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Serplulimab Plus Chemotherapy as First-Line Treatment for Locally Advanced or Metastatic LCNEC: A Phase II Trial

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INTRODUCTION & METHODS

Clinical Challenge and Rationale for Immunotherapy

- Pulmonary large cell neuroendocrine carcinoma (LCNEC) is a rare and highly aggressive malignancy with poor outcomes following platinum-based chemotherapy.
- Serplulimab, a PD-1 monoclonal antibody, has shown promising efficacy in first-line advanced NSCLC and SCLC. Given the biological overlap with NSCLC and SCLC, serplulimab-based strategies warrant investigation in LCNEC.

Study Objective :

The trial aimed to evaluate the efficacy and safety of serplulimab combined with chemotherapy as first-line therapy in locally advanced or metastatic pulmonary LCNEC.

Key Inclusion Criteria

- Age ≥ 18 years
- Histologically confirmed locally advanced or metastatic LCNEC
- No prior systemic therapy for LCNEC
- ECOG PS of 0–2
- Measurable lesions at baseline according to RECIST 1.1

Induction Phase

Cycles 1-4:

- Serplulimab (4.5 mg/kg, D1)
- Etoposide (100 mg/m², D1–3)
- Carboplatin (AUC = 5) or Cisplatin (75 mg/m², D1)

Maintenance Phase

Cycles 5+:

- Serplulimab (4.5 mg/kg, D1) until PD, unacceptable toxicity, or 2 years

Study Endpoints

- **Primary Endpoint:** ORR
- **Secondary Endpoints:** PFS, OS, DCR and safety

Disclosure: No relevant conflicts of interest to disclose.

RESULTS

Baseline

Characteristics	Total (N=37)
Gender (male), n (%)	27 (72.97)
Age (years), median (range)	65 (40–79)
≥65 years	19 (51.35)
BMI (kg/m ²), mean ± SD	23.46 ± 2.72
Smoking history, n (%)	
Ever smoker	24 (64.86)
Metastatic sites, n (%)	
Liver	7 (18.92)
Bone	11 (29.73)
Brain	7 (18.92)
ECOG PS, n(%)	
0	24 (64.86)
1	13 (35.14)

- As of March 2026, 39 patients were enrolled, and **37 were included in the analysis**.
- A total of **86.5% of patients had M1**, with bone metastases being the most common site (29.7%).

Safety

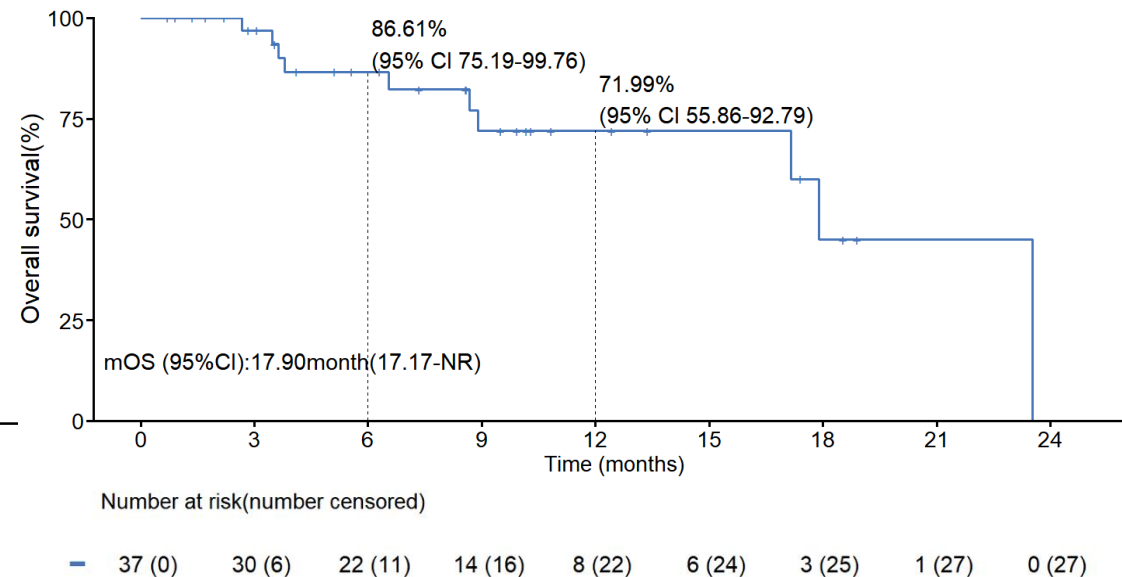
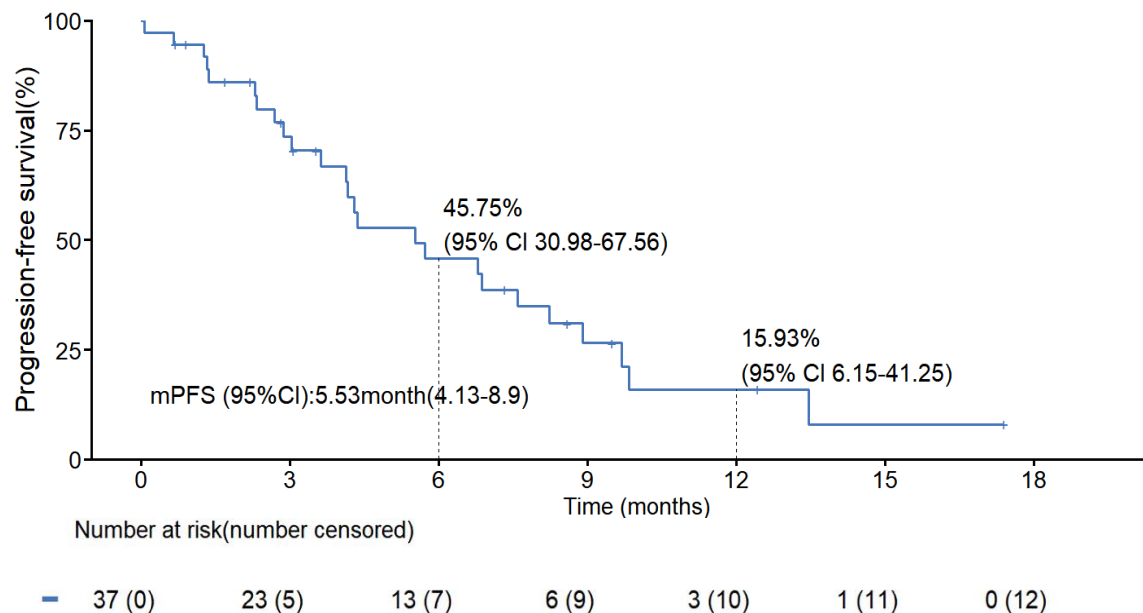
TRAE (≥ 8%)	Total	Grade 1-2	Grade 3-4
Anemia	12 (32.43)	10 (27.03)	2 (5.41)
White blood cell count decreased	9 (24.32)	7 (18.92)	2 (5.41)
Platelet count decreased	8 (21.62)	5 (13.51)	3 (8.11)
Neutrophil count decreased	7 (18.92)	4 (10.81)	3 (8.11)
Lymphocyte count decreased	6 (16.22)	6 (16.22)	–
Aspartate aminotransferase increased	5 (13.51)	5 (13.51)	–
Alanine aminotransferase increased	4 (10.81)	4 (10.81)	–
Gamma-glutamyl transferase increased	3 (8.11)	3 (8.11)	–
Hypothyroidism	3 (8.11)	3 (8.11)	–

- Treatment-related adverse events (TRAEs) occurred in 56.8% of patients (**grade 3–4, 18.9%**).
- Serious adverse events (SAEs) occurred in 16.2%, with **no treatment-related SAEs** observed.

RESULTS & CONCLUSION

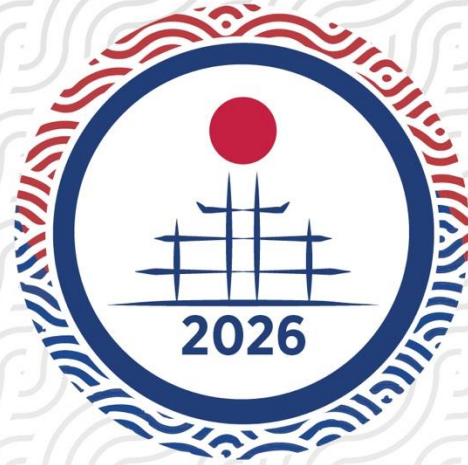
Efficacy

- The ORR was **56.8% (21/37; 95% CI, 39.5–72.9)**, with all responses being partial responses, and the DCR was **86.5% (32/37; 95% CI, 71.2–95.5)**.
- With a median follow-up of 9.5 months, the median **PFS was 5.5 months** (95% CI, 4.1–8.9), and the 12-month OS rate was 72.0% (**OS data immature**).



Conclusion

Serplulimab combined with chemotherapy demonstrated **encouraging clinical activity** and **acceptable safety** as a **first-line treatment for LCNEC** in this ongoing trial, supporting further exploration in this rare and aggressive malignancy.



Thank You.