

A first-in-human study of MT026, an off-the-shelf IL13Rα2-specific allogeneic universal CAR-T cells, in patients with recurrent high-grade glioma: an interim analysis

Yulun Huang¹, Haiping Zhu¹, Xuetao Li¹, Xuewen Zhang¹, Xiaoci Rong¹, Zhen Bao¹, Liang He¹, Yang Liu¹, Jie Shao¹, Xiaoyun Shang²

#3568

1) 1. Department of Neurosurgery, Dushu Lake Hospital affiliated to Soochow University, Suzhou, China
2) 2. Ningbo T-MAXIMUM Biopharmaceuticals Co., Ltd., Ningbo, China

Email: Email: huangyulun@suda.edu.cn

BACKGROUND

- T cell immunotherapy is becoming a powerful therapeutic strategy for hematological and solid malignancies
- Use of autologous T cell immunotherapy for treatment of high-grade glioma, a CNS tumor with rapid progression and poor prognosis, is limited
- Off-the-shelf allogeneic universal CAR-T cells has unique advantages and clinical potential for those tumors which tissues are hard to collect and progress rapidly
- ChiCTR2000028801 is a first-in-human study of MT026, an off-the-shelf IL13Rα2-specific allogeneic universal CAR-T cells (IL13Rα2 UCAR-T cells). In this single-center, open-label, IIT study, safety, PK and preliminary efficacy of MT026 administered via intra-lumbar and intra-tumoral

STUDY DESIGN

Dosage and administration

- 2.5×10⁷ cells, intra-lumbar or intra-tumoral injection, every four weeks

Primary objectives

- Safety

Secondary Objectives

- efficacy (ORR, DCR, OS, PFS)
- PK

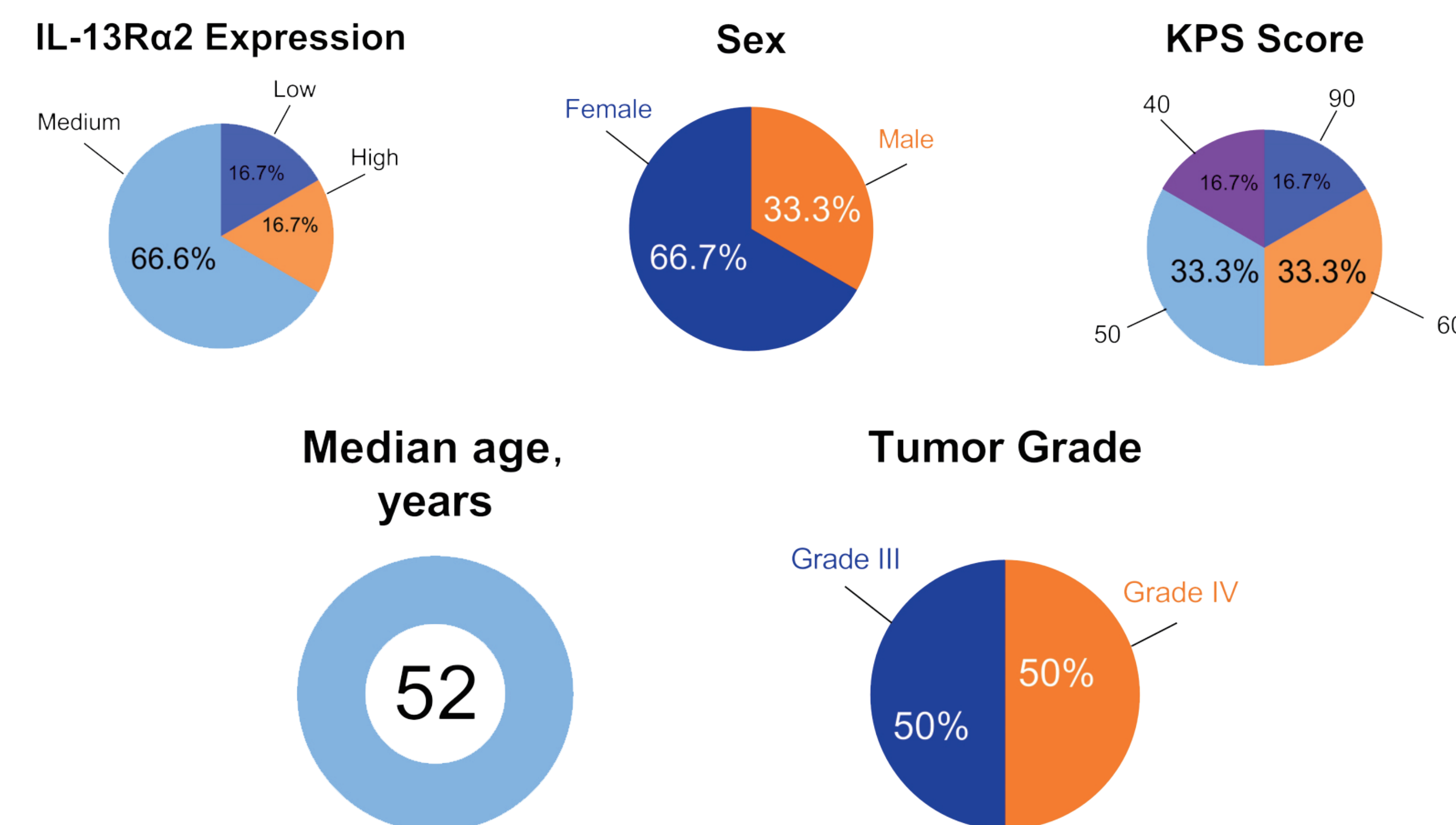
Patient population

- 18-70 years
- Life expectancy ≥ 3 months
- KPS ≥40
- Histologically- or cytologically-confirmed recurrent or refractory high-grade glioma
- Had been treated with SoC
- IL13-Rα2 IHC positive score >50%

RESULTS (interim)

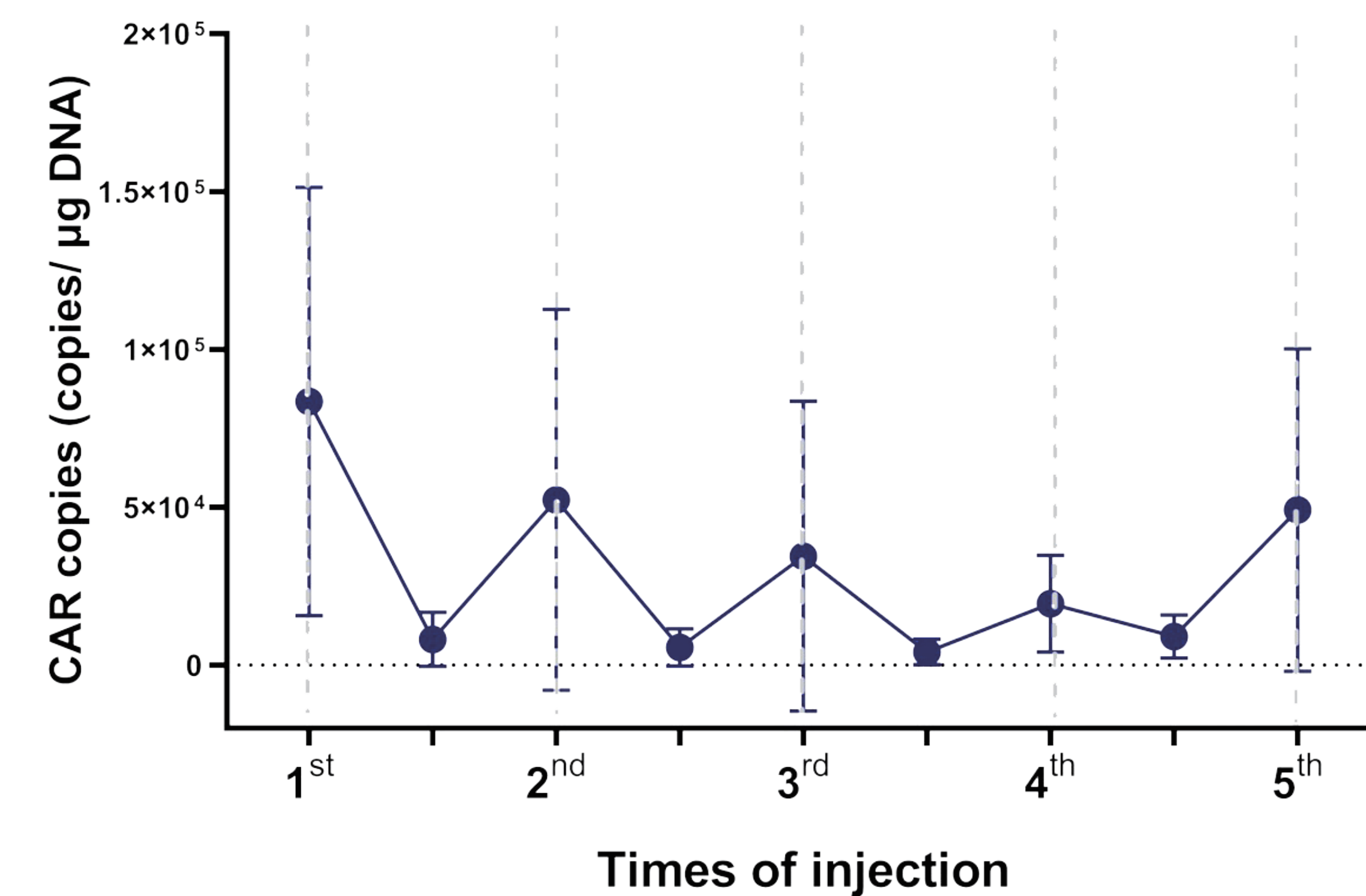
Patient Characteristics

- As of June, 2022, 6 eligible patients received MT026



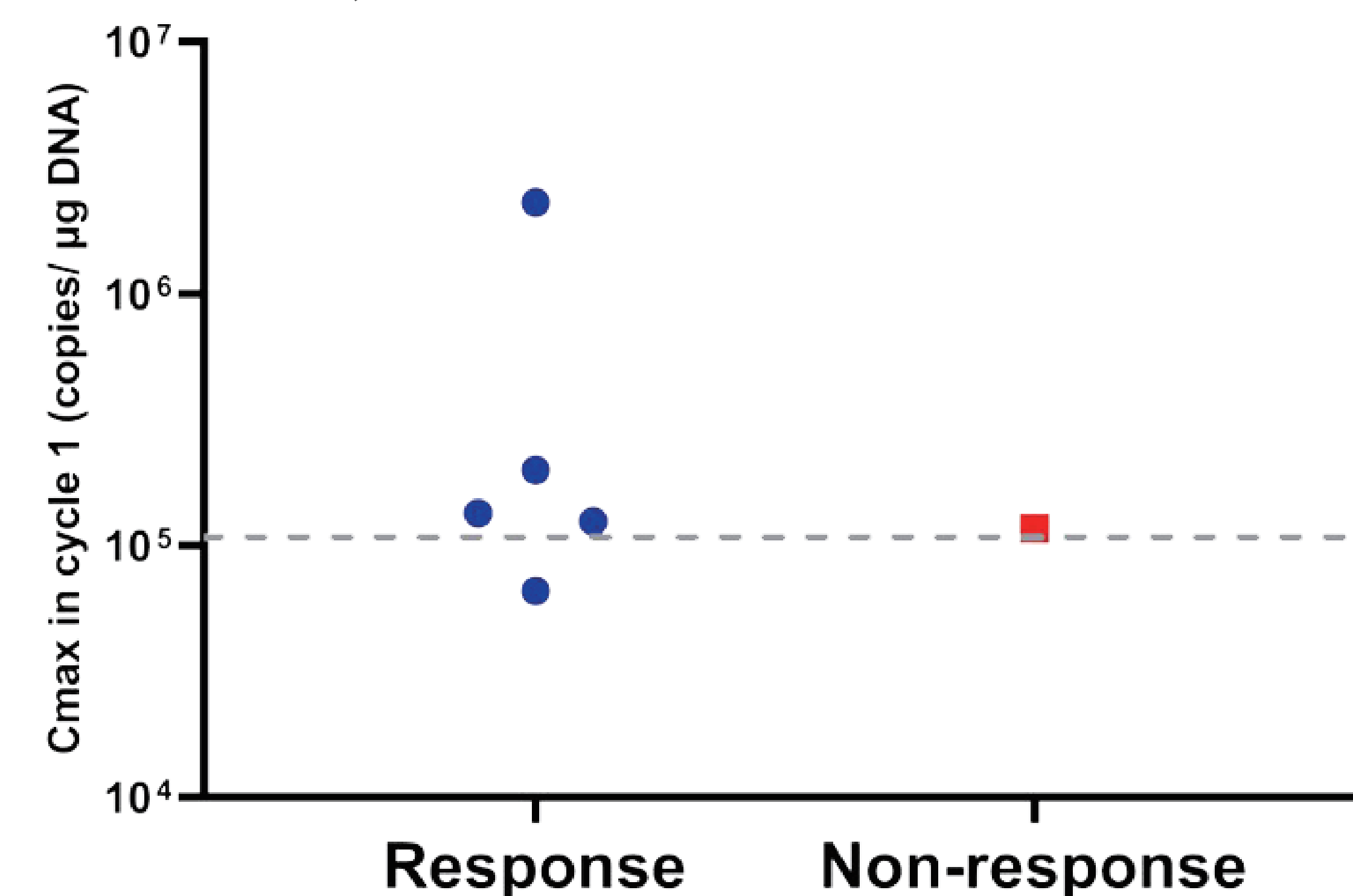
PK

- Well expansion of 1 day and persistence of >30 days



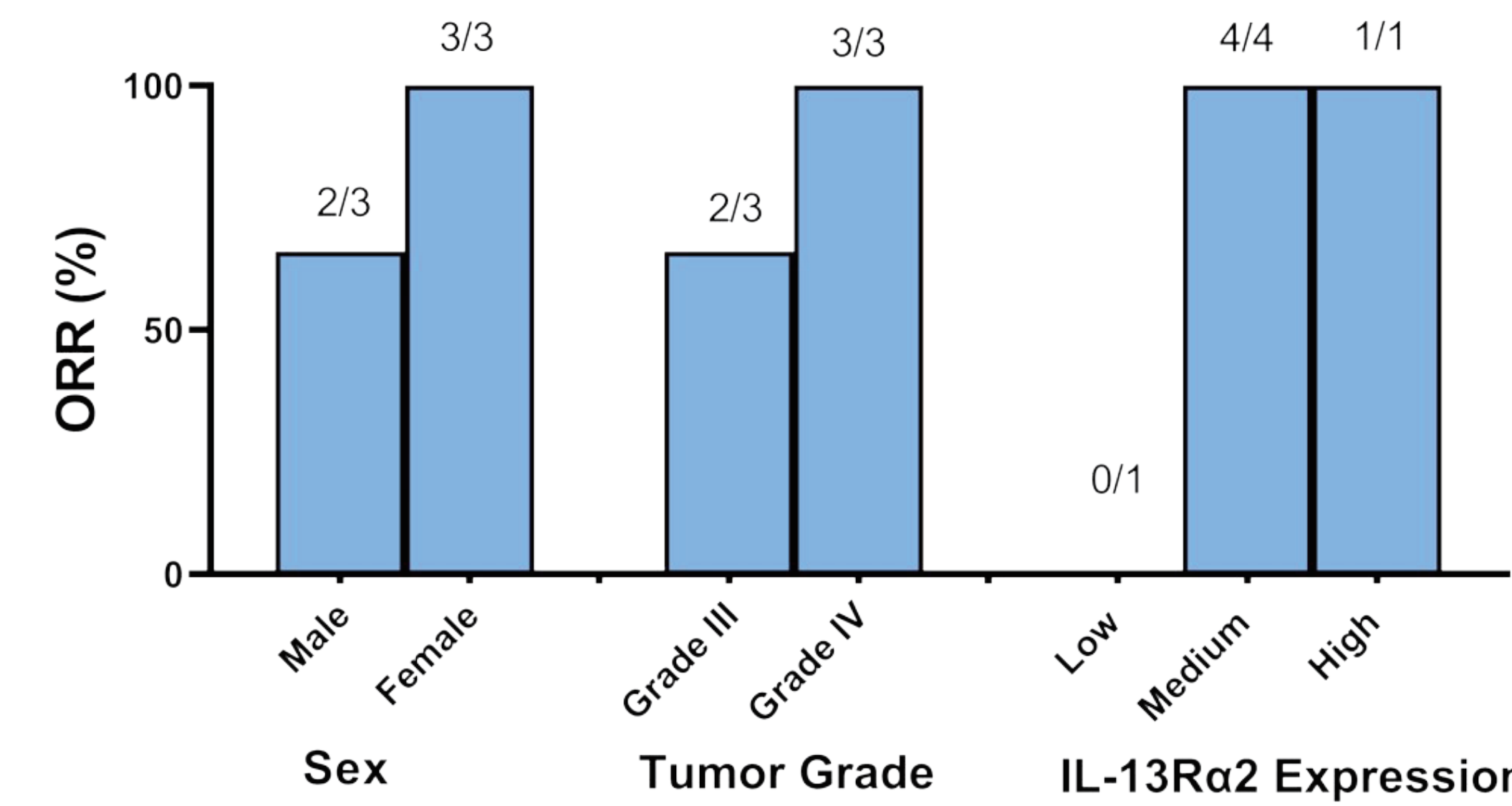
Exposure-response

- Response seems correlated with Cmax of CAR copies after 1st injection



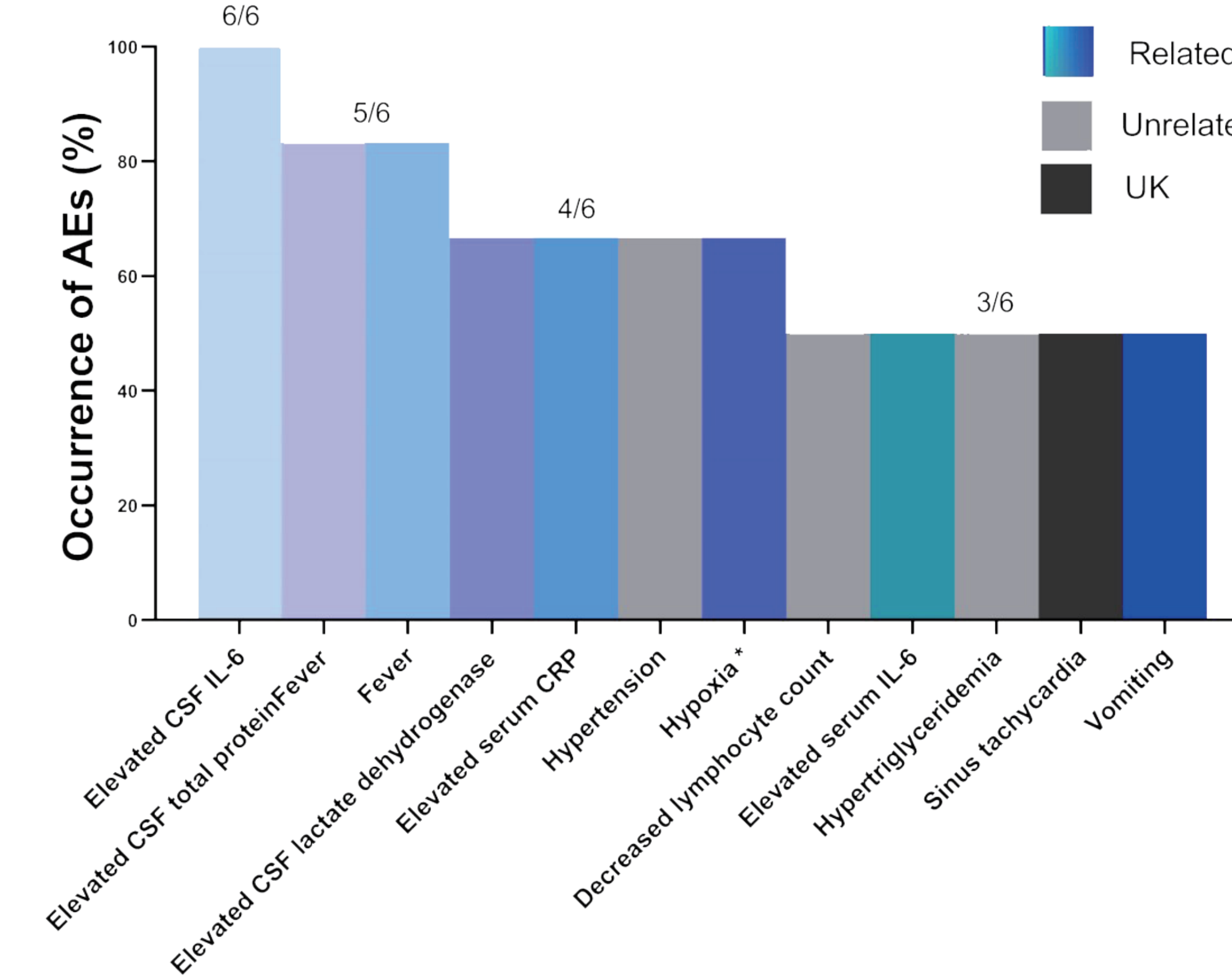
Stratification

- Response seems correlated with IL13Rα2 expression level in tumor tissue



Safety

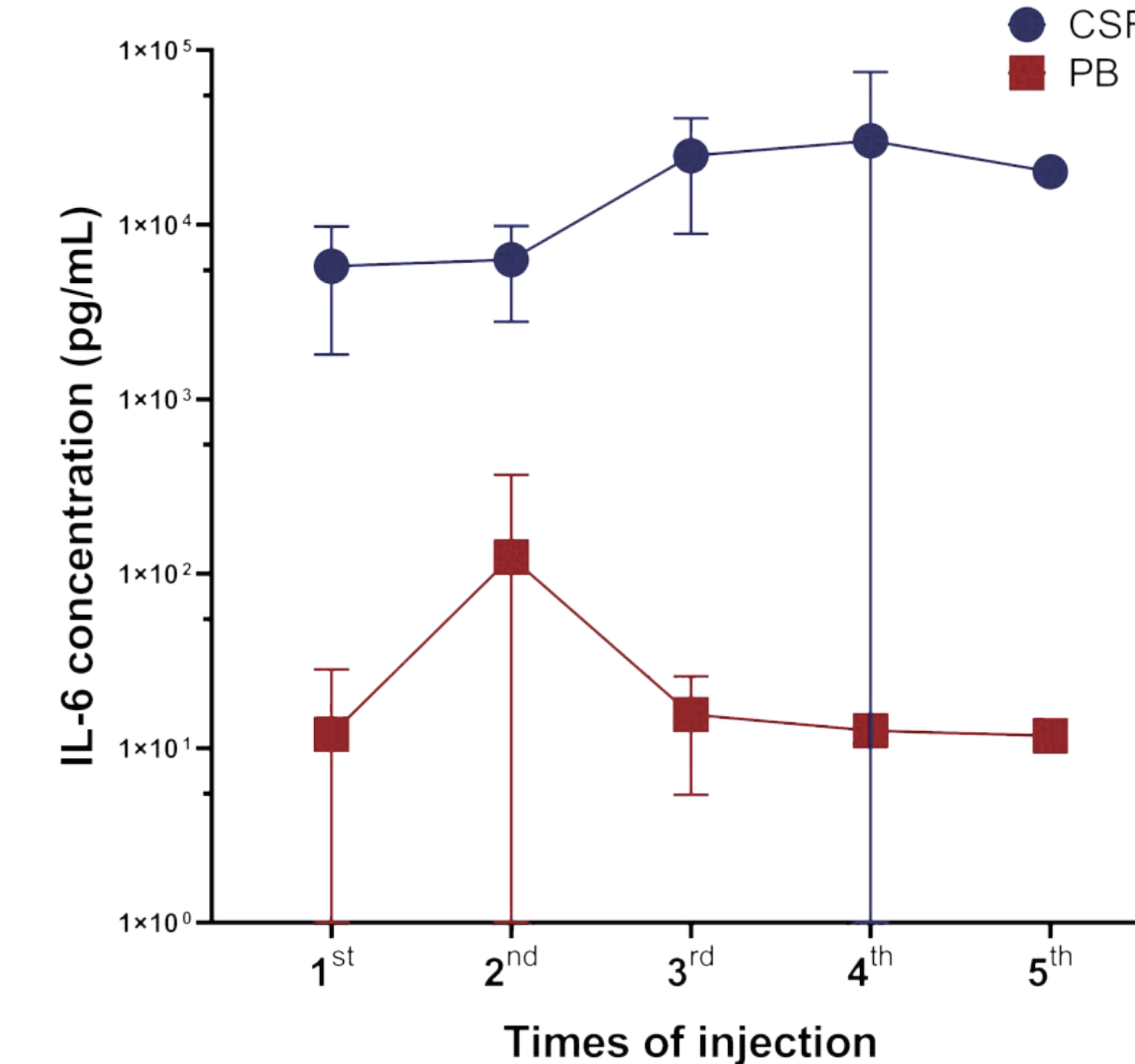
- Fever and hypoxia were the most common symptoms
- Elevated CSF IL-6 were the most common abnormal laboratory test
- No severe CRS or ICANS
- Of those AEs occurring in ≥2 subjects, most were Grade 1 or 2 except for a grade 3 hypoxia occurring in 1 subject



AEs Occurring in ≥ 3 Subjects

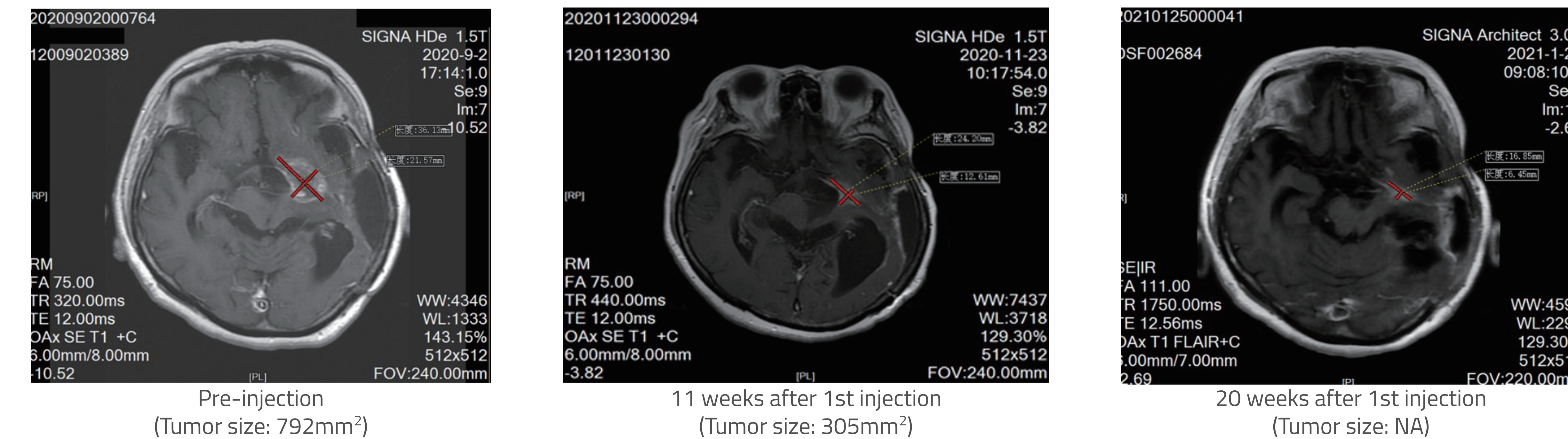
*: The only grade 3 AE is hypoxia, occurring in 1 subject

- Blood IL-6 concentration is low after administration

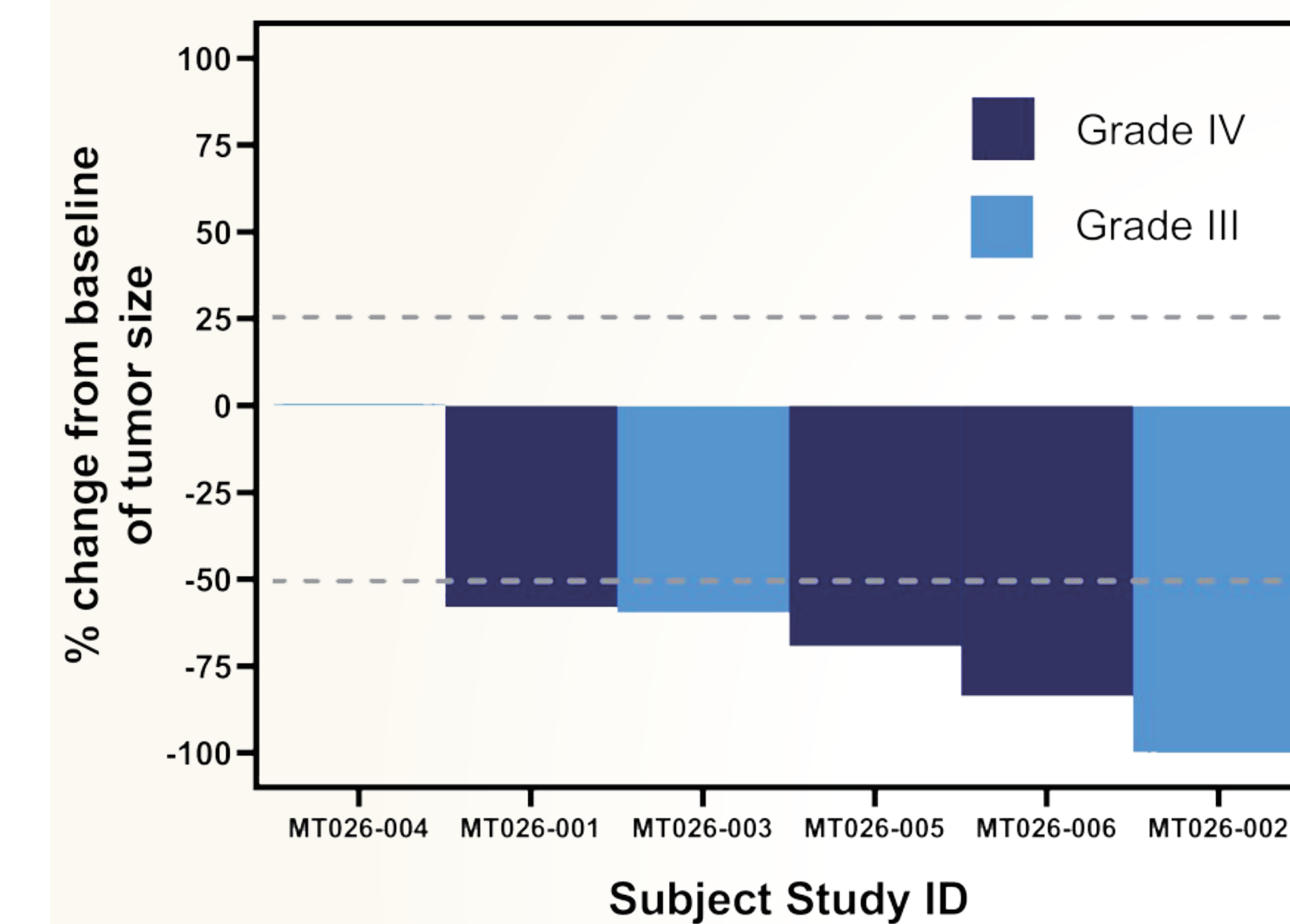


Efficacy (As of June, 2022)

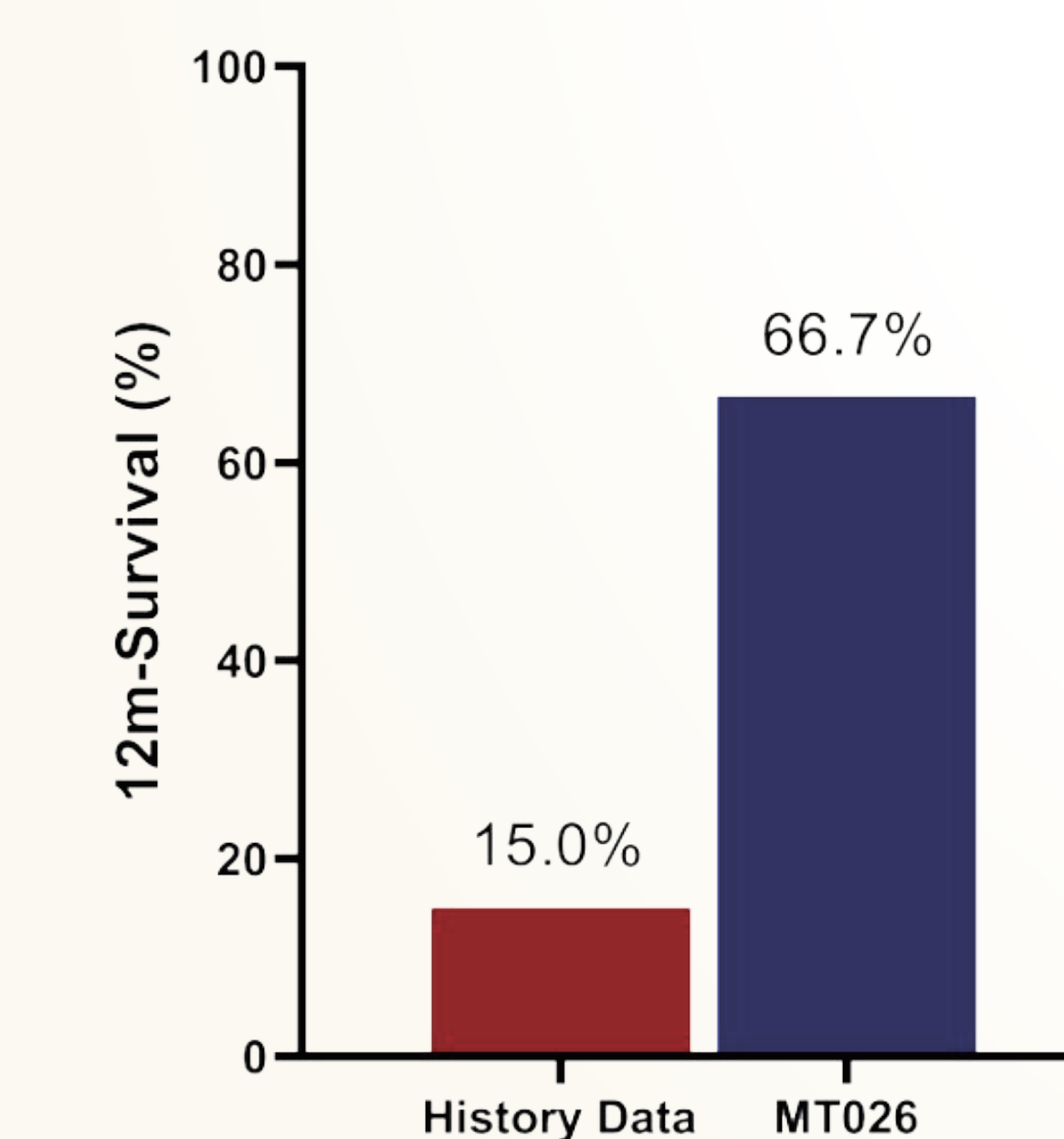
- 1 CR, 4 PR, 1 SD



- ORR 83.3% (5/6), DCR 100% (6/6)

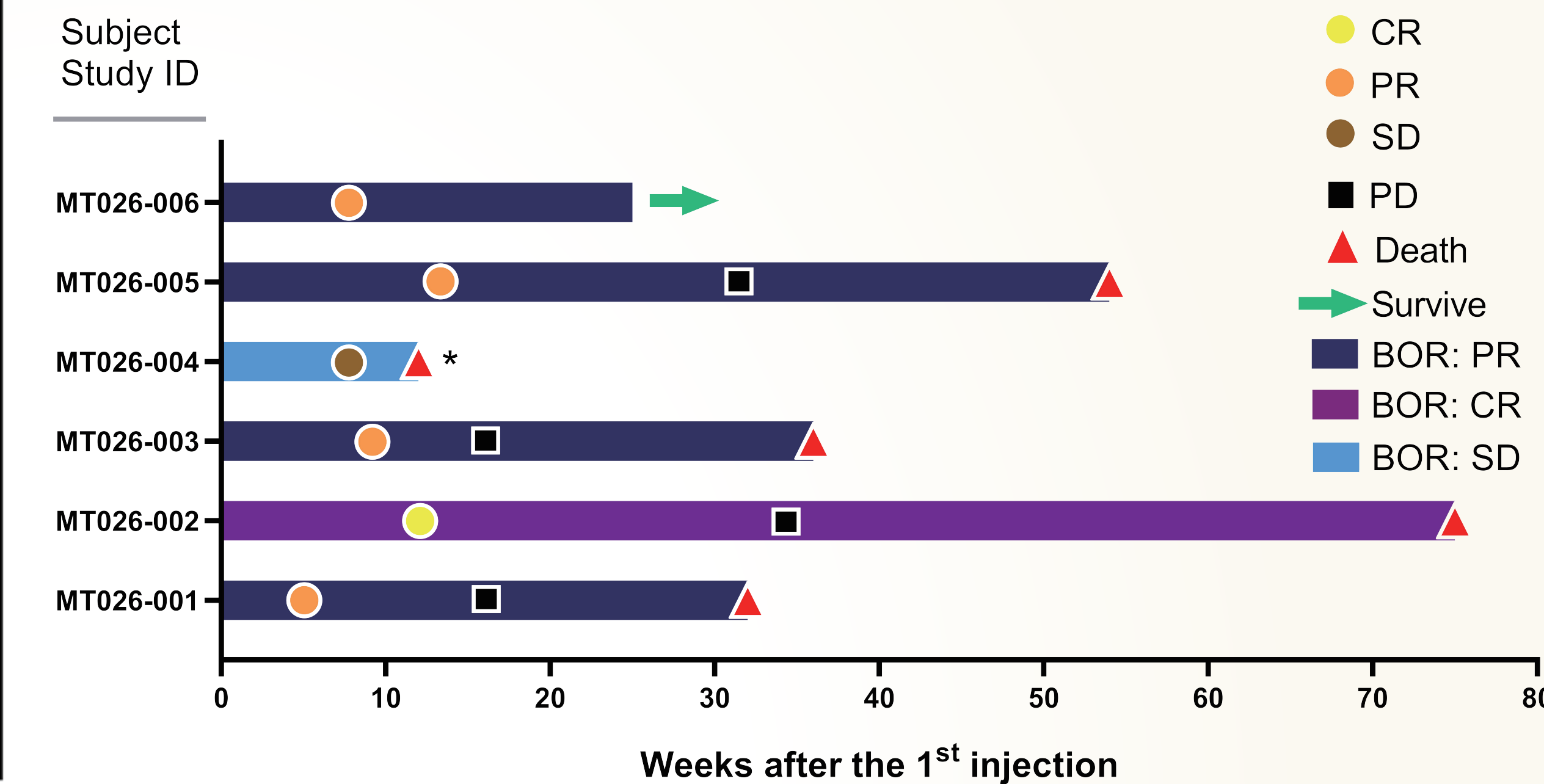


- 12m-survival rate after recurrence: 66.7% vs. 15% (history data)



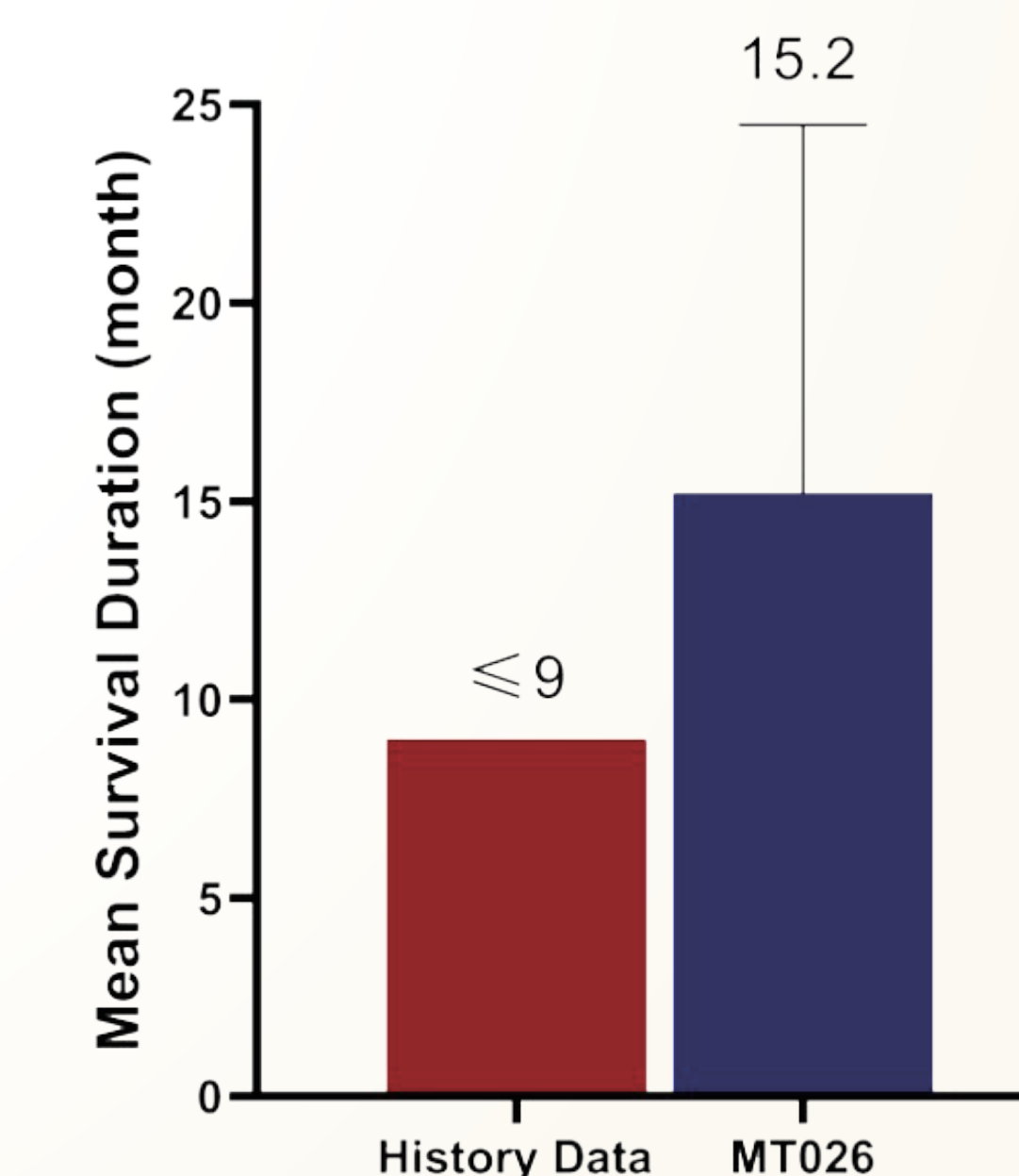
- OS after 1st injection (month): Max 17.5, Mean 9.8

- PFS (month): Max 7.9, Median 5.0



*: Died of accidental intracranial infection

- Survival duration after recurrence (month): Max 21.0, Mean 15.2 vs. ≤9 (history data)



CONCLUSION

Intra-lumbar injection of IL13Rα2 UCAR-T cells is safe and well tolerated in human, and IL13Rα2 UCAR T cells has potent anti-tumor activity for recurrent high-grade glioma. Off-the-shelf allogeneic universal CAR-T therapy is a potential option for treatment of solid malignancies with rapid progression and difficultly collected tissues.