

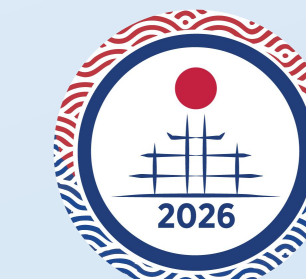


# P3.288: Serplulimab Combined with Concurrent Chemoradiotherapy Followed by Serplulimab Therapy for LS-SCLC: A Phase 2 Trial

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## INTRODUCTION

- For limited-stage small-cell lung cancer (LS-SCLC), the tumor control and survival benefits of the standard-of-care regimen remain to be improved.
- This study was conducted to evaluate the efficacy and safety of serplulimab in combination with concurrent chemoradiotherapy (cCRT) followed by serplulimab maintenance therapy as first-line treatment for patients with LS-SCLC.

## METHODS

### Study design

- This is a multicenter, prospective, single-arm, phase II trial.
- During cycles 1-4, patients received serplulimab plus platinum-based doublet chemotherapy concurrently with thoracic radiotherapy.
- During cycles 5-21, patients received serplulimab monotherapy as maintenance therapy.

#### Key Inclusion Criteria

- Histologically or cytologically confirmed LS-SCLC
- Clinical stage II-III
- No previous anti-tumor treatment
- ≥1 measurable lesion (RECIST v1.1)
- ECOG PS 0-1

#### cCRT phase: cycles 1-4

|                                                                               |                                                                                |
|-------------------------------------------------------------------------------|--------------------------------------------------------------------------------|
| Serplulimab,<br>300 mg, D1<br>Q3W                                             | Cisplatin, 75 mg/m <sup>2</sup> , D1 + Etoposide, 100 mg/m <sup>2</sup> , D1-3 |
|                                                                               | Cisplatin, 60 mg/m <sup>2</sup> , D1 + Etoposide, 120 mg/m <sup>2</sup> , D1-3 |
|                                                                               | Carboplatin, AUC=5, D1 + Etoposide, 100 mg/m <sup>2</sup> , D1-3               |
| Thoracic radiotherapy: 45 Gy (1.5 Gy bid/3w) or 60-70 Gy (1.8-2.0 Gy qd/6-8w) |                                                                                |

#### Maintenance phase: cycles 5-21

Serplulimab, 300 mg, Q3W, D1 up to progression, unacceptable toxicity, or 1 year

- The primary endpoint was progression-free survival (PFS). Secondary endpoints included overall survival (OS), objective response rate (ORR), duration of response (DOR), disease control rate (DCR), and safety profile.

## CONCLUSIONS

- In this ongoing phase II trial, serplulimab combined with cCRT followed by serplulimab maintenance therapy has demonstrated promising antitumor activity and a favorable early survival trend, with acceptable tolerability and manageable safety profile. Longer follow-up is warranted to validate the survival benefits of this regimen.

## ACKNOWLEDGEMENTS

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## RESULTS

### Baseline

- Among the 59 patients analyzed, the average age was 62 years.
- All enrolled patients completed the 4-cycle combination therapy, and 79.7% (47/59) received serplulimab maintenance therapy.

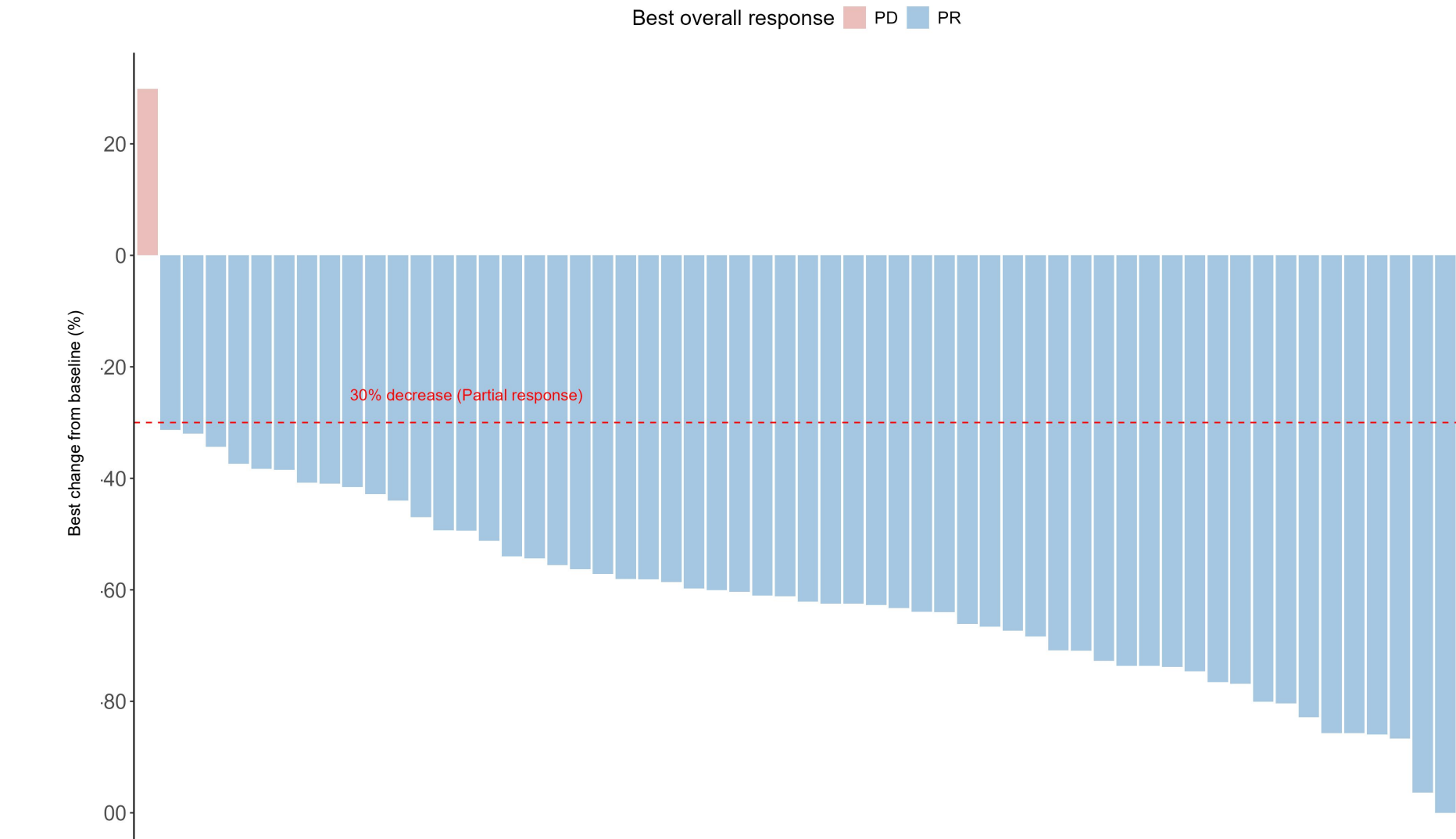
Table 1. Baseline characteristics of included patients

| Characteristics         | Total (N=59)      |
|-------------------------|-------------------|
| Age (years), median     | 62 (range, 31-76) |
| Gender (male, n, %)     | 47 (79.7)         |
| ECOG PS (1, n, %)       | 22 (37.3)         |
| Clinical stage (n, %)   |                   |
| II                      | 5 (8.5)           |
| III                     | 54 (91.5)         |
| Clinical N stage (n, %) |                   |
| N 0-1                   | 9 (15.6)          |
| N 2-3                   | 49 (83.1)         |
| N x                     | 1 (1.7)           |

### Efficacy

- 58 patients achieved partial response (PR).
- The confirmed ORR and DCR were both **98.3% (57/58), with a 95% CI of 90.91-99.96%.**

Figure 1. Waterfall plot of best change in target lesions



### Survival

- At the data cutoff date (March 24, 2026), the median follow-up duration was 16.4 months.

Figure 2. Swimmer plot of treatment duration and clinical outcomes

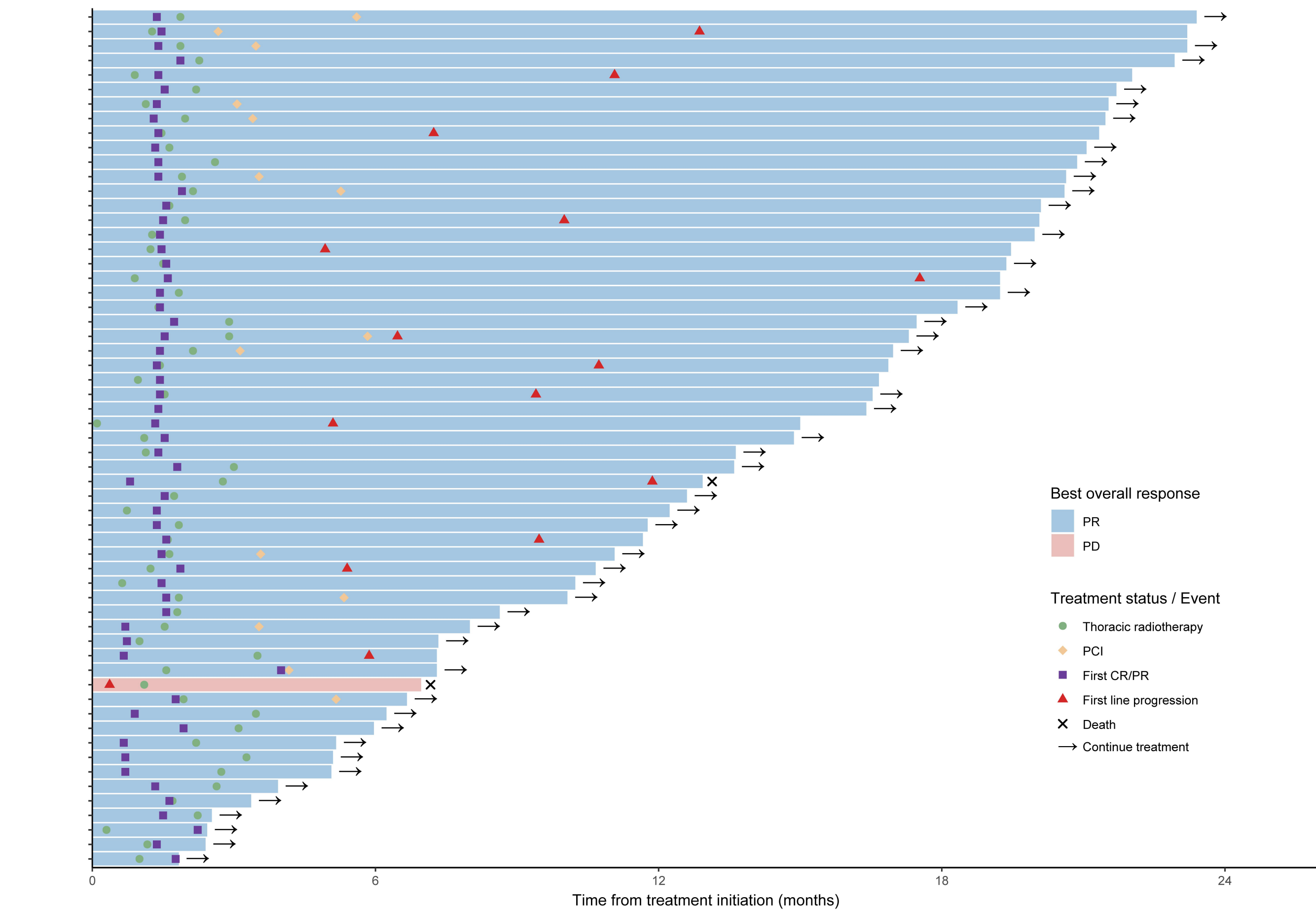


Figure 3. Kaplan-Meier curve of PFS

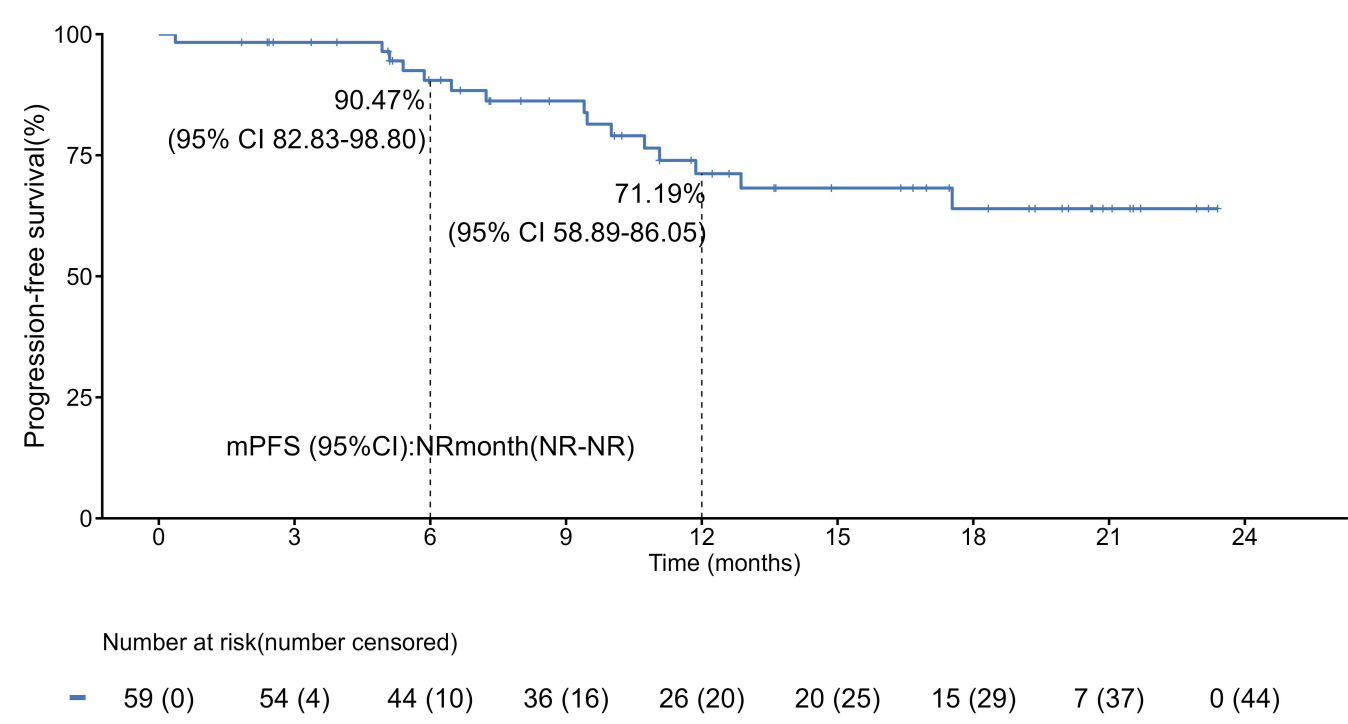


Figure 4. Kaplan-Meier curve of OS

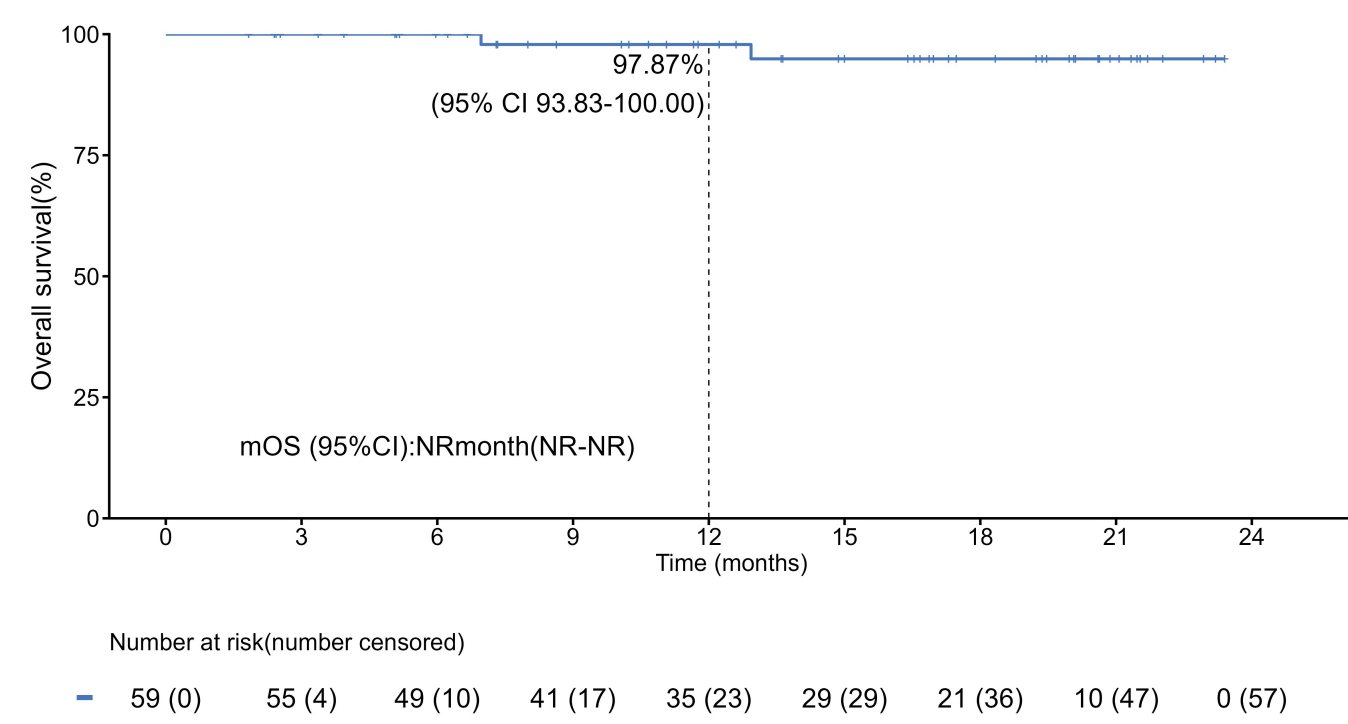
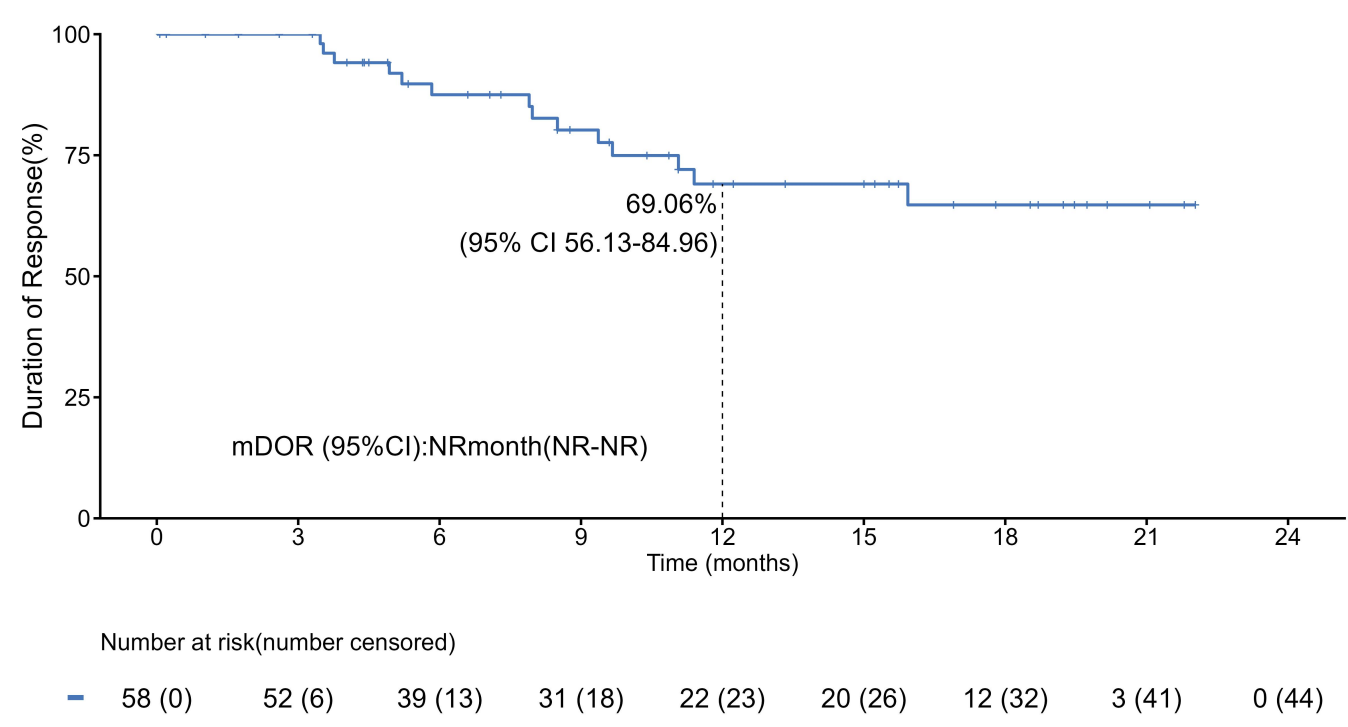


Figure 5. Kaplan-Meier curve of DOR



### Safety

- The incidence of **Grade 3-4 adverse events (AEs)** was **52.5%**, and Grade 3-4 immune-related AEs occurred in 11.9% of patients.
- Grade 3-4 radiation pneumonitis and immune-mediated pneumonitis were observed in only **5.1%** and **8.5% of patients**.
- No grade 5 AEs were observed.