

P3.292: PESGA Trial: A Phase II Study of Induction Chemoimmunotherapy Followed by Pembrolizumab and Sacituzumab Govitecan in ES-SCLC

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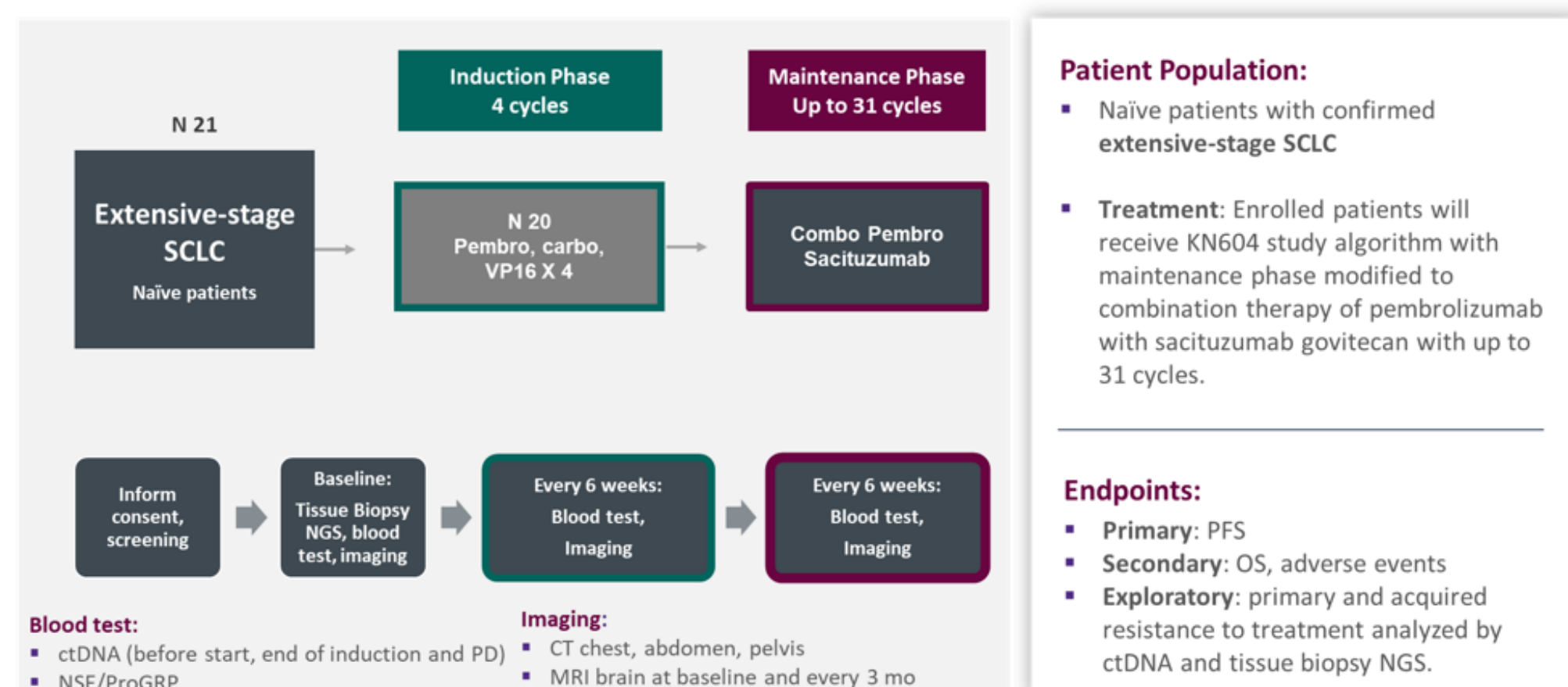
INTRODUCTION

- Despite the addition of immune-checkpoint inhibitors to first-line therapy, extensive-stage small cell lung cancer (ES-SCLC) remains characterized by short progression-free survival (PFS), and no effective maintenance strategies have been established.
- Sacituzumab govitecan (SG), a Trop-2-directed antibody–drug conjugate, has demonstrated activity in relapsed SCLC.
- We evaluated SG in combination with pembrolizumab as maintenance therapy following chemoimmunotherapy induction.

METHODS

Design: prospective, open-label, single-arm, phase II study (NCT06667167; SZMC-0079-24) in treatment-naïve patients with confirmed ES-SCLC (planned N=21).

- Induction (4 × 21-day cycles): carboplatin AUC 5 (day 1) + etoposide 100 mg/m² (days 1–3) + pembrolizumab 200 mg (day 1).
- Maintenance (up to 31 cycles): pembrolizumab 200 mg q3w (continued from induction) + sacituzumab govitecan 10 mg/kg IV on days 1 and 8 of each 21-day cycle.
- Primary endpoint: PFS. Secondary: objective response rate (ORR), OS, duration of response, safety.
- Exploratory: serial liquid and tissue biopsies for biomarker assessment (ctDNA, NSE/ProGRP).



DISCUSSION AND CONCLUSION

Actionable Take Away Message

- In this preliminary analysis, maintenance with pembrolizumab (continued from induction) plus sacituzumab govitecan was associated with an ORR of 88.9% (95% CI 65.3–98.6), median PFS of 6.8 months and median OS of 9.3 months.
- Most treatment-related adverse events were grade 1–2; hematologic toxicity predominated during induction, and no AE-related discontinuations occurred during maintenance.
- For context, median PFS in historical first-line ES-SCLC trials (IMpower133, CASPIAN, KEYNOTE-604) was 4.5–5.2 months; cross-trial comparisons warrant caution given the small, single-arm design.

Future Direction for Research

- Enrollment completion is expected in October 2026; final efficacy and biomarker analyses (ctDNA dynamics, NSE/ProGRP) will follow.
- These data support further evaluation of Trop-2-ADC plus PD1 -blockade maintenance.

KEY OUTCOMES - PRELIMINARY

88.9%
ORR (16/18, all confirmed PR)
95% CI 65.3–98.6

94.4%
Disease control rate
95% CI 72.7–99.9

6.8 mo
Median PFS
95% CI 2.2–8.3

9.3 mo
Median OS
95% CI 4.7–15.5

BASELINE CHARACTERISTICS

Median age, years (range)	67.5 (53–85)
Male N (%)	14 (70%)
ECOG PS 0 / 1	9 / 11
Brain metastases at baseline	4 (20%)
Liver metastases at baseline	9 (45%)

STUDY STATUS

Enrolled	20 / 21 planned (first patient: 31 Dec 2024)
Completed induction (4 cycles)	15
Started maintenance	13 (1–18 cycles; mean 6.7)
On active treatment	4
Alive at data cutoff	9 / 20

RESULTS

- As of the data cutoff (August 2026; median follow-up 12.9 months), 20 of 21 planned patients were enrolled; 13 started maintenance (1–18 cycles, mean 6.7) and 4 remain on active treatment. An ORR of 88.9% (16/18 response-evaluable, all confirmed PR per RECIST v1.1; 95% CI 65.3–98.6) and a disease control rate of 94.4% (95% CI 72.7–99.9) were observed.
- Tumor shrinkage occurred in 18/19 patients with ≥1 post-baseline assessment; in 7 of 13 patients who started maintenance, the deepest response was achieved during the maintenance phase (Figures 3–4). CNS was a site of progression in 3 patients.
- Treatment discontinuation due to AEs occurred in 2/20 patients (hepatitis; cardiac failure — both during induction); no AE-related discontinuations occurred during maintenance (Figures 5–6).

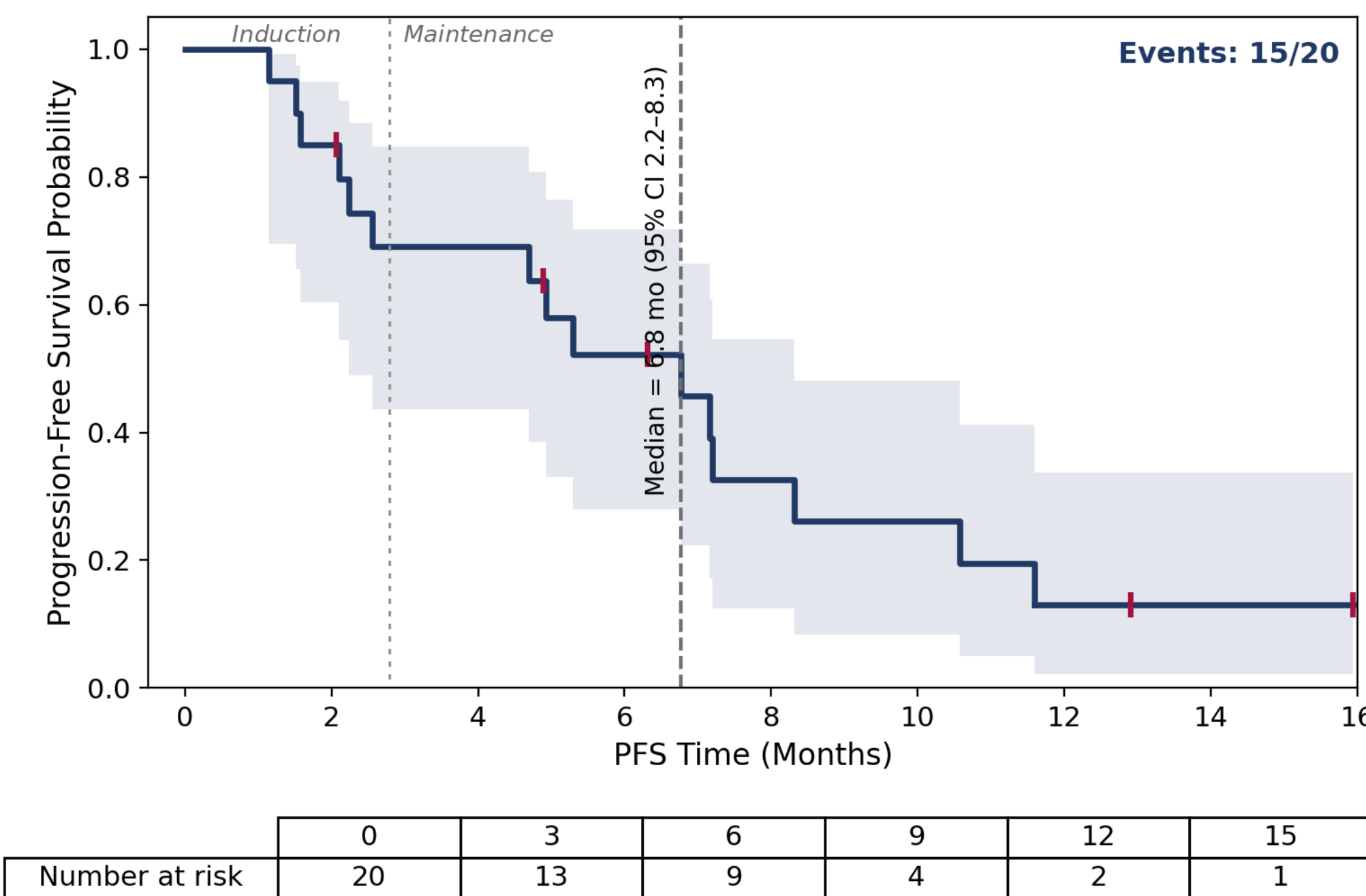


Figure 1. Kaplan–Meier estimate of PFS with 95% CI (N=20).

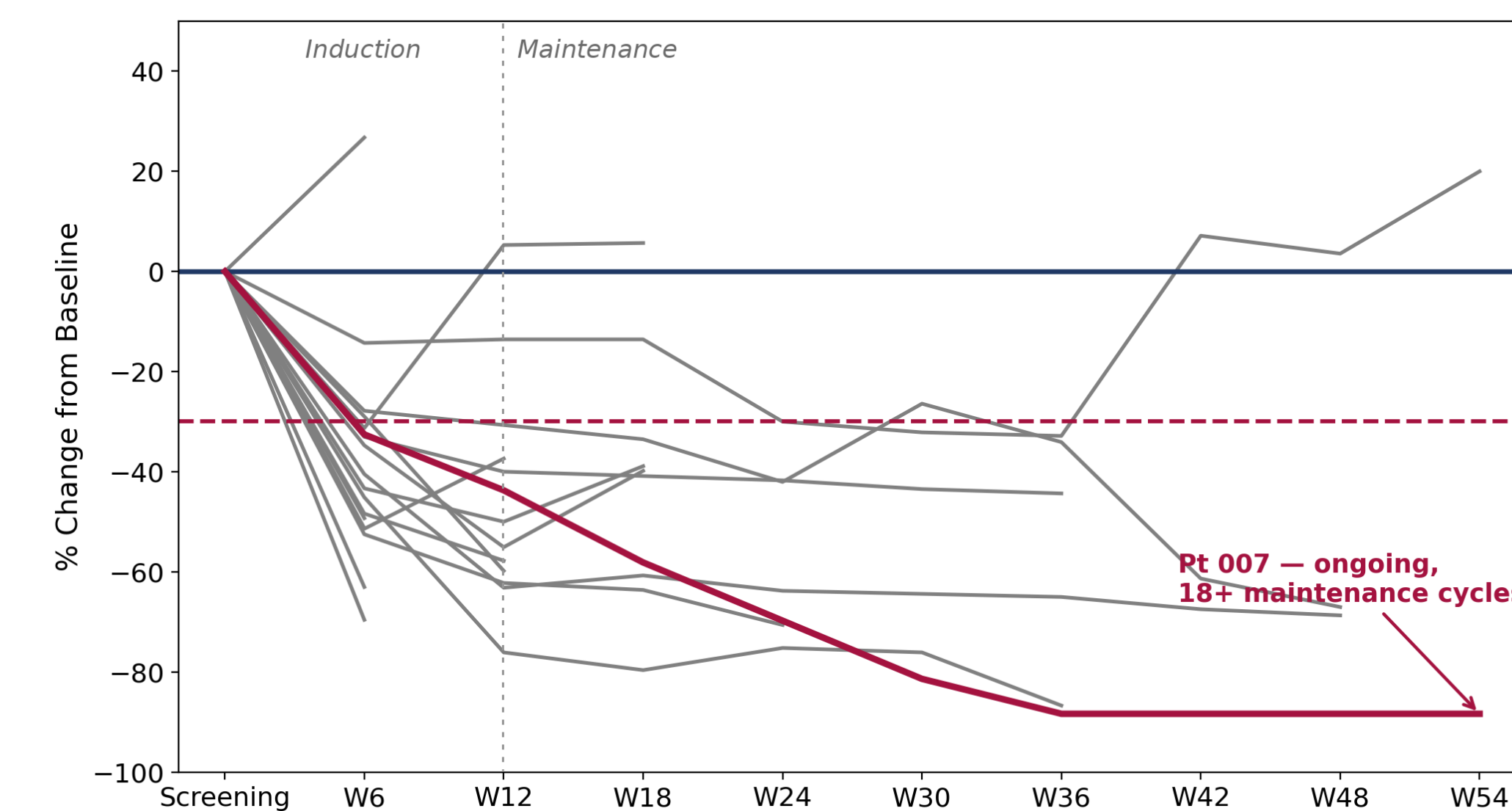


Figure 3. Spider plot of tumor size (% change from baseline; N=20).

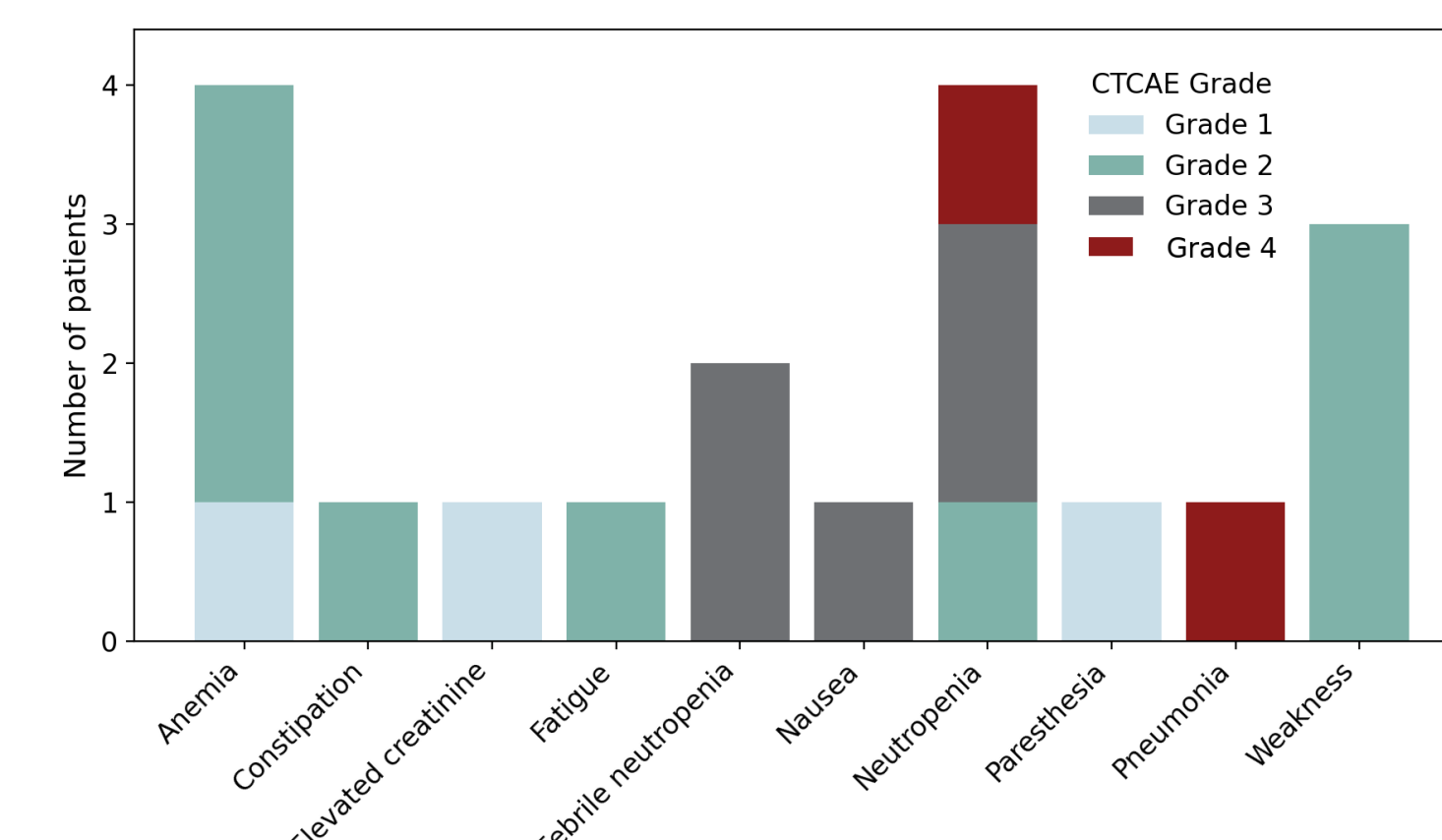


Figure 5. TRAEs — induction (max grade/patient; N=20).

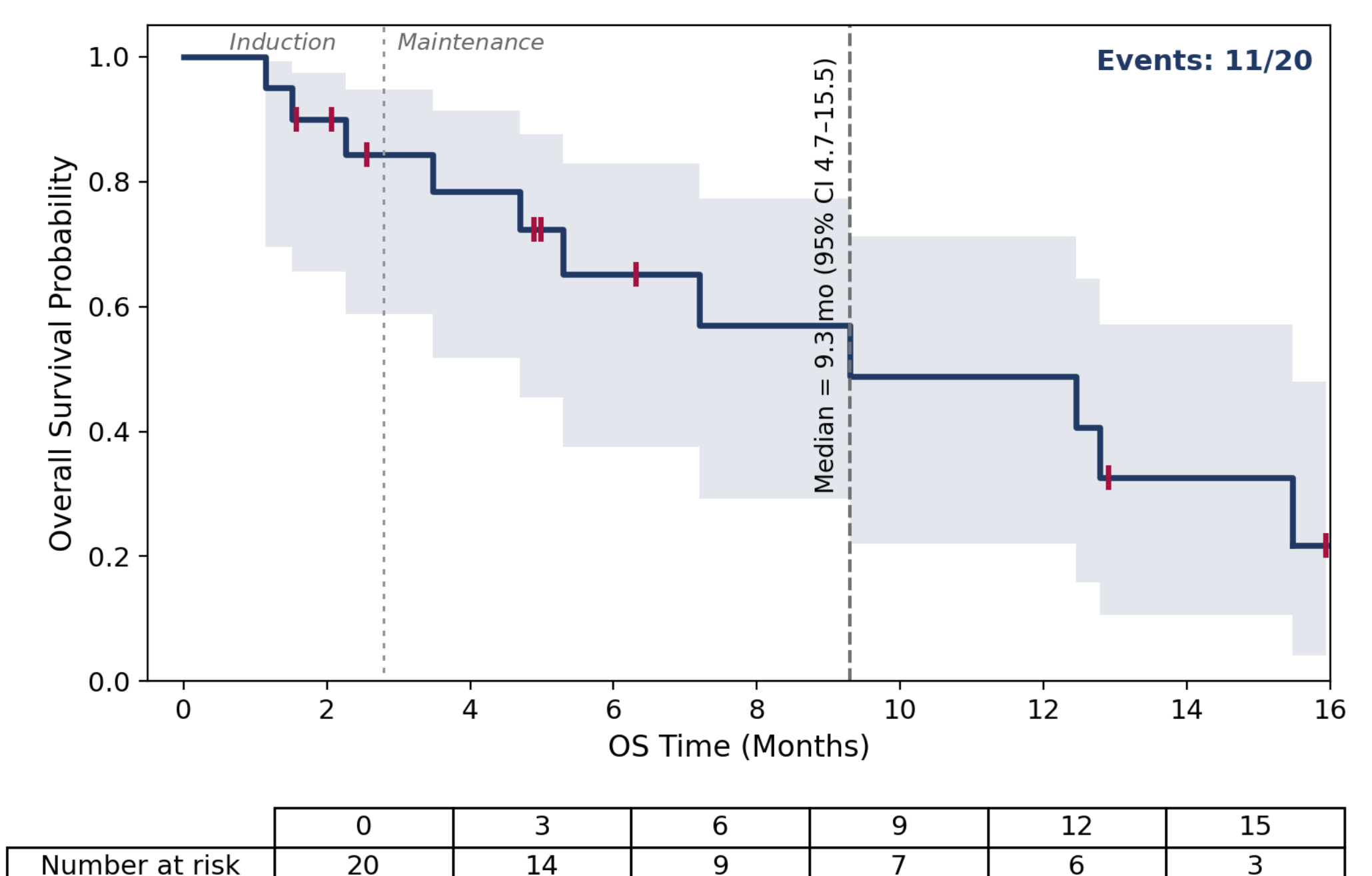


Figure 2. Kaplan–Meier estimate of OS with 95% CI (N=20).

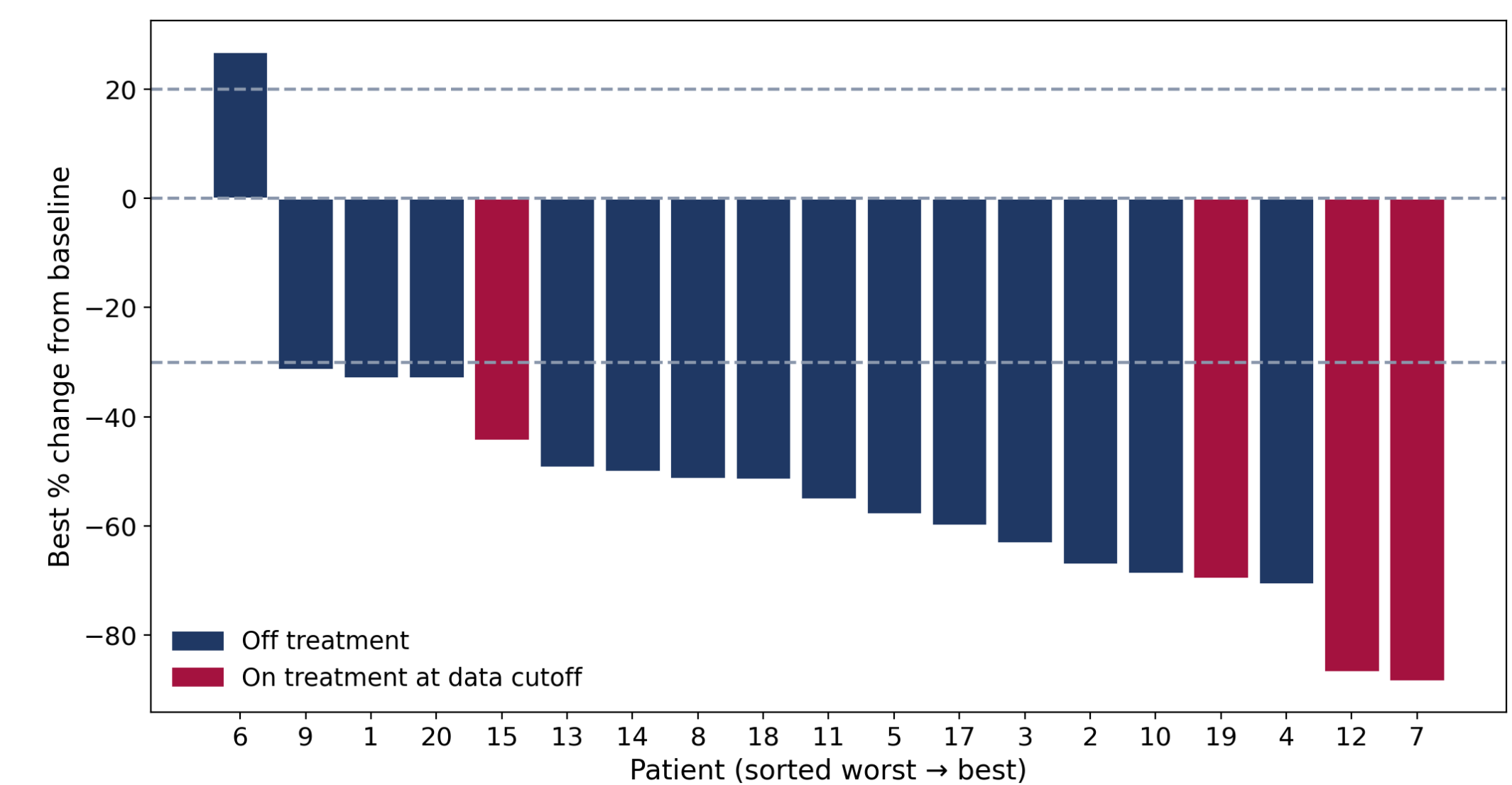


Figure 4. Waterfall plot of best tumor response (N=19 evaluable).

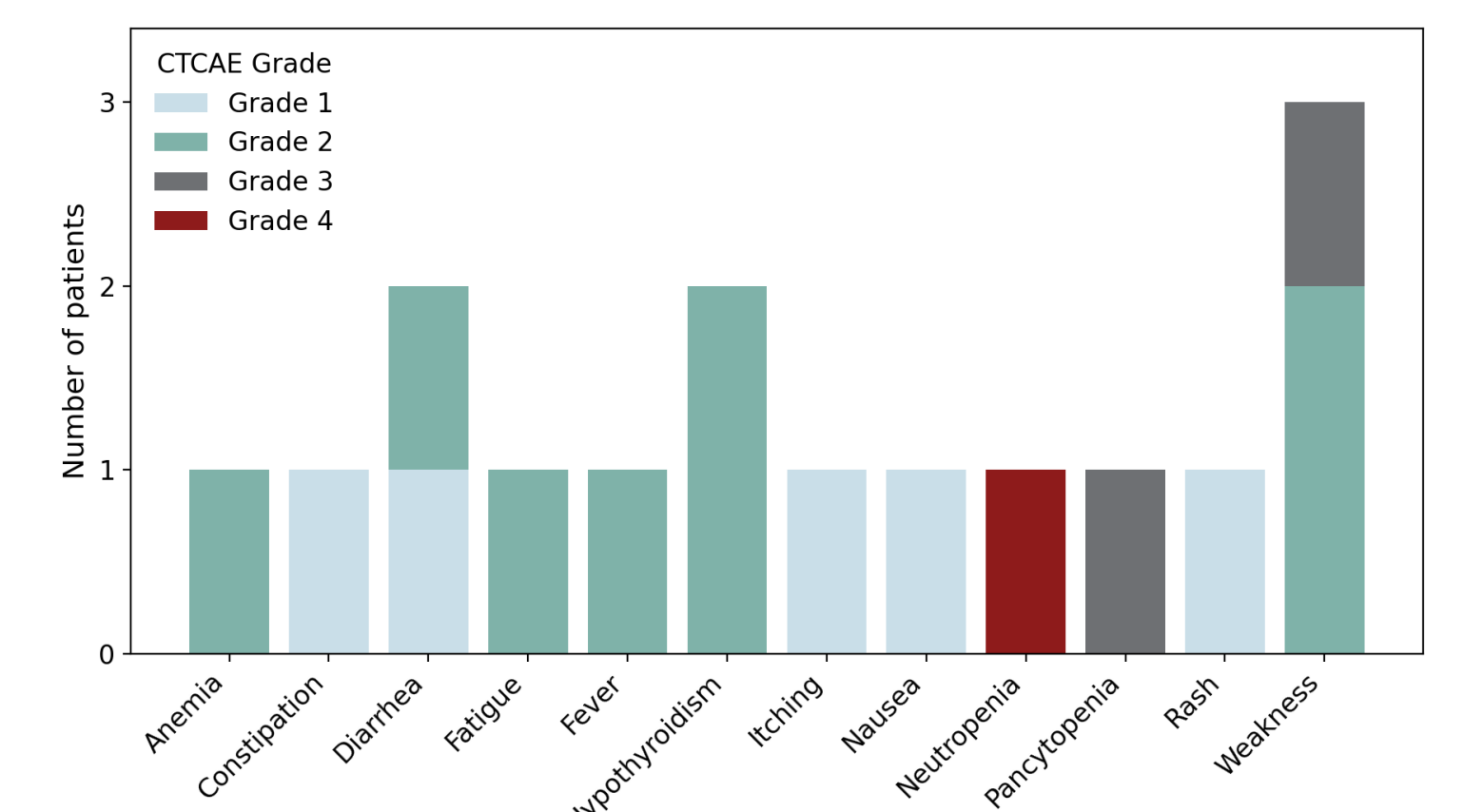


Figure 6. TRAEs — maintenance (max grade/patient; N=13).

