

IMA203CD8 PRAME-directed T-cell receptor T-cell therapy in ovarian cancer: results from a phase 1a study



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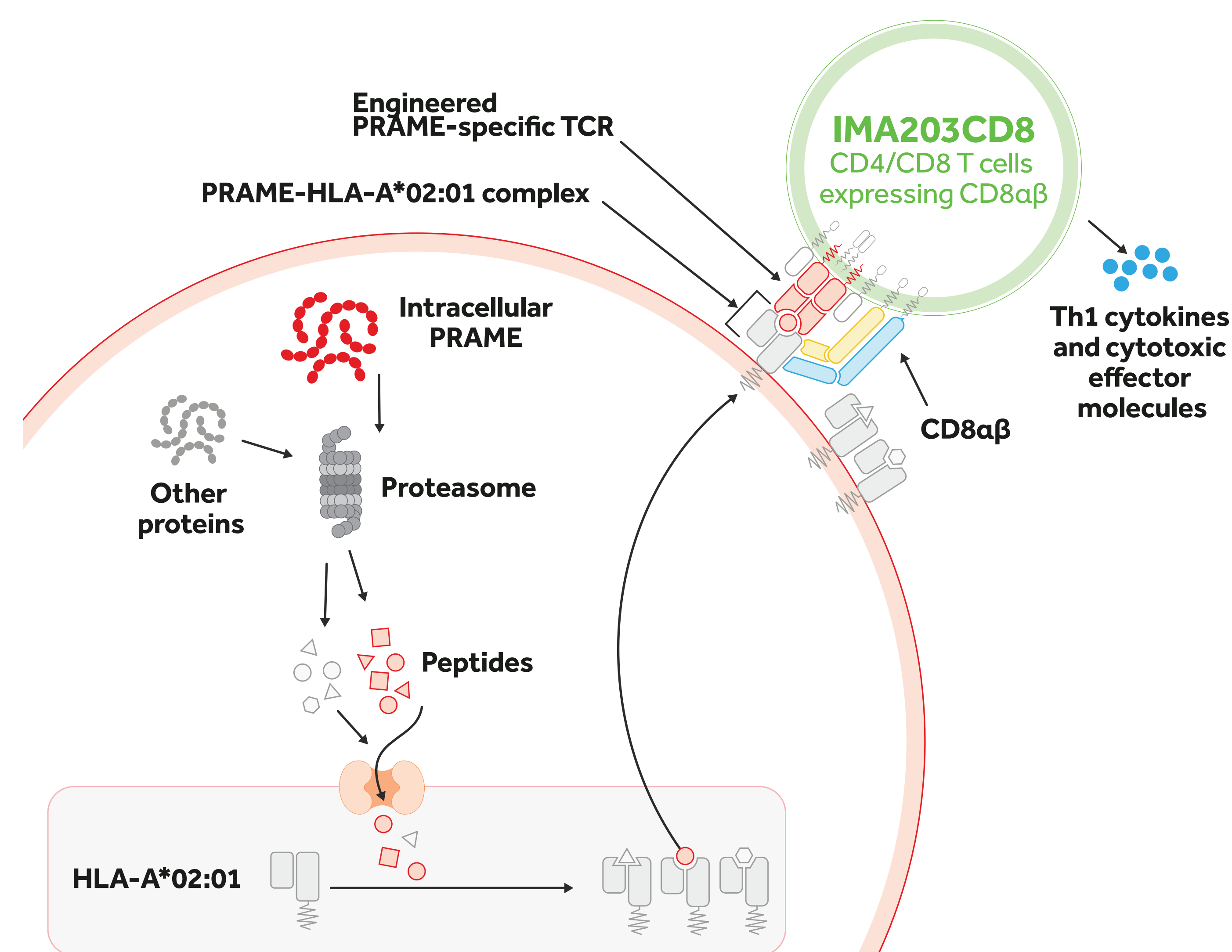
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BACKGROUND

- Patients with advanced ovarian cancer (OC) that progresses after platinum-based chemotherapy and subsequent treatment are lacking therapeutic options with durable clinical benefit¹
- TCR T-cell therapies enable immune recognition of intracellular tumor antigens presented by cell-surface HLA, expanding the therapeutic landscape beyond targets accessible to conventional immunotherapies²
- Ovarian cancer expresses multiple tumor antigens that inform treatment decisions, including PRAME, which is expressed in >50 cancers³
- IMA203CD8 is a TCR T-cell therapy precision-engineered to co-express a PRAME-directed TCR and CD8 $\alpha\beta$, enabling both CD4+ and CD8+ T cells to detect and destroy PRAME+ tumors that evade conventional therapeutic approaches (Fig. 1)⁴
- Here we present IMA203CD8 dose-escalation results for the subset of patients with OC

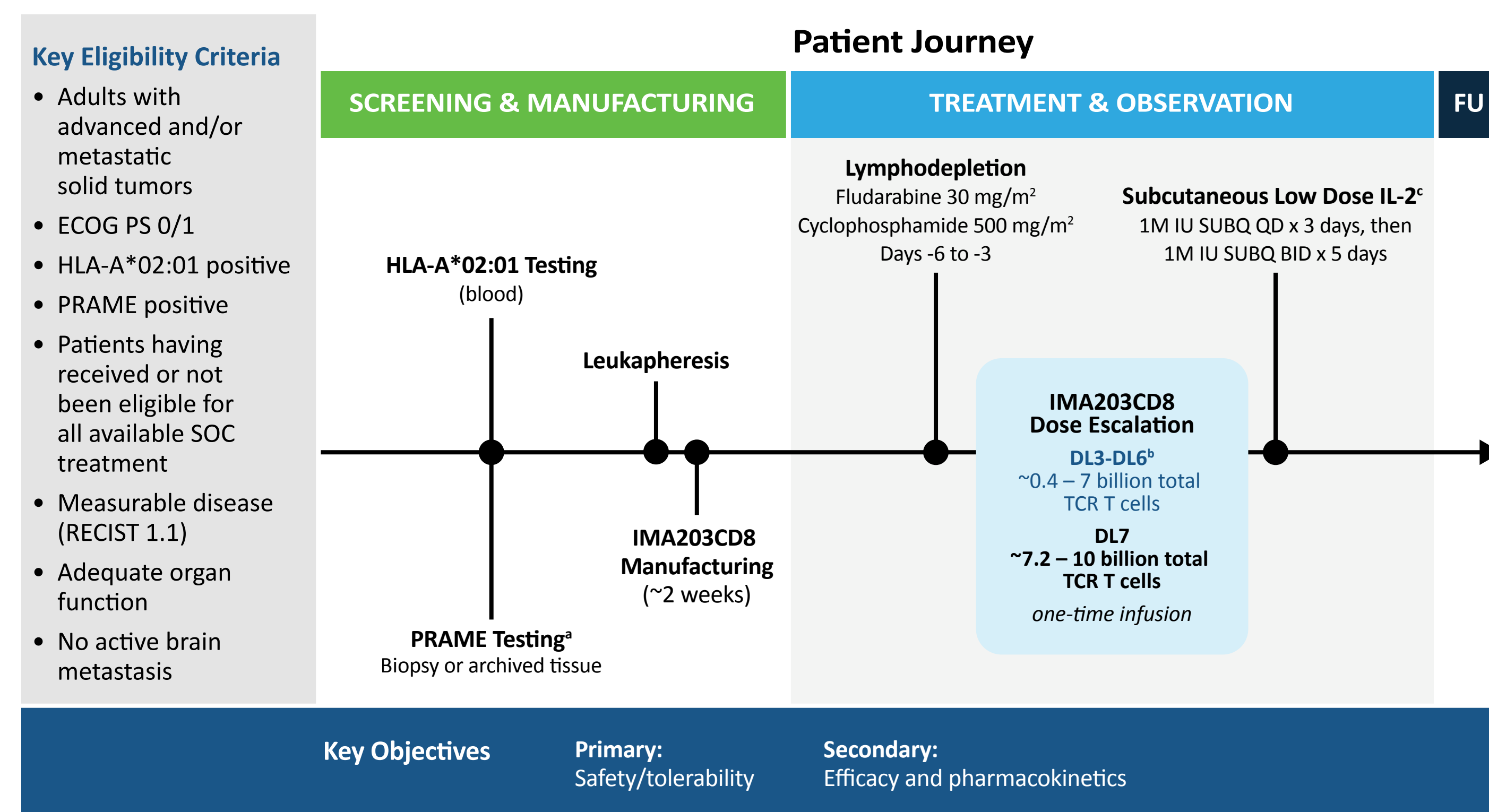
Figure 1. IMA203CD8 mechanism of action



METHODS

- IMA203-101 (NCT03686124) is an ongoing phase 1 study evaluating IMA203CD8 in patients with solid tumors expressing PRAME (Fig. 2)

Figure 2. Study design of IMA203CD8 portion of IMA203-101



*PRAME testing no longer required for indications with high PRAME prevalence, including OC. ⁵Based on initial safety data observed with anzu-cel (IMA203), dose escalation for IMA203CD8 was initiated at DL3. Total TCR T cells calculated from defined number of TCR T cells/m² BSA per DL x 1.8 m² BSA (BSA of average patient). ⁶Each TCR T-cell dose level \geq DL4c is evaluated \pm IL-2: start without IL-2; if considered tolerable, either add IL-2 at the same dose, or escalate to the next dose without IL-2; outpatient IL-2 administration at investigator's discretion. Some patients received IL-2 starting on Day 1, but most started IL-2 on Day 3 post-infusion.

RESULTS

- As of October 27, 2025, 16 patients with OC were infused with IMA203CD8
- Patients were heavily pretreated (Table 1)

Table 1. Baseline demographics and patient characteristics

Characteristic	Safety Population (n=16)	Characteristic	Safety Population (n=16)
Age, median (range), years	60.5 (35, 75)	Treatment, n (%)	
ECOG PS 1, n (%)	9 (56)	Radiation	4 (25)
LDH \geq 1 x ULN, n (%)	6 (38)	Systemic treatment	16 (100)
Tumor burden, ^a target lesion SLD [cm], median (range)	10.2 (1.6, 21.6)	Lines of previous systemic treatment, median (range)	4 (1, 7)
Number of tumor lesions, ^a median (range)	5.5 (2, 25)	\geq 3, n (%)	14 (88)
Liver metastasis, ^a n (%)	6 (36)	Chemotherapy, n (%)	15 (94)
Platinum-resistant, ^b n (%)	8 (53)	Median (range)	4 (0, 4)
		Platinum-based regimen, n (%)	15 (94)
		Targeted therapies (eg, ADCs, TKIs, PARPi), n (%)	7 (44)

^aNot available for 2 patients. ^bNot available for 1 patient.

Tolerability

- The most common TEAEs were lymphodepletion-related cytopenias, some of which may persist beyond 90 days (Table 2)
 - Cytopenias and nausea related to lymphodepleting chemotherapy occurred within the first 30 days
 - No late-onset (\geq Day 90) immune toxicity occurred
- CRS events occurred in 94% of patients, occurred early, and were mostly mild to moderate (Table 3). CRS events resolved within the first 23 days post-IMA203CD8 infusion
- ICANS occurred in 1 patient at grade 1 and resolved within 2 days
- One patient died due to grade 5 sepsis in the setting of asymptomatic IEC-HS
 - This event prompted protocol amendments excluding patients with LDH $>$ 2x ULN, tumor lesions $>$ 10 cm, or ascites/pleural/pericardial effusions requiring repeated or continuous drainage within 2 months

Table 2. Any grade (\geq 25%) and grade \geq 3 TEAEs

Preferred Term, n (%)	Safety Population (n=16)			
	Any Grade	Grade \geq 3	Occurring \leq Day 30 ^a	Occurring \geq Day 90 ^a
CRS	15 (94)	1 (6)	15 (94)	0
Nausea	13 (81)	0	13 (81)	0
Anemia	10 (63)	9 (56)	10 (63)	2 (13)
Neutropenia	10 (63)	10 (63)	10 (63)	2 (13)
Rash/ Rash maculopapular	8 (50)	1 (6)	8 (50)	1 (6)
Thrombocytopenia	8 (50)	5 (31)	8 (50)	2 (13)
Vomiting	8 (50)	0	8 (50)	0
Abdominal pain	6 (38)	1 (6)	4 (25)	2 (13)
Fatigue	6 (38)	0	6 (38)	2 (13)
Hypomagnesemia	6 (38)	1 (6)	6 (38)	0
Lymphopenia	6 (38)	6 (38)	6 (38)	4 (25)
Hypokalemia	5 (31)	0	4 (25)	0
Hypophosphatemia	5 (31)	1 (6)	5 (31)	0
Constipation	4 (25)	0	4 (25)	1 (6)
Diarrhea	4 (25)	0	4 (25)	1 (6)
Hyponatremia	4 (25)	0	4 (25)	0
Pyrexia	4 (25)	0	4 (25)	0

^aDay: Date of AE - date of lymphodepletion. If date of resolution is completely missing, it is assumed that the AE resolved at the date of the end of the AE assessment period. Occurring \leq Day 30: Any event \leq Day 30. Occurring \geq Day 90: New events or worsening or unresolved events by Day 90. If date of resolution is completely missing, it is assumed that the AE resolved at the date of the end of the AE assessment period.

Table 3. Adverse events of special interest

Characteristic	Safety Population (n=16)
CRS	
Any grade, n (%)	15 (94)
Grade 1	6 (38)
Grade 2	8 (50)
Grade 3	1 (6)
Grade 4	0 (0)
Time to onset, median (range), d ^a	1 (0, 1)
Duration, median (range), d	5 (1, 23)
HLH	
Any grade, n (%)	1 (6)
Grade 1	0 (0)
Grade 2	0 (0)
Grade 3	0 (0)
Grade 4	1 (6)
Time to onset, median (range), d ^a	4 (4, 4)
Duration, median (range), d	5 (5, 5)
ICANS	
Any grade, n (%)	1 (6)
Grade 1	1 (6)
Grade 2	0 (0)
Grade 3	0 (0)
Time to onset, median (range), d ^a	1 (1, 1)
Duration, median (range), d	2 (2, 2)

^aFrom IMA203CD8 infusion.

CONCLUSIONS

- In patients with advanced OC, IMA203CD8 demonstrated a tolerability profile consistent with prior experience in other solid tumors
 - The most common TEAEs were lymphodepletion-related cytopenias
 - CRS occurred early in all patients, and was generally mild to moderate
 - No late-onset immune toxicity occurred
 - Ongoing monitoring may include blood counts and infection surveillance/prevention per institutional guidelines
- Encouraging dose-dependent antitumor activity was demonstrated, including durable responses at higher dose levels

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DISCLOSURES

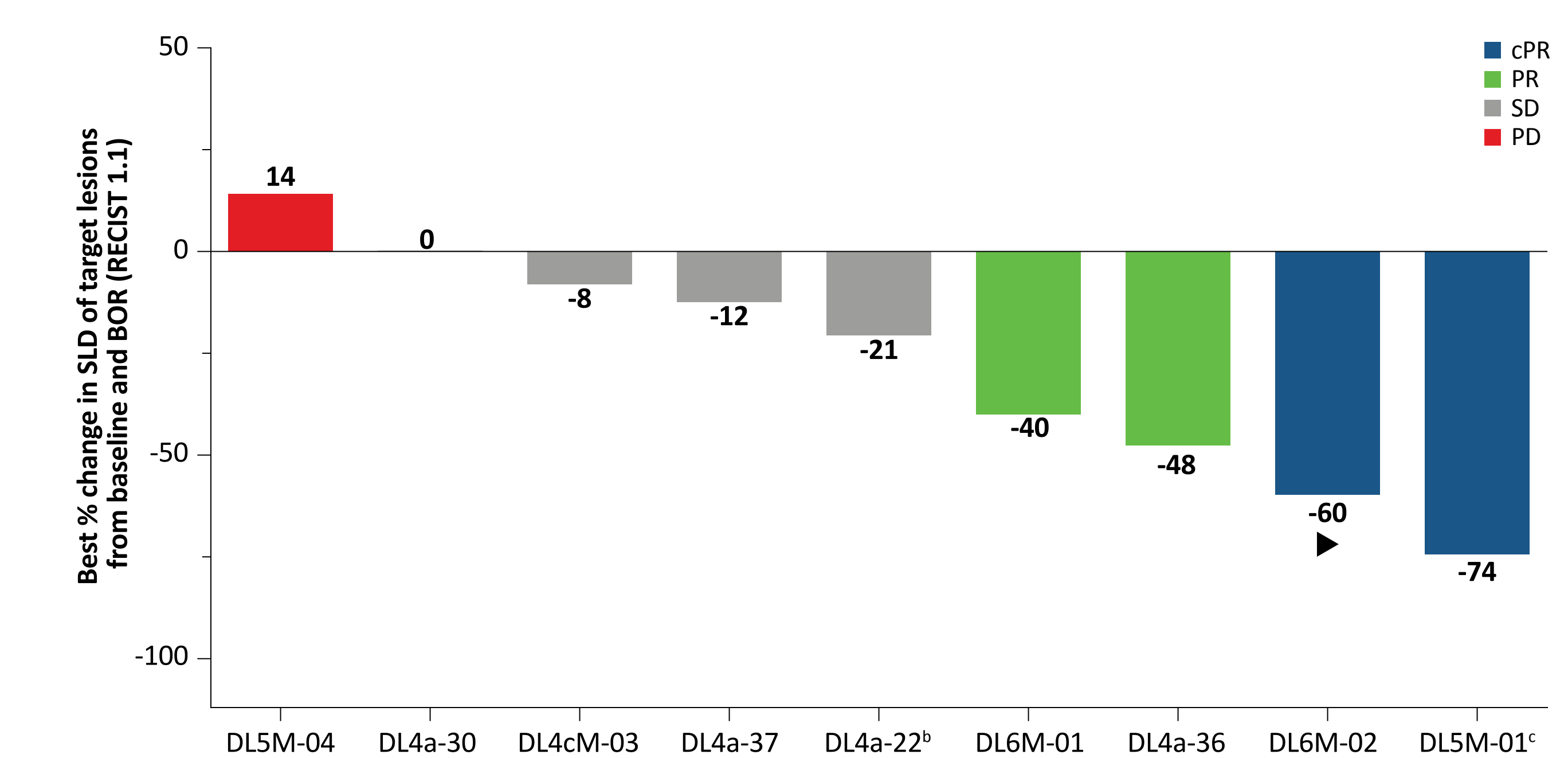
MW: Research funding: Roche; Consulting fees: BMS, Novartis, Lilly, Boehringer Ingelheim, ISA Pharmaceuticals, Amgen, Immatics, Bayer, ImCheck Therapeutics, AstraZeneca, Tactyl, Regeneron, Daiichi Sankyo Europe, Zymeworks, PharmaMar, Iovance Biotherapeutics, Tknife, and Genentech; Honoraria: Lilly, Boehringer Ingelheim, SYNLAB, Janssen, Merck Serono, GWT, Amgen, Novartis, Pfizer, BMS, Regeneron, MJH-PER, and Takeda; Travel, accommodations, or expenses: Pfizer, BMS, AstraZeneca, Amgen, GEMoAb, Sanofi Aventis, Immatics, Merck Serono, Janssen Oncology, Iovance Biotherapeutics, and Daiichi Sankyo Europe, WA: Travel grants: Janssen, Immatics and BioTech; Honoraria: GSK, Astellas, Janssen, and AstraZeneca; Research funding: Affimed and BioTech; AAJ: Consulting fees: Gerson Lehrman Group, Guidepoint; Paid advisory activities: Iovance, Eisai, MacroGenics, Sentinel Bio, Avenge Bio, IQVIA, and Theolytics; grant funding to the institution for clinical trials: AstraZeneca, Iovance, Immatics US, Eli Lilly, Merck, MacroGenics, Immunon, GSK, and Lixte; OY: Grants: Ascendis Pharma A/S, Immunocore Limited, Quality Biologics, Merck Sharp & Dohme Corporation, ProfoundBio, and the Department of Defense; Consulting fees: Aadi Bioscience, Advisory board: HC Bioscience; SH, NH, ML, AM, MS, NC, CMB: Employee of Immatics; ST, SA, KW, TAWH, DM, AM, AB, DJ: No conflicts of interest.

ABBREVIATIONS: ADC, antibody drug conjugate; AE, adverse event; anzu-cel, aneztregrine autolucel; BID, twice daily; BL, baseline; BOR, best overall response; BSA, body surface area; cPR, confirmed partial response; CR, complete response; CRS, cytokine release syndrome; d, day; DL, dose level; ECOG, Eastern Cooperative Oncology Group; FU, follow-up; IL, interleukin; HLA, human leukocyte antigen; HLH, hemophagocytic lymphohistiocytosis; ICANS, immune effector cell-associated neurotoxicity syndrome; IEC-HS, immune effector cell (IEC) associated HLH-like syndrome; IU, international unit; LDH, lactate dehydrogenase; OC, ovarian cancer; PARPi, poly (ADP-ribose) polymerase; PD, progressive disease; PR, partial response; PRAME, preferentially expressed antigen in melanoma; QD, daily; RECIST, Response Evaluation Criteria in Solid Tumors; SD, stable disease; SOC, standard-of-care; SLD, sum of the longest diameters; SUBQ, subcutaneous; TCR, T-cell receptor; TEAE, treatment-emergent adverse event; TKI, tyrosine kinase inhibitor; ULN, upper limit of normal.

Efficacy

- Eleven patients were efficacy evaluable (\geq 1 post-baseline scan after IMA203CD8 treatment) across escalating dose levels (median: 2.26×10^9 total TCR T cells; range: $1.4-7.1 \times 10^9$ TCR T cells)
- Tumor reduction was observed in 7 patients with a maximum reduction of 74% (Fig. 3)
- Three patients had responses lasting at least 6 months and 1 had disease control for up to 12 months (Fig. 4)
- A dose-dependent signal of activity was observed in patients treated at higher doses (n=5; range: $2.3-7.1 \times 10^9$ TCR T cells), including 2 cPRs with 1 ongoing metabolic CR at 6 months and 1 unconfirmed PR

Figure 3. Overall response rate and depth of response^a

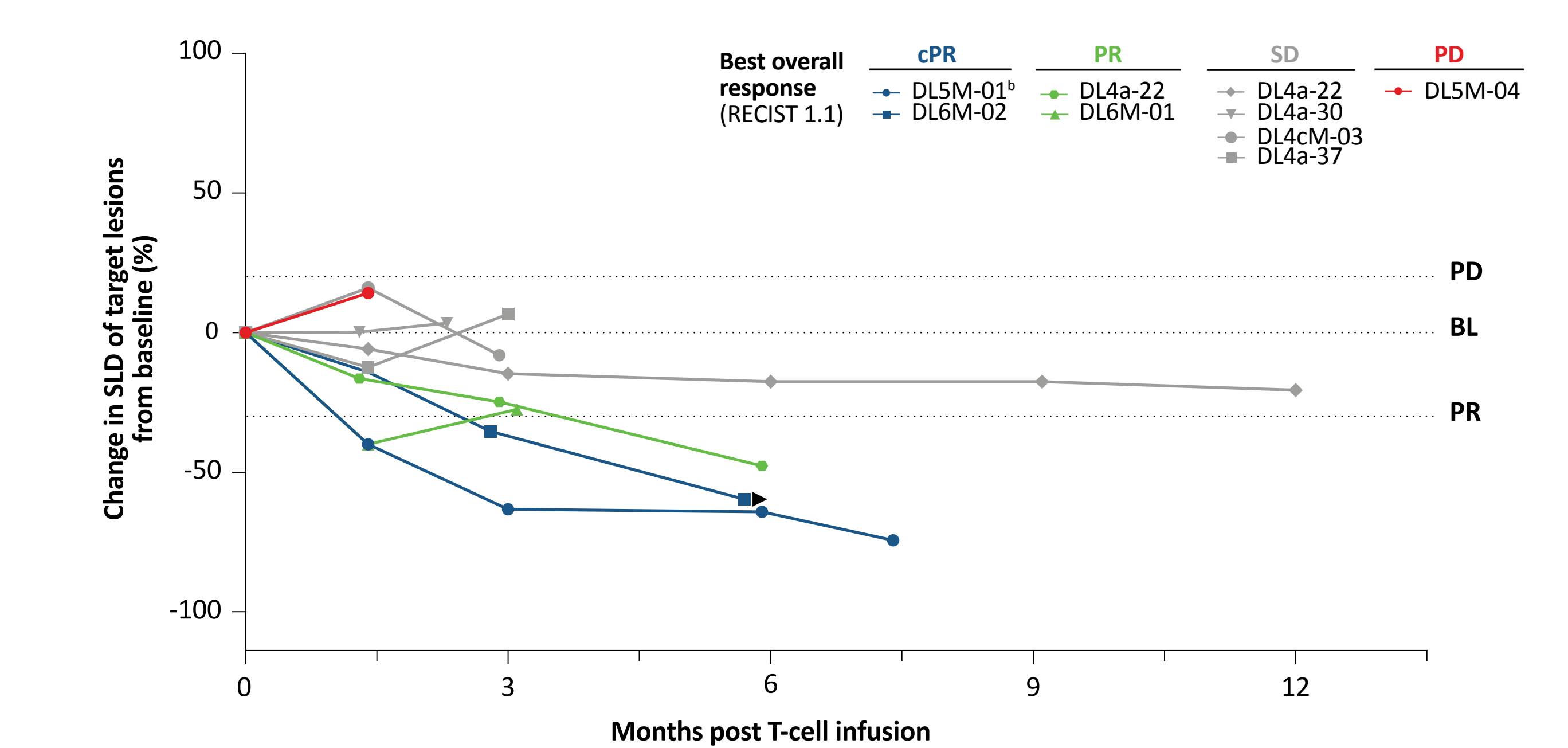


^aTwo patients without post-baseline scan not depicted in plot deceased prior to first scan (1 DL4a, 1 DL5).

^bBest change and RECIST BOR at different timepoints.

^cOngoing confirmed PR (RECIST 1.1) as of last scan at Month 7.5, suspected clinical progression by clinical site at Month 6 in discrepancy to RECIST response due to tumor marker CA-125 increase; patient off study at Month 8 and receiving new anti tumor treatment.

Figure 4. Duration of response^a



^aTwo patients without post-baseline scan not depicted in plot deceased prior to first scan (1 DL4a, 1 DL5).

^bOngoing confirmed PR (RECIST 1.1) as of last scan at Month 7.5, suspected clinical progression by clinical site at Month 6 in discrepancy to RECIST response due to tumor marker CA-125 increase; patient off study at Month 8 and receiving new antitumor treatment.