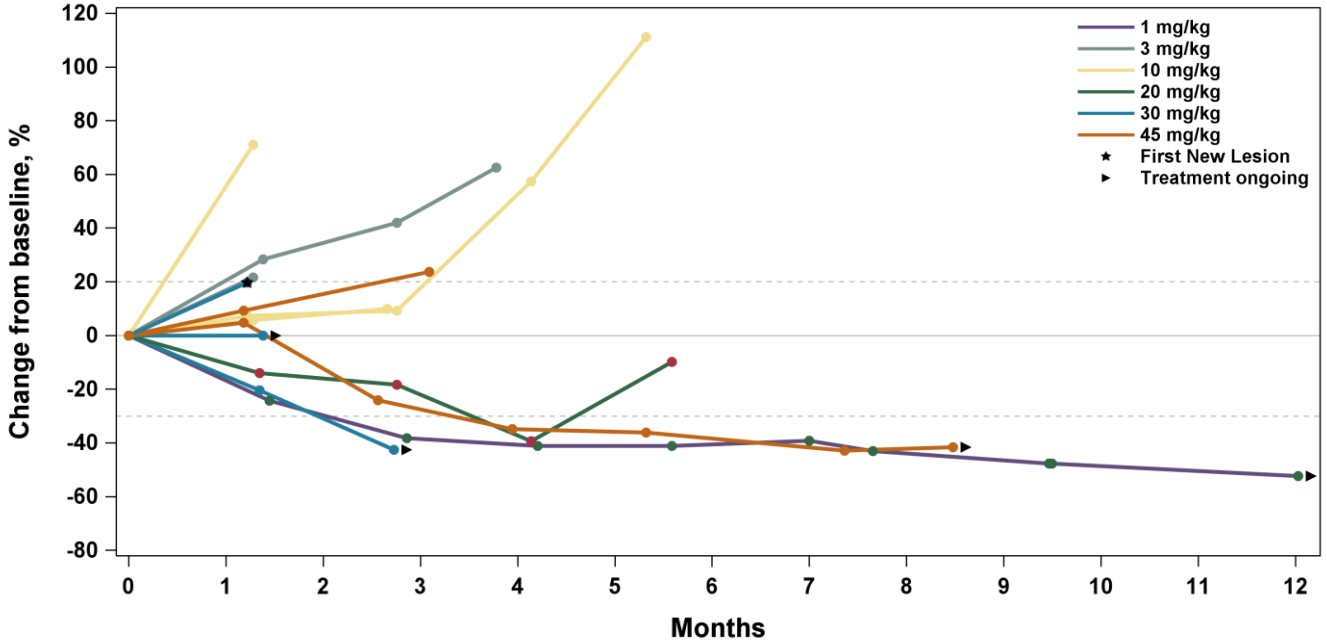
** TRAE related to any treatment–either CS2009 or chemo*
*Note: The current efficacy readout remains immature due to the short follow-up for most patients.*
*pMMR/MSS: proficient mismatch repair / microsatellite stable; mCRC: metastatic colorectal cancer; ECOG PS: Eastern Cooperative Oncology Group performance status; ORR: objective response rate; DCR: disease control rate; XELOX: capecitabine plus oxaliplatin*

# (3/4) CS2009 monotherapy demonstrated promising clinical efficacy in later-line soft tissue sarcoma (STS)–a "cold tumor" not sensitive to PD-(L)1 mAb

Among patients with at least one post-baseline tumor assessment (n=12),

**ORR 33.3%** (4/12), **DCR 66.7%** (8/12)



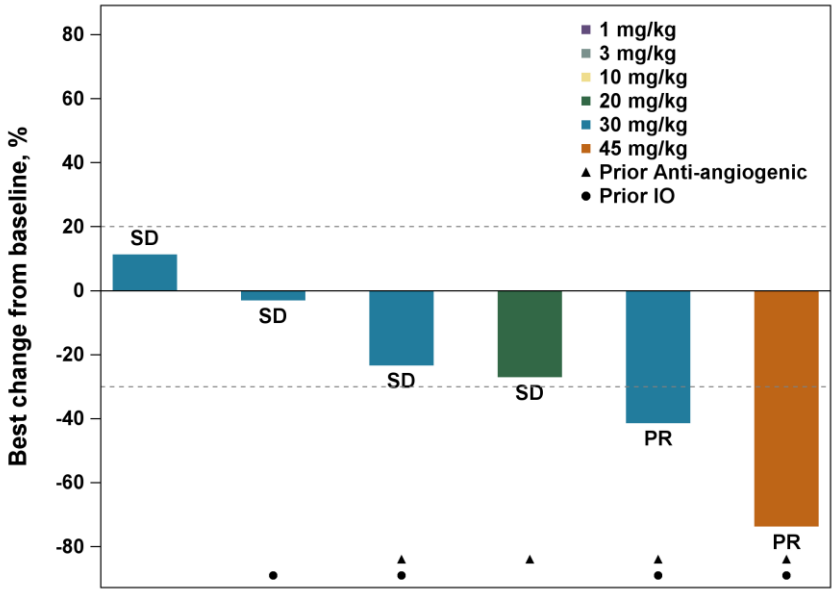

- **Subtype**: leiomyosarcoma (n=3), undifferentiated pleomorphic sarcoma (n=3), epithelioid sarcoma (n=2), liposarcoma (n=2), high-grade round cell sarcoma (n=1), synovial sarcoma (n=1)
- **Prior TKI**: 41.7% (n=5); **prior I/O**: 25% (n=3)
- **Responders**: undifferentiated pleomorphic sarcoma (n=2), high-grade round cell sarcoma (n=1), epithelioid sarcoma (n=1)

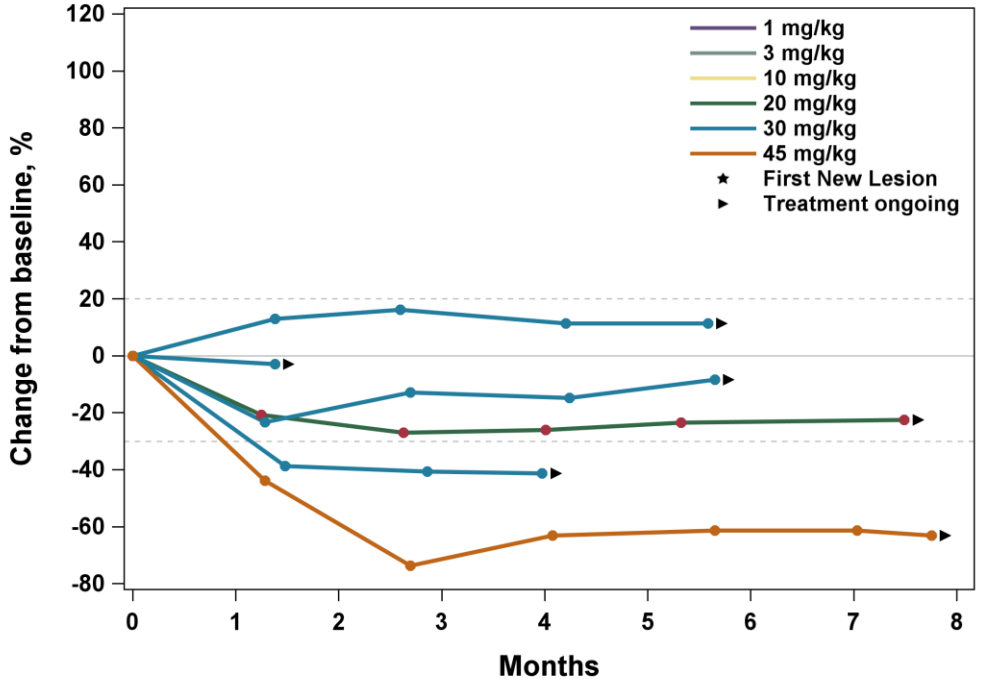
***Note**: Treatment options in clinic for STS are mainly TKIs, of which ORR is typically ~20% and ~6% in the first-line and later-line setting, respectively.*
*ORR: objective response rate; DCR: disease control rate; TKI: tyrosine Kinase Inhibitor: I/O: immuno-oncology*

# (4/4) CS2009 monotherapy demonstrated promising clinical efficacy in later-line non-clear-cell renal cell carcinoma (nccRCC)—a "cold tumor" not sensitive to PD-(L)1 mAb

Among patients with at least one post-baseline tumor assessment (n=6),

**ORR 33.3%** (2/6), **DCR 100%** (6/6)




- **Subtype**: papillary (n=3), chromophobe (n=3)
- **Prior anti-angiogenic**: 66.7% (n=4); **prior I/O**: 66.7% (n=4)
- **Responders**: papillary (n=2)

***Note:*** *1st-tier recommendation is clinical trial; Current investigator's choice for later-line nccRCC typically results in ORR ~14%.*
*ORR: objective response rate; DCR: disease control rate; I/O: immuno-oncology*

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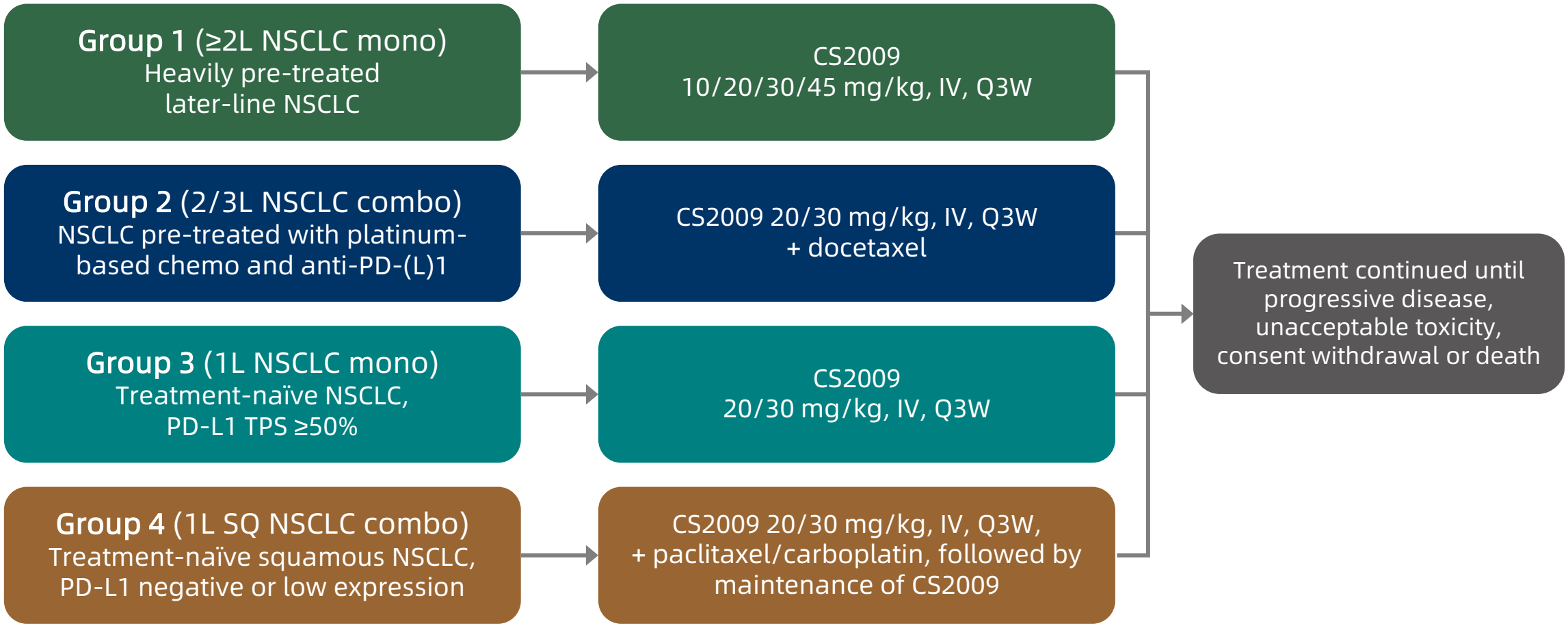
5. **Solidified Clinical Efficacy in NSCLC**
6. Commercial Potential: Multi-Billion I/O Market

# Four groups of advanced NSCLC (w/o known AGA) patients analyzed as of 2026 ASCO




*Data cutoff date: April 13, 2026*
*AGA: actionable oncogenic alterations; NSCLC: non-small cell lung cancer; L: line; IV: intravenous; Q3W: every 3 weeks; TPS: tumor proportion score*

# Baseline Characteristics of NSCLC Cohorts: Over 100 Patients with Advanced NSCLC Treated with CS2009 Monotherapy or in Combination with Chemo

Prior lines of therapy - Group 1 (≥2L NSCLC mono): 1 line, 61.4%; 2 lines, 21.1%; ≥ 3 lines, 17.5%
- Group 2 (2/3L NSCLC combo): 1 line, 100%

| Characteristics | Group 1<br>≥2L NSCLC mono<br>(n=57) | Group 2<br>2/3L NSCLC combo<br>(n=9) | Group 3<br>1L NSCLC mono<br>(n=23) | Group 4<br>1L SQ NSCLC combo<br>(n=19) |
|---|---|---|---|---|
| **Age, years** | | | | |
| Median (range) | 67.0 (37-78) | 62.0 (44-74) | 69.0 (48-82) | 70.0 (38-74) |
| **Sex, n (%)** | | | | |
| Female | 14 (24.6) | 1 (11.1) | 2 (8.7) | 4 (21.1) |
| Male | 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 |

*Chemo: chemotherapy; Combo: combination therapy; ECOG PS: Eastern Cooperative Oncology Group performance status; L: line; mono: monotherapy; NSCLC: non-small cell lung cancer.*

# Safety in NSCLC: CS2009 monotherapy and in combination with chemo were well-tolerated and demonstrated favorable safety profiles across different line settings

Safety data for Groups 2/3/4 remain preliminary due to limited follow-up

| n (%) | Group 1<br>≥2L NSCLC mono<br>(n=57) | Group 2<br>2/3L NSCLC combo<br>(n=9) | Group 3<br>1L NSCLC mono<br>(n=23) | Group 4<br>1L SQ NSCLC combo<br>(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 |

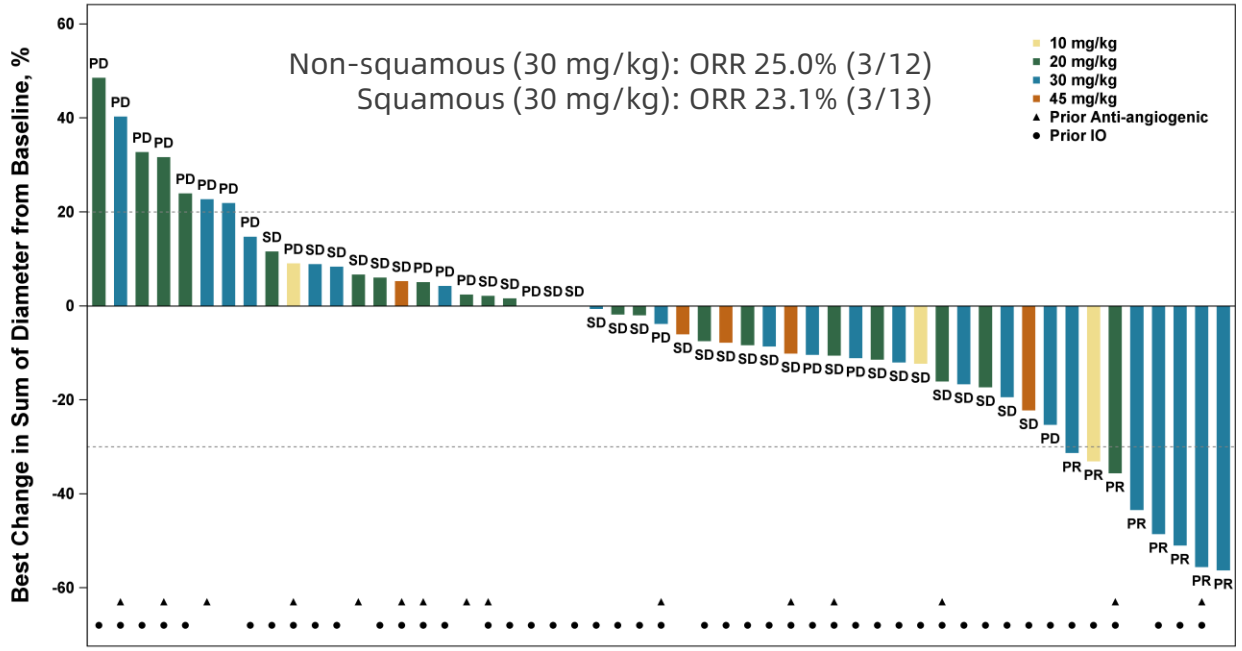
** TRAE related to any treatment–either CS2009 or chemo*
*NSCLC: non-small cell lung cancer; mono: monotherapy; combo: combination; L: line; SQ: squamous;*

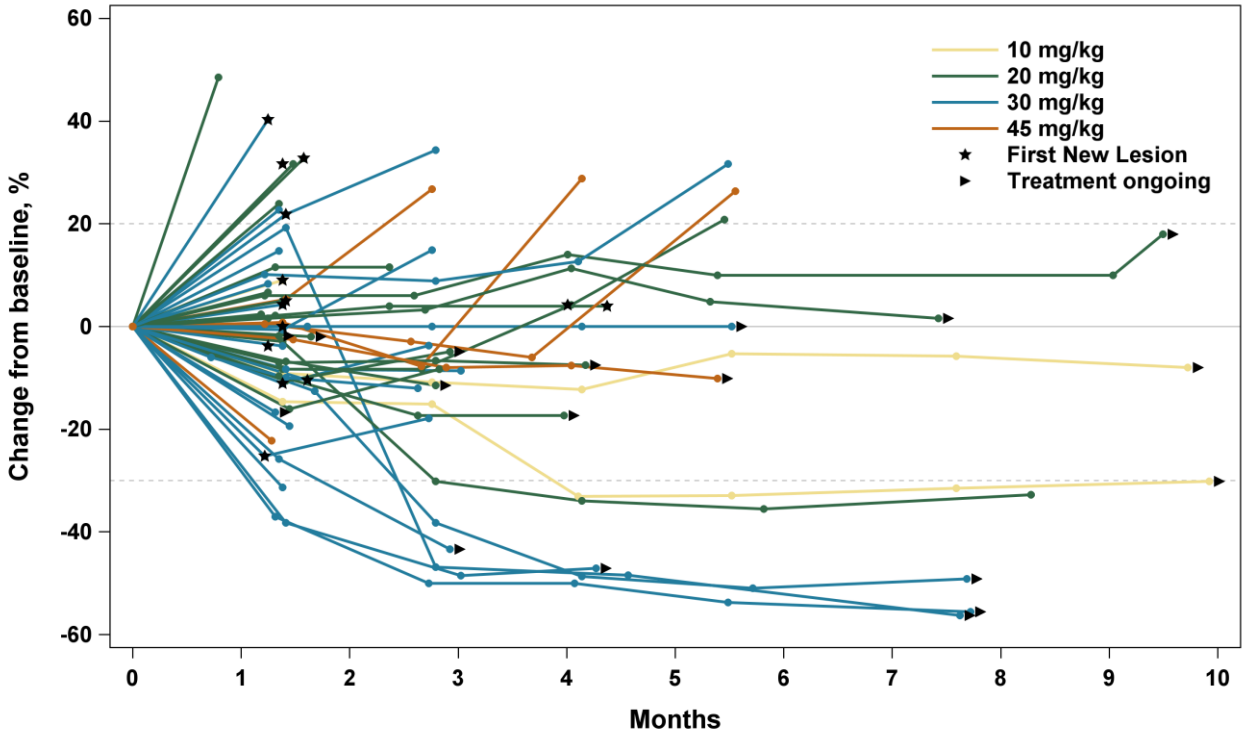
# Group 1 (≥2L NSCLC mono): CS2009 monotherapy data solidified clinical efficacy in heavily pre-treated NSCLC

CS2009 monotherapy at 10, 20, 30, or 45 mg/kg, Q3W

Among patients treated at 30 mg/kg, **ORR 24.0%** (6/25), **DCR 60.0%** (15/25)

**6-month DOR rate 80.0%.** Tumor burden shrinkage sustained in most patients.




*NSCLC: non-small cell lung cancer; mono: monotherapy; L: line; Q3W: every 3 weeks; ORR: objective response rate; DCR: disease control rate; DOR: duration of response*

# Monotherapy Activity in Heavily Pre-Treated NSCLC vs. Bispecific Antibodies

| | CS2009[1] (PD-1/VEGF/CTLA-4) | AK104+AK109[2] (PD-1/CTLA-4+VEGF) | AK104+anlotinib[3] (PD-1/CTLA-4+TKI) | AK104[4] (PD-1/CTLA-4) | AK104[5] (PD-1/CTLA-4) | AK112[6] (PD-1/VEGF) | BNT327/PM8002[7] (PD-L1/VEGF) |
|---|---|---|---|---|---|---|---|
| **Stage of data cited** | Phase 1/2 In **≥2L AGA(-) NSCLC 30 mg/kg** | Phase 1b/2 in **2L NSCLC** | Phase 1b/2 | Phase 1 dose escalation | Phase 1b/2 | Phase 1 dose escalation | Phase 1b/2a |
| **Evaluable patients**, n | 25 | 47^ | 6 | 6 | 23† | 2 | 8^ |
| **ORR** | **6/25 (24.0%*)** | **6/47 (12.8%)** | **1/6 (16.7%)** | **0/6 (0%)** | **0/23 (0%)** | **0/2 (0%)** | **1/8 (12.5%)** |
| **DCR** | **15/25 (60%)** | **45/47 (95.7%)** | **6/6 (100%)** | **2/6 (33.3%)** | **7/23 (30.4%)** | **1/2 (50%)** | **5/8 (62.5%)** |

* For patients who had only been treated with immunotherapy plus platinum-based doublet chemotherapy (n=13), ORR and DCR were 30.8% (4/13) and 84.6% (11/13).

^ All patients are AGA-negative and 2L post-IO NSCLC.

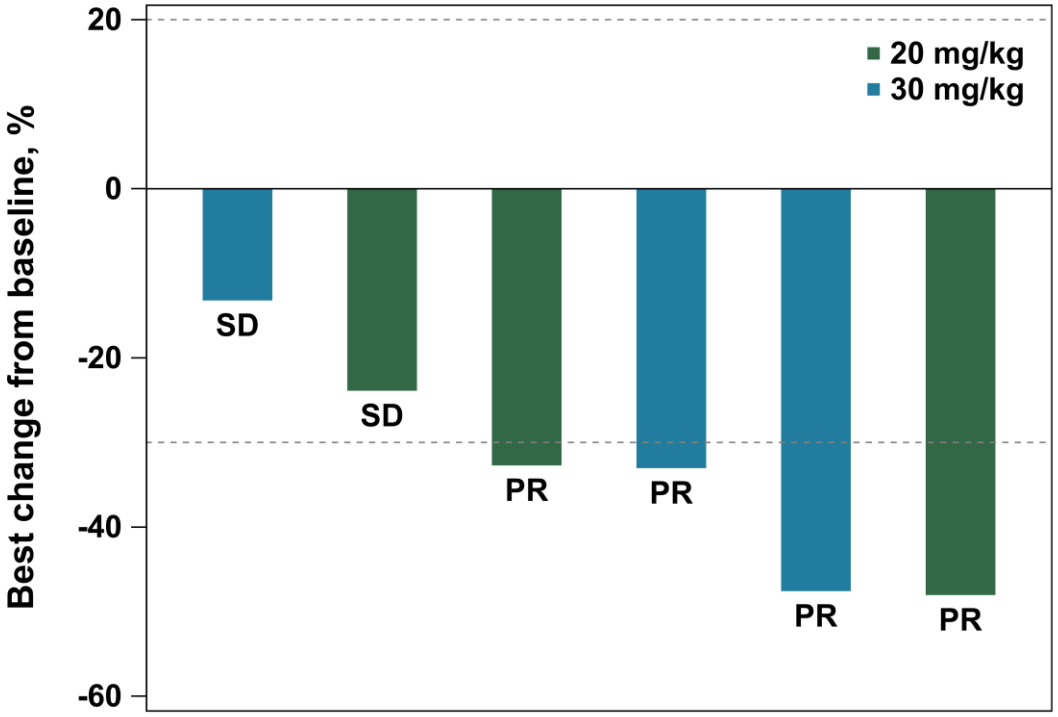
† All patients are AGA-negative/unknown and ≥2L post-IO NSCLC.

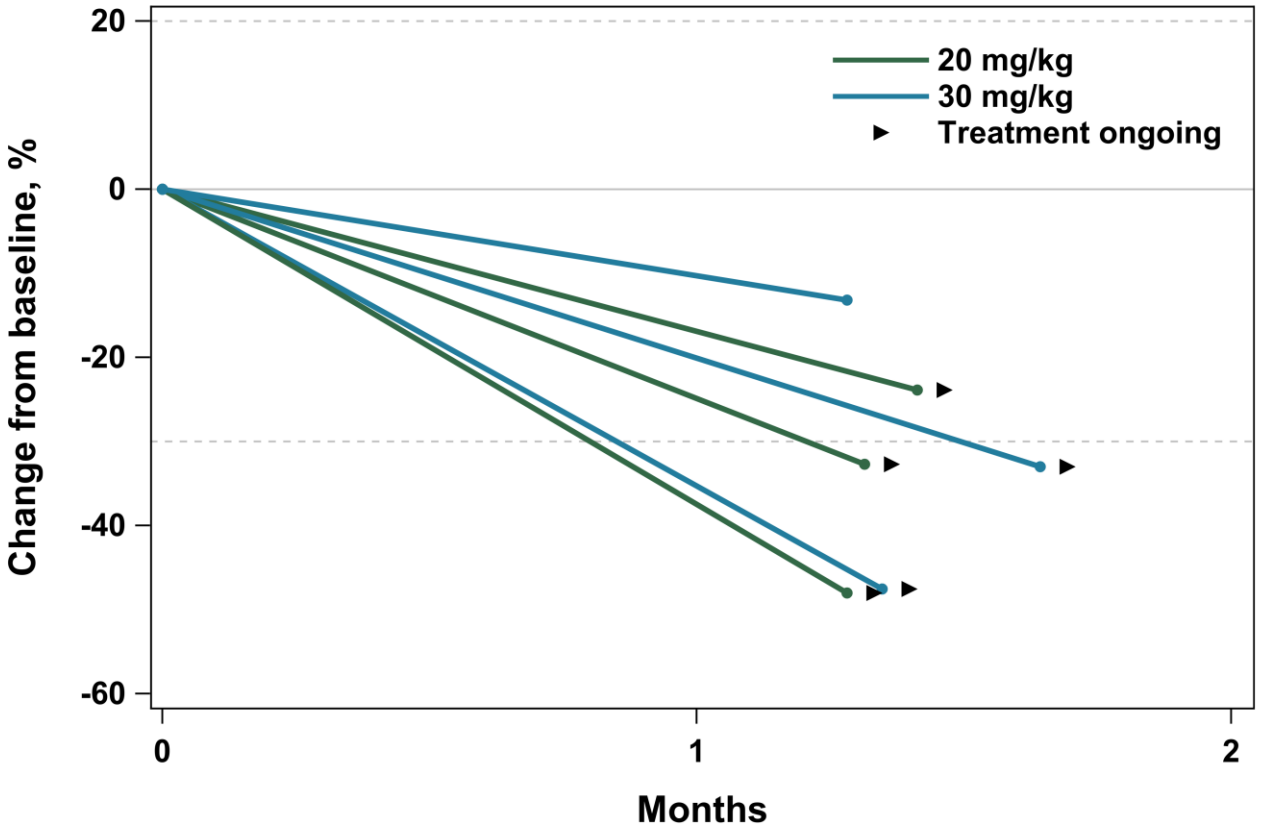
*≥2L: second-/later-line; NSCLC: non-small cell lung cancer; AGA: actionable oncogenic alterations; ORR: objective response rate; DCR: disease control rate; I/O: immuno-oncology; mAb: monoclonal antibody*
*Note: 1. ASCO 2026; 2. WCLC 2025 (2L NSCLC); 3. ESMO 2021; 4. Cell Reports Medicine 2023; 5. Lung Cancer 2023; 6. JITC 2024; 7. ASCO 2024*

# Group 2 (2/3L NSCLC combo): CS2009 + docetaxel data solidified clinical efficacy in I/O- & chemo-treated NSCLC

CS2009 at 20 or 30 mg/kg, Q3W, plus docetaxel

## ORR 66.7% (4/6), DCR 100% (6/6)



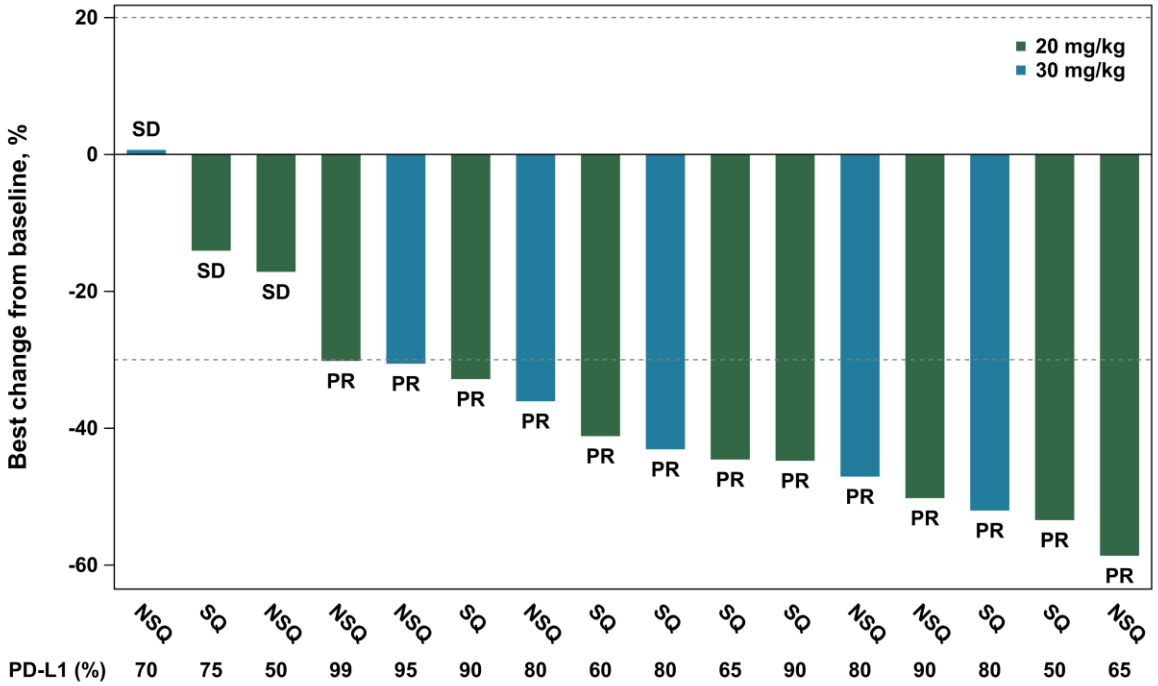

*Note: The current efficacy readout remains immature due to the short follow-up for most patients. Many of the SDs at the 1st or 2nd post-baseline tumor assessment are expected to convert to PRs as demonstrated in NSCLC cohorts with longer follow-up.*
*NSCLC: non-small cell lung cancer; mono: monotherapy; L: line; Q3W: every 3 weeks; ORR: objective response rate; DCR: disease control rate*

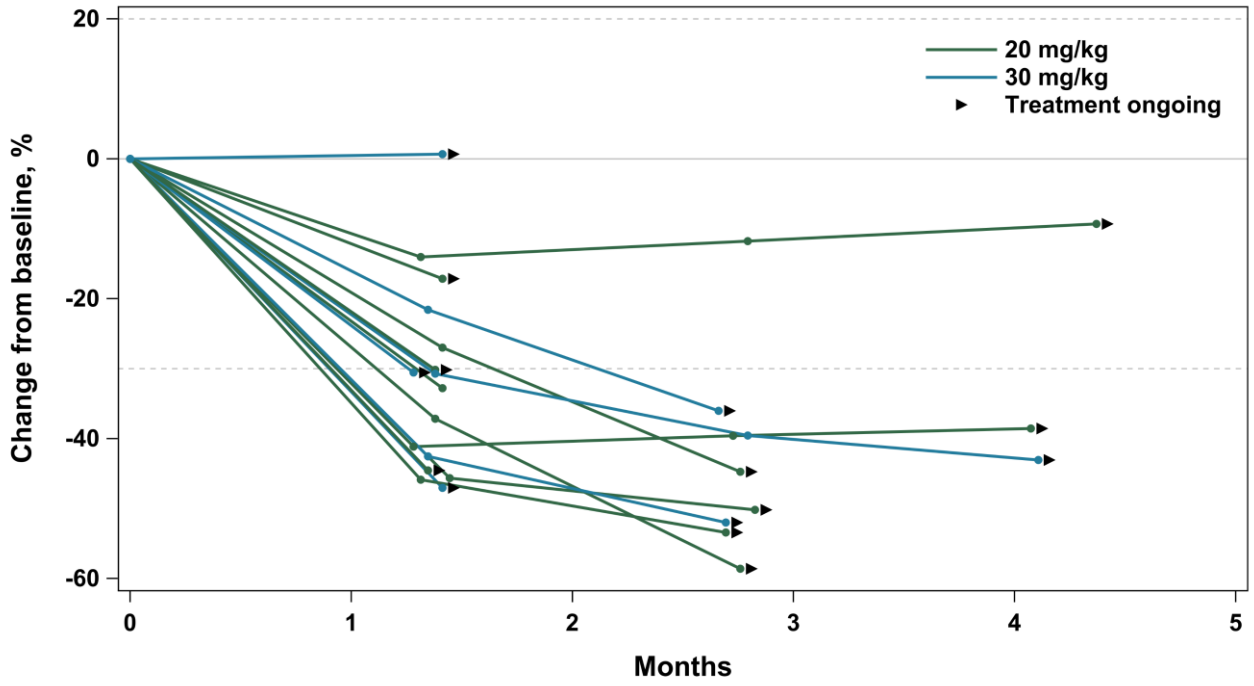
# Group 3 (1L NSCLC mono): CS2009 monotherapy data solidified clinical efficacy in first-line NSCLC (PD-L1 TPS ≥50%)

CS2009 monotherapy at 20 or 30 mg/kg, Q3W; 50.0% squamous and 50.0% non-squamous

## ORR 81.3% (13/16), DCR 100% (16/16)

Comparable ORR in squamous vs. non-squamous NSCLC: 87.5% (7/8) vs. 75.0% (6/8)




*NSCLC: non-small cell lung cancer; mono: monotherapy; Q3W: every 3 weeks; ORR: objective response rate; DCR: disease control rate; SQ: squamous; NSQ: non-squamous*

# Monotherapy Activity in First-Line NSCLC (PD-L1 TPS ≥50%) vs. Bispecific Antibodies

| | CS2009[1] (PD-1/VEGF/CTLA-4) | AK112[2] (PD-1/VEGF) | BNT327/PM8002[3] (PD-L1/VEGF) | SSGJ-707[4] (PD-1/VEGF) | RC148[5] (PD-1/VEGF) | AK104+anlotinib[6] (PD-1/CTLA-4+TKI) |
|---|---|---|---|---|---|---|
| **Stage of data cited** | Phase 2 | Phase 3 HARMONi-2 | Phase 1b/2a | Phase 2 | Phase 2 | Phase 1b/2 |
| **Dose levels** | 20/30 mg/kg, Q3W | AK112 20 mg/kg, Q3W vs. pembrolizumab 200 mg, Q3W | 20 mg/kg, Q2W | 10 mg/kg, Q3W | 20 mg/kg, Q3W | 10/15 mg/kg, Q3W |
| **Evaluable patients**, n | 16 | 82 vs. 85 | 15 | 13 | 9 | 8 |
| **ORR** | **81.3%** | **60% vs 48%** | **60.0%** | **77%** | **77.8%** | **75.0%** |

**Note**: The ORR of **pembrolizumab + chemo** for 1L NSCLC (PD-L1 TPS ≥50%) was **61.4%** (non-squamous, KEYNOTE-189) or **60.3%** (squamous, KEYNOTE-407)

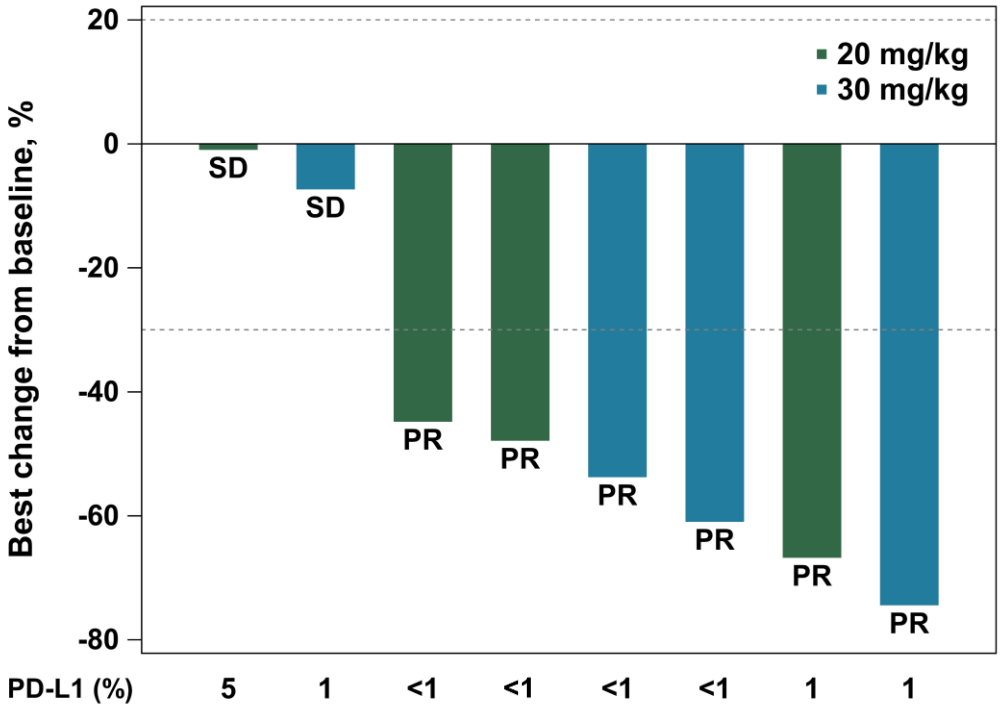
*NSCLC: non-small cell lung cancer; TPS: tumor proportion score; ORR: objective response rate; Q3W: once every 3 weeks*
*1. ASCO 2026; 2. WCLC 2025; 4. ELCC 2026; 3. ASCO 2025; 5. ESMO IO 2025; 6. British Journal of Cancer (2024) 130:450–456*

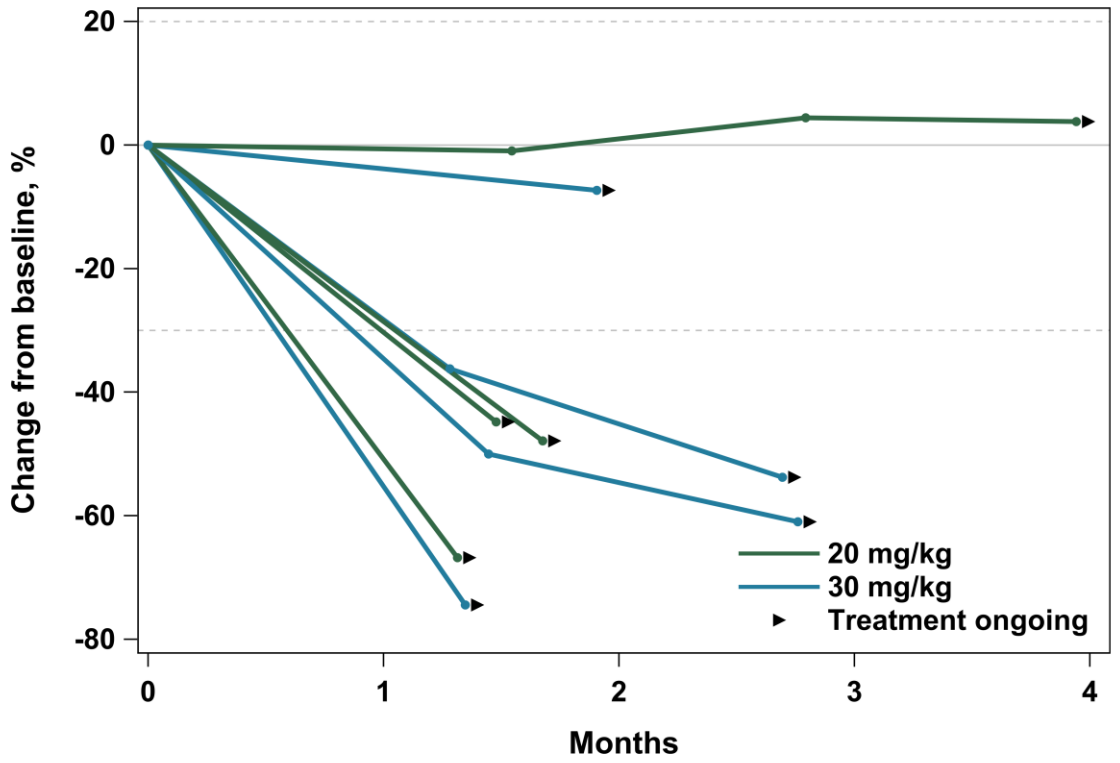
# Group 4 (1L squamous NSCLC combo): CS2009 + chemo data solidified clinical efficacy in first-line NSCLC (PD-L1 negative/low)

**All patients had PD-L1 TPS ≤5%.** Patients received CS2009 at 20 or 30 mg/kg, Q3W, plus paclitaxel and carboplatin for up to 4 cycles, followed by maintenance therapy of CS2009.

## ORR 75.0% (6/8), DCR 100% (8/8)

Among patients PD-L1 TPS <1% (n=4), **ORR 100%** (4/4)




*Note: The current efficacy readout remains immature due to the short follow-up for most patients. Many of the SDs at the 1st or 2nd post-baseline tumor assessment are expected to convert to PRs as demonstrated in NSCLC cohorts with longer follow-up.*

*NSCLC: non-small cell lung cancer; combo: combination; chemo: chemotherapy; TPS: tumor proportion score; Q3W: once every 3 weeks; ORR: objective response rate; DCR: disease control rate*

# Clinical Data and CMC Readiness for FDA Meetings and Phase III Initiation

*Clinical Safety & Efficacy Dataset for NSCLC Meetings* ▶

- Phase 1, All solid tumors (n≈130)
- Phase 2, 1L NSCLC mono (n≈40)
- Phase 1/2, Later-line NSCLC mono (n≈57)
- Phase 2, 1L NSCLC combo (n≈50)
- Phase 2, 2L NSCLC combo (n≈20)

**FDA Meetings Planned**

- **Q3 2026** — **CMC Meeting**: 120,000 vials planned for Year 2027, covering >1000 patients in Phase III clinical trials
- **Q4 2026** — **1L AGA(-) NSCLC (SQ & NSQ)**: CS2009 + chemo vs. pembrolizumab + chemo
- **Q4 2026** — **1L mCRC**: CS2009 + chemo vs. bevacizumab + chemo
- **Q1 2027** — **2L AGA(-) NSCLC (SQ & NSQ)**: CS2009 + docetaxel vs. docetaxel
- **Q1 2027** — **1L AGA(-) NSCLC (SQ & NSQ, TPS ≥50%)**: CS2009 vs. pembrolizumab

*Clinical Safety & Efficacy Dataset for CRC Meeting* ▶

- Phase 1, All solid tumors (n≈130)
- Phase 1, Later-line CRC mono (n≈20)
- Phase 2, 1L CRC combo (n≈40)

*AGA: actionable oncogenic alterations; NSCLC: non-small cell lung cancer; SQ: squamous; NSQ: non-squamous; mCRC: metastatic colorectal cancer; chemo: chemotherapy*

# Agenda


1. CS2009 Differentiation: Above & Beyond Bispecifics
2. Development Strategy for Next-Gen I/O Backbone
3. Phase I Update in Advanced Solid Tumors
4. Promising Clinical Efficacy in "Cold Tumors" – pMMR/MSS CRC, STS, and nccRCC
5. Solidified Clinical Efficacy in NSCLC
6. **Commercial Potential: Multi-Billion I/O Market**

# PD-1/VEGF/CTLA-4 trispecific mAb holds great clinical and commercial value with potentially durable OS benefit

Greater potential than PD-1/VEGF bsAbs to become the next-generation I/O backbone to replace anti-PD-(L)1 antibodies in current SOC

**Approved indications for 3 targets**

- Lung cancer ▶
- Hepatocellular carcinoma ▶
- Renal cell carcinoma ▶
- Colorectal cancer ▶

**Approved indications for PD-(L)1 & VEGF**

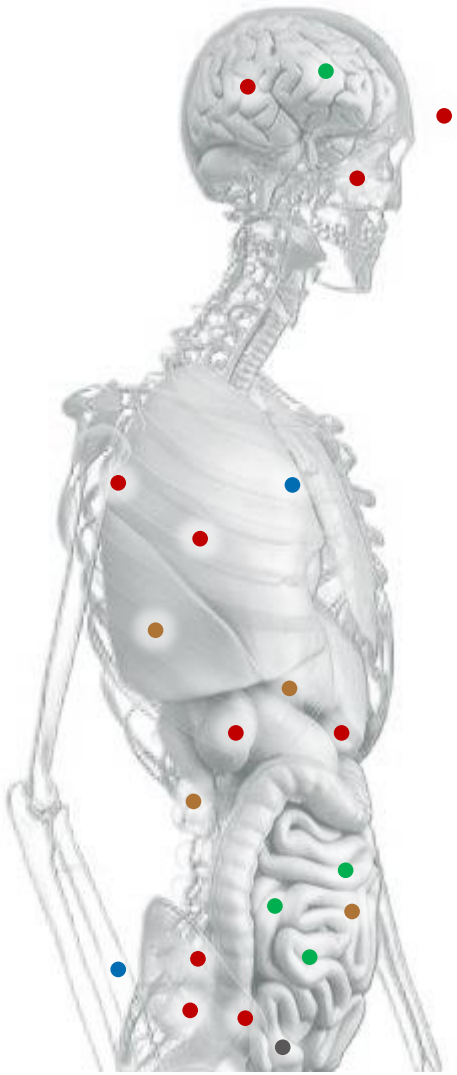
- Cervical cancer ▶

**Approved indications for PD-(L)1 & CTLA-4**

- Esophageal cancer ▶
- Melanoma ▶

**Approved indications for VEGF**

- Glioblastoma ▶
- Peritoneal cancer ▶
- Ovarian cancer ▶
- Fallopian tube carcinoma ▶
- …… ……



**Approved indications for PD-(L)1**

- ◀ Head and neck squamous cell carcinoma
- ◀ Nasopharyngeal carcinoma
- ◀ Hodgkin lymphoma
- ◀ Triple negative breast cancer
- ◀ Biliary tract cancer
- ◀ Gastric cancer
- ◀ Urothelial carcinoma
- ◀ Bladder cancer
- ◀ Endometrial cancer
- …… ……

*Broad indications with huge clinical potential*

**60+** Approved indications targeting PD-(L)1, VEGF, CTLA-4 (mono or multi-targeting)

*Remarkable commercial value to exceed current market potential for CPI*

| | |
|---|---|
| **$30bn** | Keytruda 2024 global sales revenue |
| **$53bn** | PD-(L)1 inhibitors 2024 global sales revenue |
| **$90bn** | PD-(L)1 global sales revenue by 2028 (IQVIA forecast) |
| **$90bn** | Current CPI market potential (Summit's projection) |

*Note: The indications listed above are not exhaustive of all approved indications for the three targets.*
*CPI, checkpoint inhibitor*


# Q&A


# Company Portfolio

# Well-balanced portfolio of 16 innovative assets (1/2)

## - Commercial/Late-stage Programs

| Asset | Indication | POC | Pivotal | NDA | Marketed | Approval | | | | | | Partners | Partnering Regions |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | CN | TW | HK | US | EU | UK | | |
| **Pralsetinib** (RET) | 1L NSCLC | ■ | ■ | ■ | ■ | ✓ | ✓ | ✓ | | | | blueprint MEDICINES a sanofi company | |
| | 2L NSCLC | ■ | ■ | ■ | ■ | ✓ | ✓ | ✓ | | | | | |
| | NSCLC | ■ | ■ | ■ | ■ | | | | ✓ | | | | ◀ Mainland China |
| | TC | ■ | ■ | ■ | ■ | ✓ | | | ✓ | | | rigel | |
| | Multiple tumors | ■ | | | | | | | | | | | |
| **Avapritinib** (KIT/PDGFRA) | PDGFRA exon 18 GIST | ■ | ■ | ■ | ■ | ✓ | ✓ | ✓ | ✓ | | | blueprint MEDICINES a sanofi company | ◀ Mainland China |
| | PDGFRA D842V GIST | ■ | ■ | ■ | ■ | | | | | ✓ | | | |
| | ISM[1] | ■ | ■ | ■ | ■ | | | | | ✓ | | | |
| | ASM[1] | ■ | ■ | ■ | ■ | | | | | ✓ | ✓ | | |
| **Sugemalimab** (PD-L1) | 1L Stage IV NSCLC | ■ | ■ | ■ | ■ | ✓ | | | | ✓ | ✓ | Pfizer | ◀ Mainland China |
| | Stage III NSCLC | ■ | ■ | ■ | ■ | ✓ | | | | ✓ | ✓ | ewo pharma | ◀ Switzerland and Central Eastern Europe |
| | 1L G/GEJ | ■ | ■ | ■ | ■ | ✓ | | | | | | PHARMALINK | ◀ Middle East and Africa |
| | 1L ESCC | ■ | ■ | ■ | ■ | ✓ | | | | | | STEINCARES | ◀ Latin America |
| | R/R ENKTL | ■ | ■ | ■ | ■ | ✓ | | | | | | GENTILI | ◀ West Europe and the UK |
| **CS1002** (CTLA-4) | Solid tumors | ■ | ■ | | | | | | | | | | ◀ Greater China |

*CN = Mainland China, TW = Taiwan, China, HK = Hong Kong SAR, China, US = United States, EU = European Union, UK = United Kingdom, POC = Proof of Concept, NDA = New Drug Application, NSCLC = Non-small Cell Lung Cancer, TC = Thyroid Cancer, GIST = Gastrointestinal Stromal Tumor, ISM = Indolent Systemic Mastocytosis, ASM = Advanced Systemic Mastocytosis, G/GEJ = gastric/gastroesophageal junction adenocarcinoma, ESCC = Esophageal Squamous Cell Carcinoma, R/R = Relapsed or Refractory, ENKTL = Extranodal NK/T Cell Lymphoma*

*1. POC study was conducted in North American and Europe. No clinical trials have been conducted in China while IND application is under preparation.*

# Well-balanced portfolio of 16 innovative assets (2/2)
## – Pipeline 2.0

| Asset | Right | Indication | Discovery | Preclinical Development | IND-Enabling | FIH | POC |
|---|---|---|---|---|---|---|---|
| **CS2009** (PD-1/VEGF/CTLA-4 trispecific antibody) | Global | Solid tumors | | | | | |
| **CS5001**[1] (ROR1 ADC) | Global | Solid tumors; hematologic malignancies | | | | | |
| **CS5007** (EGFR/HER3 bispecific ADC) | Global | Solid tumors | | | | | |
| **CS5006** (ITGB4 ADC) | Global | Solid tumors | | | | | |
| **CS5008** (SSTR2/DLL3 bispecific ADC) | Global | Solid tumors | | | | | |
| **CS2013** (BAFF/APRIL bispecific antibody) | Global | **Immunology & Inflammation** | | | | | |
| **CS5009** (B7H3/PD-L1 dual-payload ADC) | Global | Solid tumors | | | | | |
| **CS5010** (HER2-targeting dual-payload ADC) | Global | Solid tumors | | | | | |
| **CS5012** (HER2-targeting novel-payload ADC) | Global | Solid tumors | | | | | |
| **CS2016** (TL1A/α4β7 bispecific antibody) | Global | **Immunology & Inflammation** | | | | | |
| **CS1016** (PD-1 agonist antibody) | Global | **Immunology & Inflammation** | | | | | |
| **CS1012** (GDF-15 antibody) | Global | Solid tumors | | | | | |

*Note: Assets status denotes progress in the region(s) noted in the column titled "Rights" ; FIH = First in Human, POC = Proof of Concept,*
*1. CStone obtains the exclusive global right from LigaChem Biosciences, Inc. (LCB) to lead development and commercialization of LCB71/CS5001 outside the Republic of Korea*

Antibody ADC Global Rights