

P3.283: Second-line Serplulimab Plus Anlotinib and Nab-paclitaxel for ES-SCLC After First-line Immunochemotherapy: A Phase II Study

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INTRODUCTION

- Outcomes for patients with extensive-stage small cell lung cancer (ES-SCLC) progressing after standard first-line therapy remain dismal, constrained by limited therapeutic options.
- Immune checkpoint inhibitor re-challenge combined with anti-angiogenesis and chemotherapy offers a synergistic strategy to improve clinical outcomes in this population.
- We initiated a phase II study to evaluate the efficacy and safety of serplulimab plus anlotinib and nab-paclitaxel in patients with ES-SCLC who have failed first-line immunochemotherapy.

METHODS

- This is a single-arm, phase II study.
- Patients received maintenance therapy with serplulimab plus anlotinib until disease progression, intolerable toxicity, or withdrawal of consent.

Key Inclusion Criteria

- adult (≥ 18 years) patients with ES-SCLC
- with confirmed disease progression after first-line immunochemotherapy
- ECOG 0-1

4-6 cycles, every 3 weeks

- serplulimab 300 mg
- anlotinib 8 mg, days 1-14
- nab-paclitaxel 100 mg/m²

Maintenance Therapy

- serplulimab 300 mg
- anlotinib 8 mg, days 1-14

Primary endpoint

- objective response rate (ORR) per RECIST v1.1

Secondary endpoints

- progression-free survival (PFS)
- overall survival (OS)
- adverse events (AEs)

RESULTS

Patients

- As of November 17, 2025, 20 patients were enrolled.

Table 1. Baseline characteristics of included patients (N=20)

Male, n (%)	15 (75.0)
Age (years), median (range)	66.5 (52, 73)
Metastatic sites, n(%)	
Liver	8 (40.0)
Bone	9 (45.0)
Brain	7 (35.0)
Pattern of prior first-line progression, n(%)	
Primary tumor	4 (20.0)
Regional lymph involvement	4 (20.0)
Distant metastasis	12 (60.0)

Safety

- The incidence of grade 3-4 immune-related AEs was 20.0% (n=4), and grade 3-4 anlotinib-related AEs occurred in 15.0% of patients (n=3).
- The safety profile was manageable, and no new safety signals were identified.
- No grade 5 AEs were observed.

Table 2. Safety profile of study patients (N=20)

Grade 3-4 immune-related AEs	4 (20.0)
Grade 3-4 anlotinib-related AEs	3 (15.0)
Grade 3-4 chemotherapy-related AEs	12 (60.0)

Efficacy

- The regimen achieved a **confirmed ORR of 70.0% (14/20; 95% CI: 45.7-88.1%)**, with all responders achieving a partial response.
- At a median follow-up of 11.0 months, the median PFS was 4.6 months (95% CI: 3.7- NR).

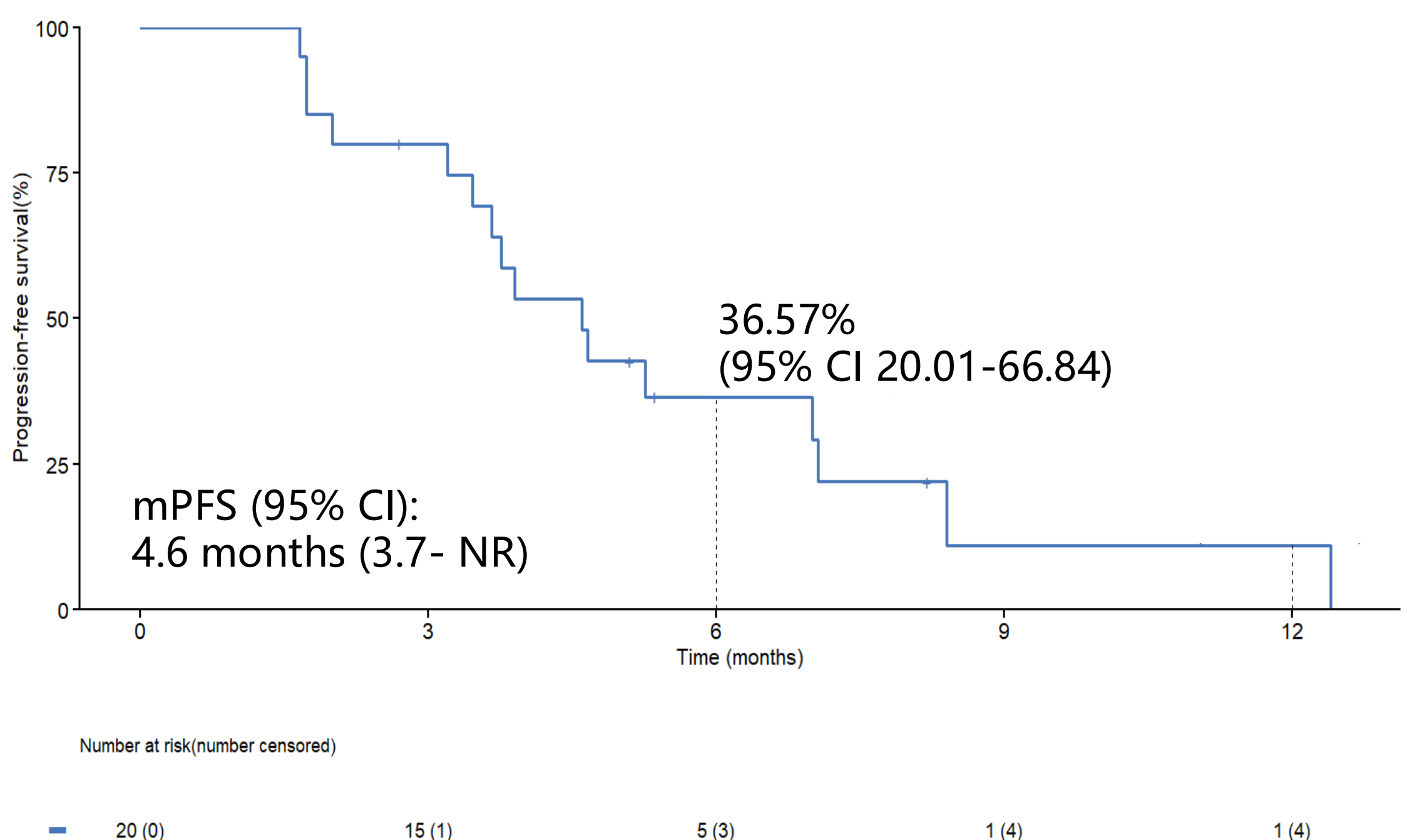


Figure 1. Kaplan-Meier estimates of progression-free survival

Exploratory subgroup analysis

- Survival benefit was predominantly observed in the subgroup of patients who transitioned to maintenance therapy, suggesting a potential signal of durable efficacy with sustained treatment exposure (P=0.005).
- Comparable PFS was observed regardless of first-line PD-1 or PD-L1 inhibitor exposure (P=0.759).

CONCLUSIONS

- ◆ The triplet combination of serplulimab, anlotinib and nab-paclitaxel demonstrated promising antitumor activity with an ORR of 70% in ES-SCLC patients progressing on prior immunochemotherapy.
- ◆ With a manageable safety profile, this regimen represents a potentially effective salvage regimen that warrants further validation in larger cohorts.