

A phase 2 study of CS2009, a first-in-class PD-1/VEGF/CTLA-4 trispecific antibody, in patients with advanced non-small cell lung cancer (NSCLC)

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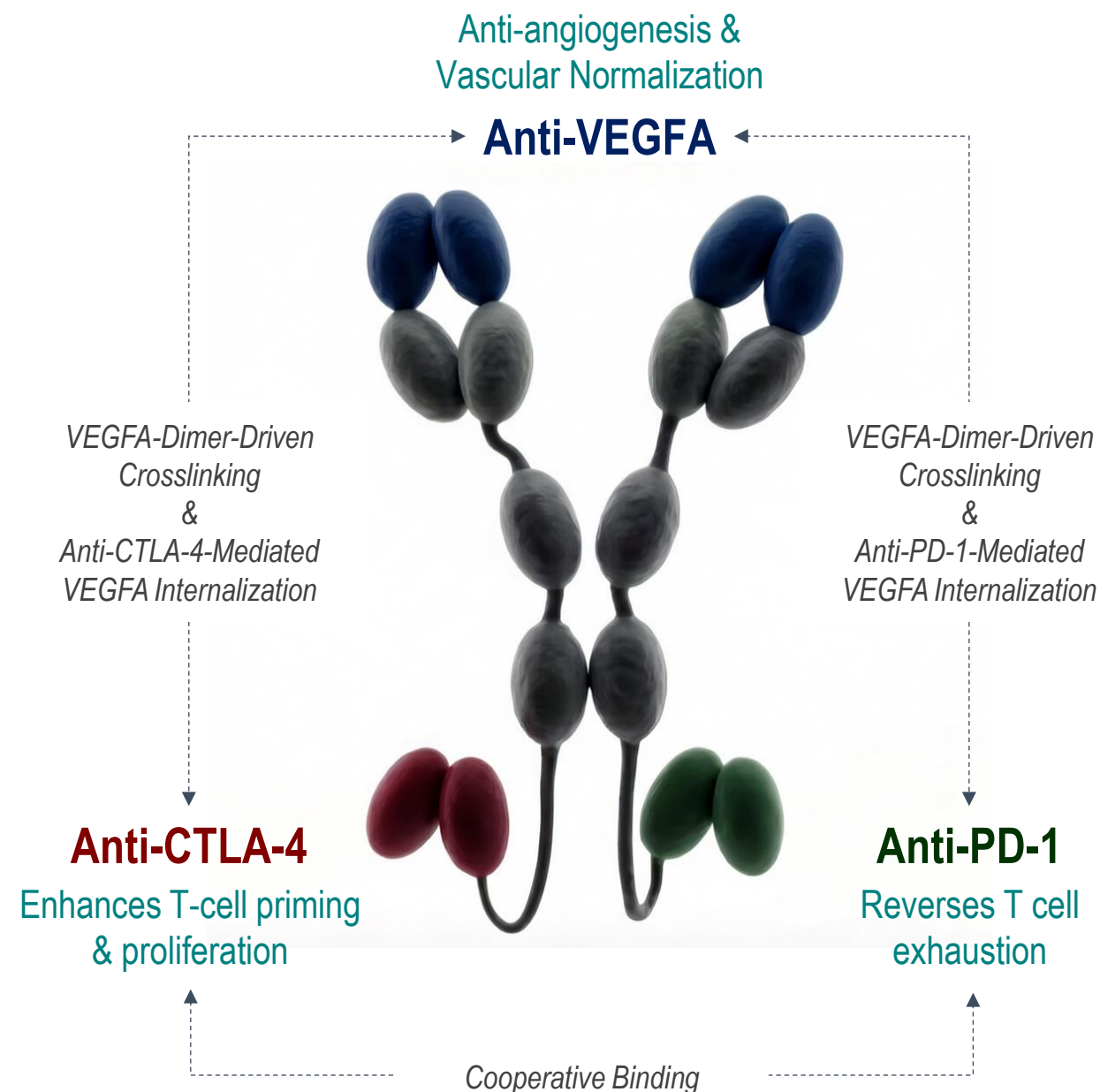
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Declaration of Interests

Dr. Anwen Xiong declares no conflict of interest.

Background



- CS2009 is a potential first-in-class/best-in-class trispecific antibody integrating clinically validated **anti-PD-1**, **anti-VEGFA**, and **anti-CTLA-4** antibody clones.
- Multi-target engagement and synergistic interactions enhance CS2009's activities in TME while sparing peripheral CTLA-4+ T cells to widen its therapeutic window.
- CS2009 demonstrated a favorable tolerability and safety profile in a Phase 1 study, with promising antitumor activity across multiple tumor types.

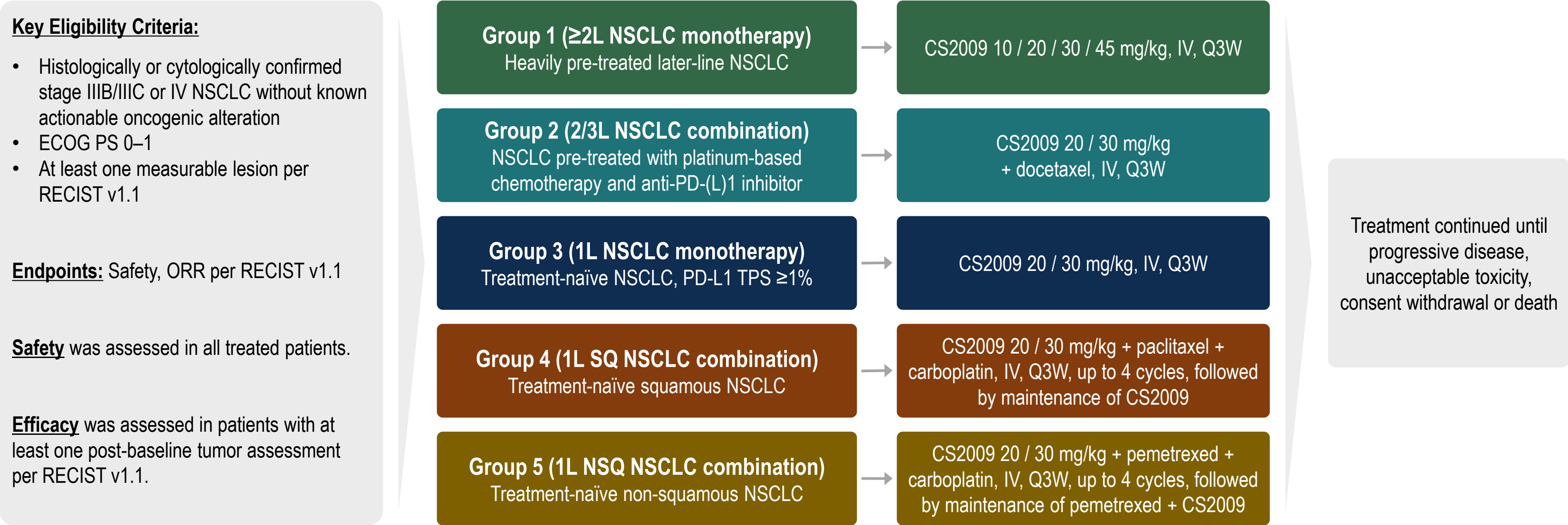
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CTLA-4: cytotoxic T-lymphocyte-associated protein 4; PD-1: programmed cell death protein 1; TME: tumor microenvironment; VEGFA: vascular endothelial growth factor A.

Study Design

A Phase 1/2 study (NCT06741644) is ongoing to evaluate CS2009 as **monotherapy or in combination with chemotherapy** in patients with **advanced non-small cell lung cancer (NSCLC)** across **first-line and later-line settings**.



Note: Demographic and safety data for Group 5 are presented. Efficacy data remain immature due to short follow-up and are not presented.

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ECOG PS: Eastern Cooperative Oncology Group performance status; IV: intravenous; L: line; NSQ: non-squamous; ORR: objective response rate; PD-1: programmed cell death protein 1; PD-L1: programmed death-ligand 1; Q3W: once every 3 weeks; RECIST: Response Evaluation Criteria in Solid Tumors; SQ: squamous; TPS: tumor proportion score.

Baseline Characteristics

Characteristics	Group 1 ≥2L NSCLC monotherapy (n=57)	Group 2 2/3L NSCLC combination (n=18)	Group 3 1L NSCLC monotherapy (n=55)	Group 4 1L SQ NSCLC combination (n=27)	Group 5 1L NSQ NSCLC combination (n=18)
Age, median (range), years	67.0 (37–78)	64.0 (44–74)	66.0 (40–82)	67.0 (38–74)	63.0 (52–75)
Male, n (%)	43 (75.4)	13 (72.2)	46 (83.6)	22 (81.5)	11 (61.1)
Race, n (%)					
Asian	42 (73.7)	16 (88.9)	55 (100)	27 (100)	17 (94.4)
White	14 (24.6)	2 (11.1)	0	0	1 (5.6)
Other	1 (1.8)	0	0	0	0
ECOG performance status, n (%)					
0	13 (22.8)	3 (16.7)	7 (12.7)	11 (40.7)	3 (16.7)
1	44 (77.2)	15 (83.3)	48 (87.3)	16 (59.3)	15 (83.3)
Histology type, n (%)					
Squamous	25 (43.9)	11 (61.1)	31 (56.4)	27 (100)	0
Non-squamous	32 (56.1)	7 (38.9)	24 (43.6)	0	18 (100)
PD-L1 TPS, n (%)					
<1%	10 (17.5)	8 (44.4)	0	8 (29.6)	11 (61.1)
1%-49%	22 (38.6)	5 (27.8)	25 (45.5)	15 (55.6)	7 (38.9)
≥50%	15 (26.3)	0	30 (54.5)	2 (7.4)	0
Unknown	10 (17.5)	5 (27.8)	0	2 (7.4)	0
Prior lines of therapy, n (%)					
1 line	36 (63.2)	17 (94.4)	–	–	–
2 lines	11 (19.3)	1 (5.6)	–	–	–
≥3 lines	10 (17.5)	0	–	–	–
Prior immunotherapy, n (%)	48 (84.2)	18 (100)	–	–	–

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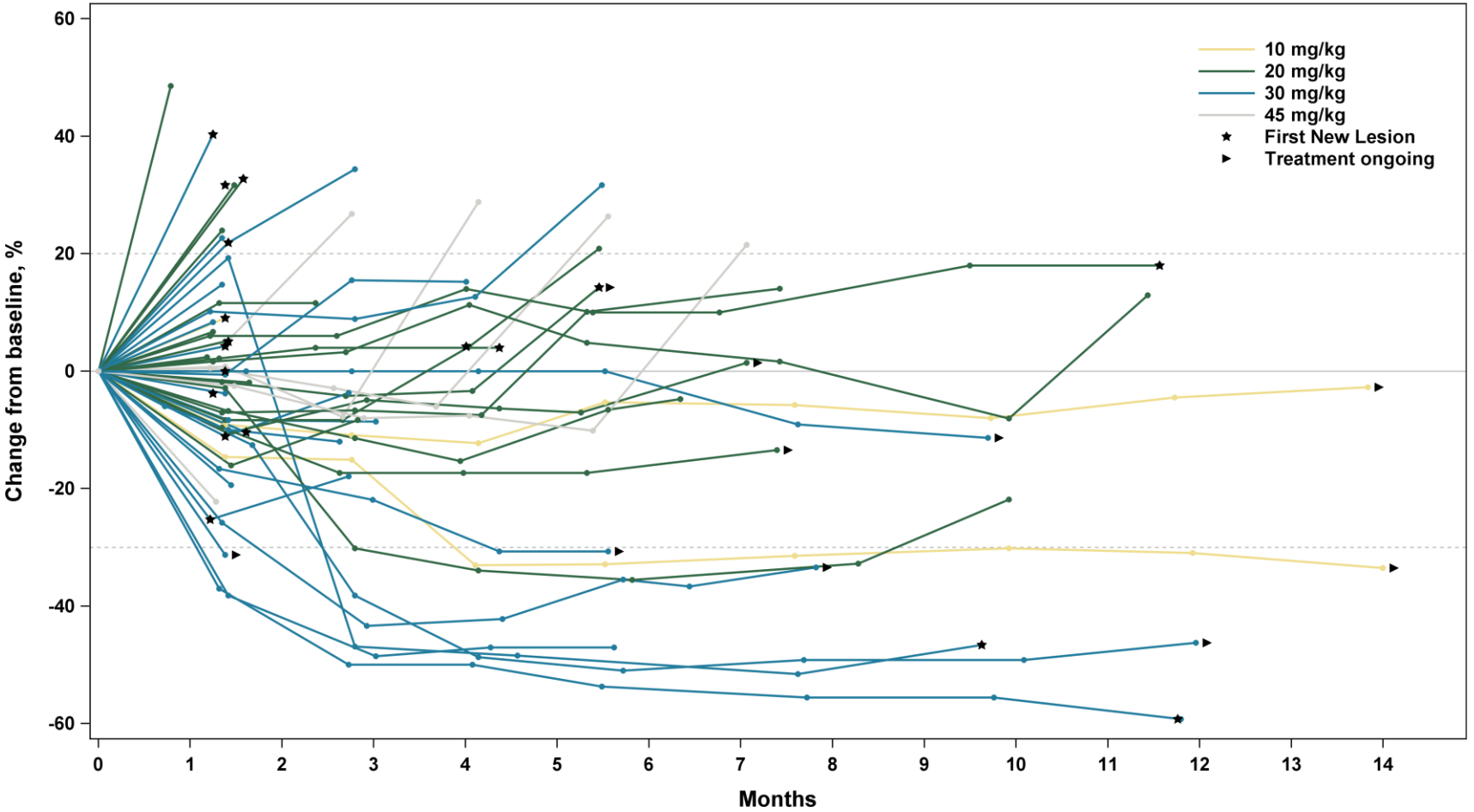
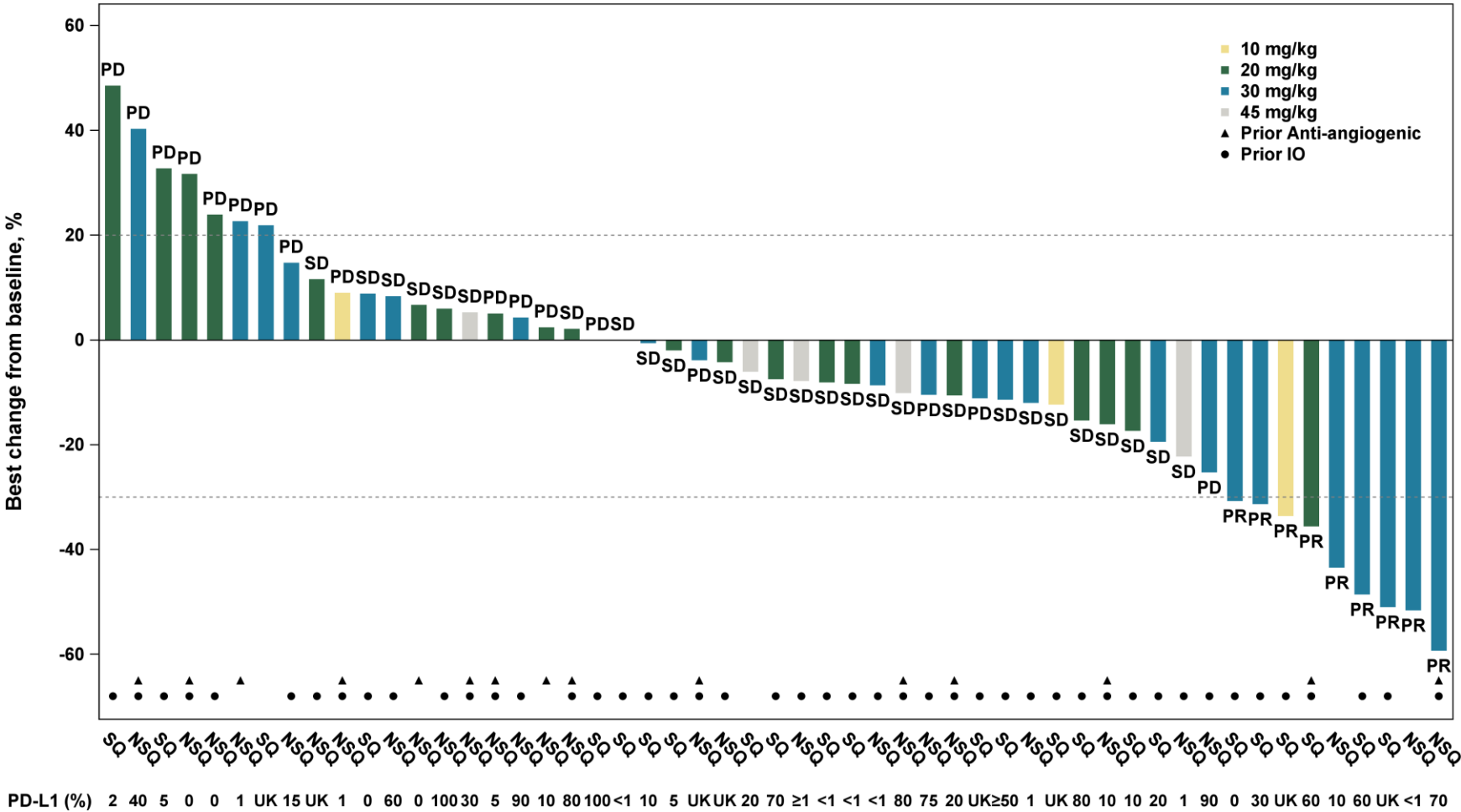
ECOG: Eastern Cooperative Oncology Group; L: line; NSCLC: non-small cell lung cancer; NSQ: non-squamous; PD-L1: programmed death-ligand 1; SQ: squamous; TPS: tumor proportion score.

Data cutoff: 06 Sep 2026

Efficacy: Group 1 (≥2L NSCLC, monotherapy)

CS2009 monotherapy demonstrated promising clinical efficacy in heavily pre-treated NSCLC

	All Evaluable Patients	30 mg/kg	Squamous, 30 mg/kg	Non-squamous, 30 mg/kg
ORR, % (n)	16.7% (9/54)	28.0% (7/25)	33.3% (4/12)	23.1% (3/13)
DCR, % (n)	68.5% (37/54)	60.0% (15/25)	75.0% (9/12)	46.2% (6/13)
mDoR, month	10.5	10.5	-	-



CS2009 is well tolerated with treatment duration exceeded 12 months at 10, 20, and 30 mg/kg.

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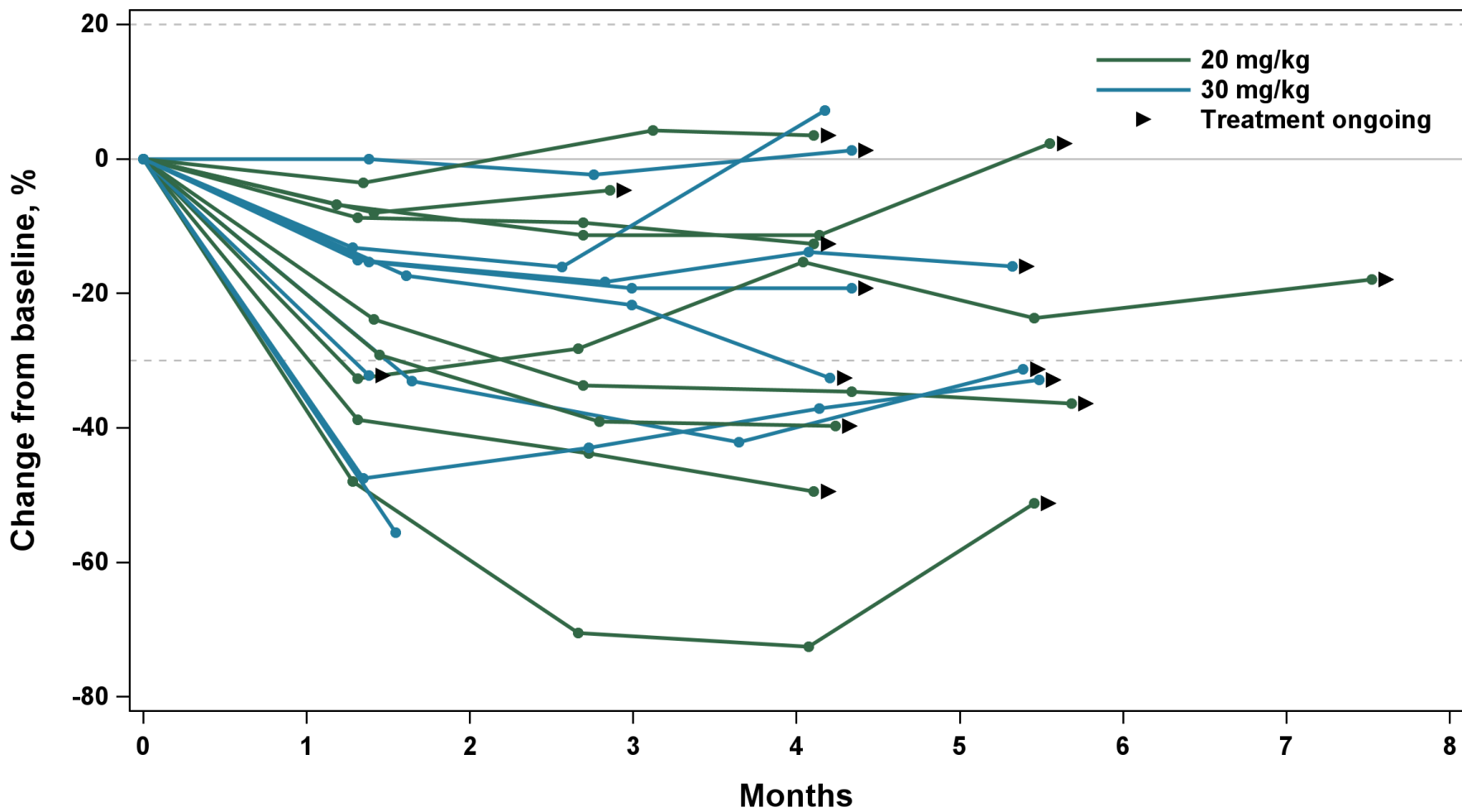
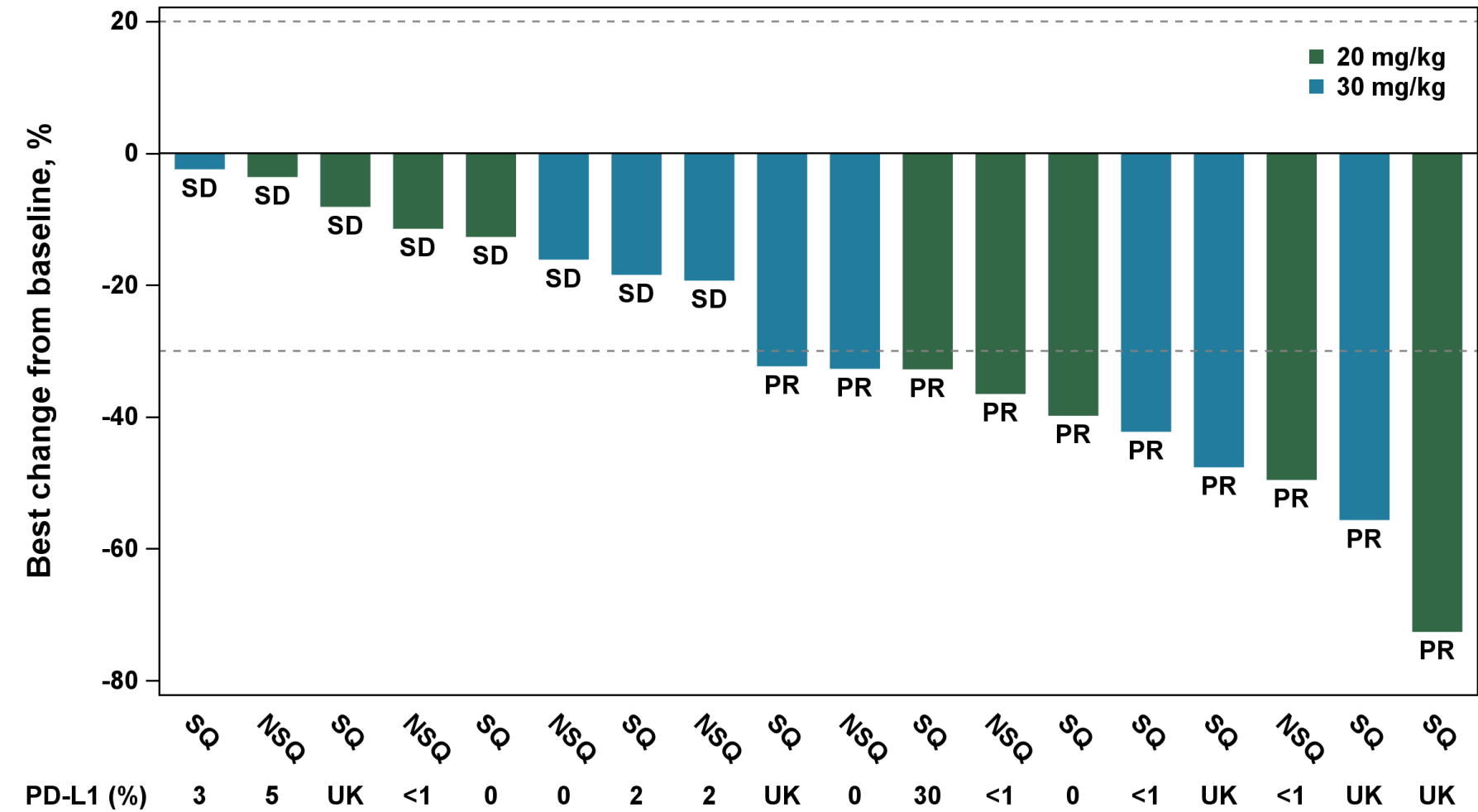
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DCR: disease control rate; IO: immunotherapy; L: line; mDoR: median duration of response; NSCLC: non-small cell lung cancer; NSQ: non-squamous; ORR: objective response rate; PD: progressive disease; PR: partial response; SD: stable disease; SQ: squamous; UK: unknown.

Efficacy: Group 2 (2/3L NSCLC, in combination with docetaxel)

CS2009 + docetaxel demonstrated promising preliminary clinical efficacy in IO-pretreated NSCLC

	All Evaluable Patients	20 mg/kg	30 mg/kg
ORR, % (n)	55.6% (10/18)	55.6% (5/9)	55.6% (5/9)
DCR, % (n)	100% (18/18)	100% (9/9)	100% (9/9)



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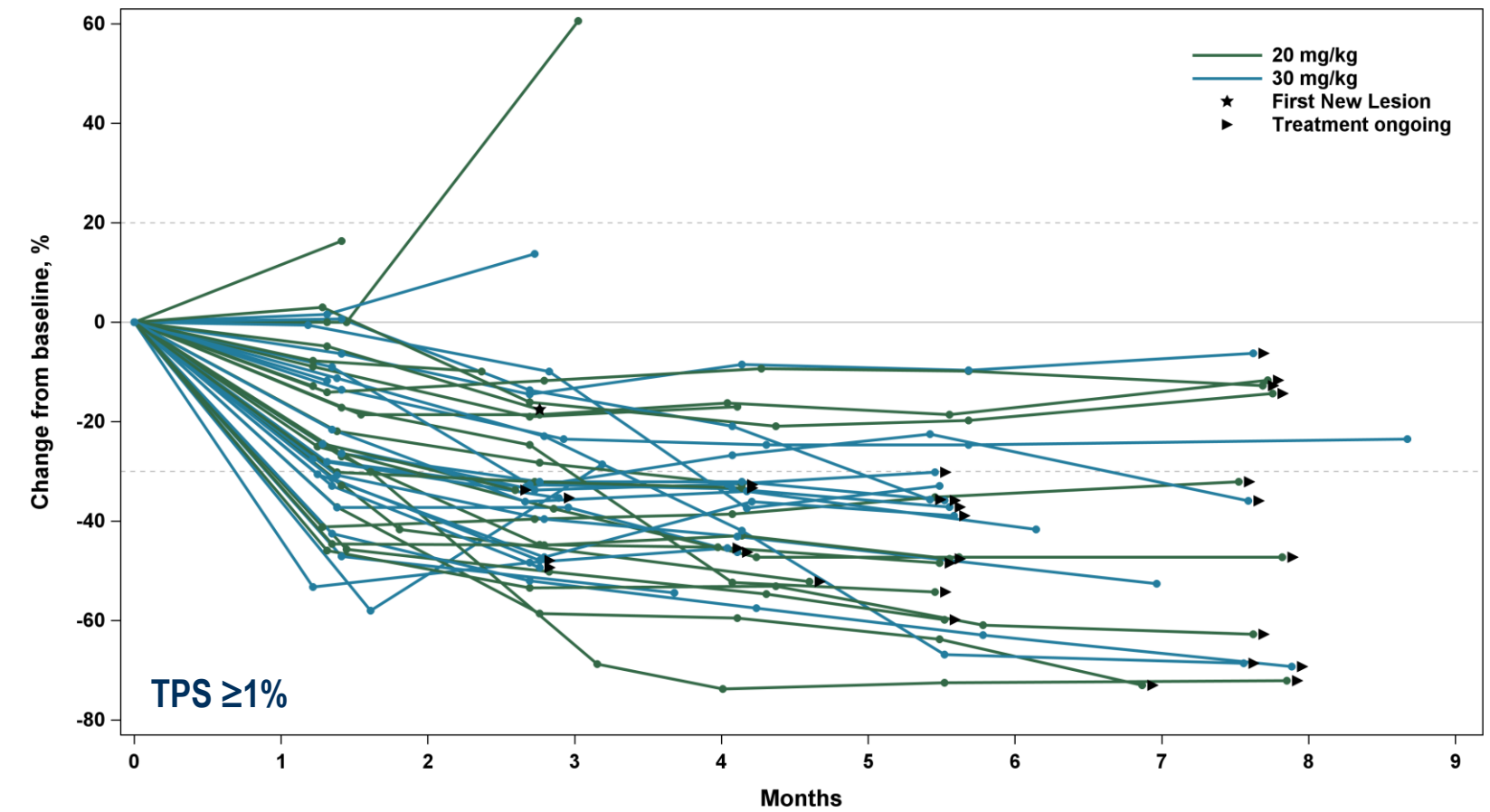
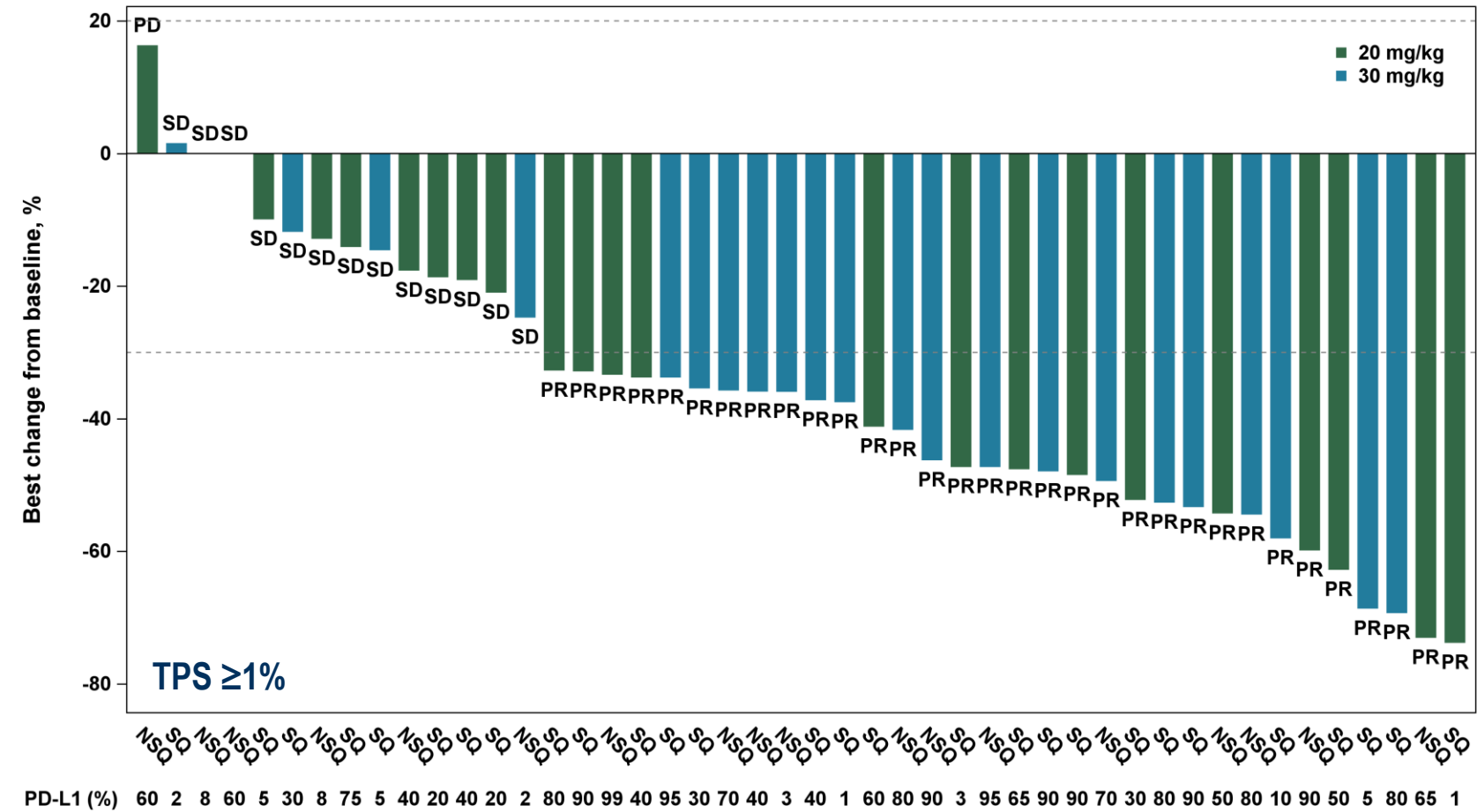
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DCR: disease control rate; DoR: duration of response; IO: immunotherapy; L: line; NSCLC: non-small cell lung cancer; NSQ: non-squamous; ORR: objective response rate; PFS: progression-free survival; PR: partial response; SD: stable disease; SQ: squamous; UK: unknown.

Efficacy: Group 3 (1L NSCLC, monotherapy)

CS2009 monotherapy demonstrated compelling clinical efficacy in first-line, PD-L1 TPS ≥1% NSCLC

		All Evaluable Patients	20 mg/kg	30 mg/kg	Squamous	Non-squamous
TPS ≥1%	ORR, % (n)	66.7% (32/48)	58.3% (14/24)	75.0% (18/24)	69.0% (20/29)	63.2% (12/19)
	DCR, % (n)	93.8% (45/48)	95.8% (23/24)	91.7% (22/24)	96.6% (28/29)	89.5% (17/19)
TPS ≥50%	ORR, % (n)	87.5% (21/24)	76.9% (10/13)	100% (11/11)	91.7% (11/12)	83.3% (10/12)
	DCR, % (n)	95.8% (23/24)	92.3% (12/13)	100% (11/11)	100% (12/12)	91.7% (11/12)



Median DoR and median PFS were not reached due to short follow-up.

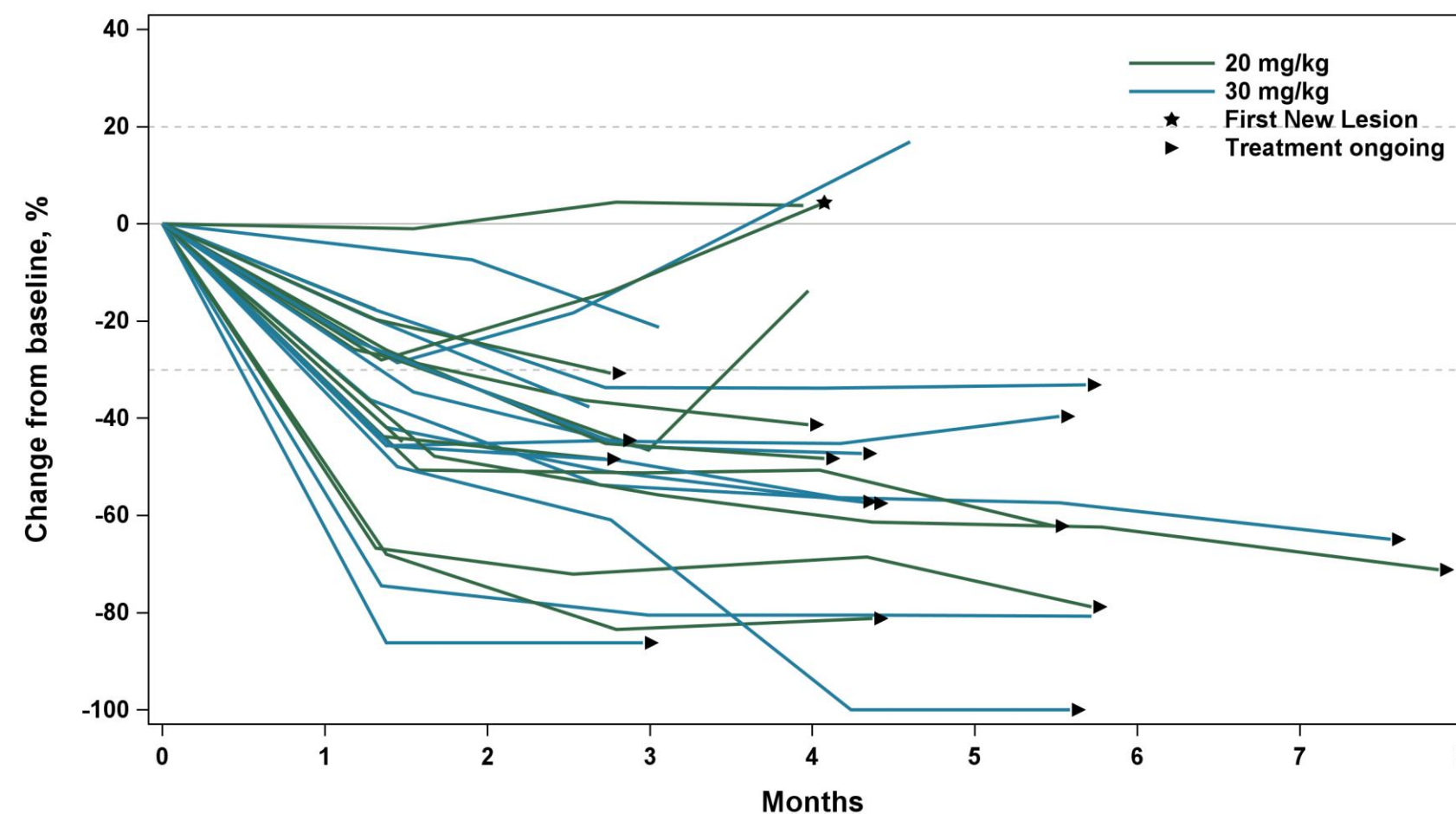
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DCR: disease control rate; DoR: duration of response; L: line; NSCLC: non-small cell lung cancer; NSQ: non-squamous; ORR: objective response rate; PD: progressive disease; PFS: progression-free survival; PR: partial response; SD: stable disease; SQ: squamous; TPS: tumor proportion score.

CS2009 + paclitaxel + carboplatin demonstrated compelling clinical efficacy in first-line squamous NSCLC

* 14/15 with PD-L1 TPS $\leq 5\%$
Note: One additional patient with unknown PD-L1 status achieved a PR.



Safety

CS2009 monotherapy and in combination with chemotherapy demonstrated a favorable safety profile in advanced NSCLC

- CS2009 combined with standard chemotherapy showed no additive immune or VEGF toxicity.
- CS2009 showed no excessive CTLA-4-related toxicities typically observed with conventional PD-(L)1 + CTLA-4 antibody combinations; incidence of Grade ≥ 3 VEGF-related toxicity was much lower than that reported for PD-(L)1/VEGF bispecific antibodies.
- No new safety signals were identified; CS2009’s safety profile remains consistent with that presented at 2026 ASCO and 2025 ESMO.

n (%)	CS2009 Monotherapy (n=112)	CS2009 + Chemotherapy (n=63)
TEAE	106 (94.6)	58 (92.1)
Grade ≥ 3 TEAE	45 (40.2)	37 (58.7)
Treatment-related TEAE (TRAE)	96 (85.7)	57 (90.5)*
Grade ≥ 3 TRAE	29 (25.9)	33 (52.4)*
Immune-related TEAE (irAE)	51 (45.5)	23 (36.5)
Grade ≥ 3 irAE	13 (11.6)	8 (12.7)
Possible anti-VEGF-related TRAE	35 (31.3)	11 (17.5)
Grade ≥ 3 possible anti-VEGF-related TRAE	6 (5.4)	3 (4.8)
TRAE leading to CS2009 discontinuation	9 (8.0)	3 (4.8)

*TRAE related to any treatment—either CS2009 or chemotherapy.

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CTLA-4: cytotoxic T-lymphocyte-associated protein 4; NSCLC: non-small cell lung cancer; PD-1: programmed cell death protein 1; PD-L1: programmed death-ligand 1; TEAE: treatment-emergent adverse event; VEGF: vascular endothelial growth factor.

Conclusion

- CS2009 demonstrated robust and consistent antitumor activity in advanced NSCLC, both as monotherapy and in combination with chemotherapy, across treatment-naïve and IO-pretreated populations.
- CS2009 was well tolerated with a favorable safety profile in advanced NSCLC, both as monotherapy and in combination with chemotherapy, without excessive CTLA-4- or VEGF-related toxicities observed. The safety profile is consistent with that previously reported at 2026 ASCO and 2025 ESMO.
- Phase 3 MRCT in first-line NSCLC is being planned.

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