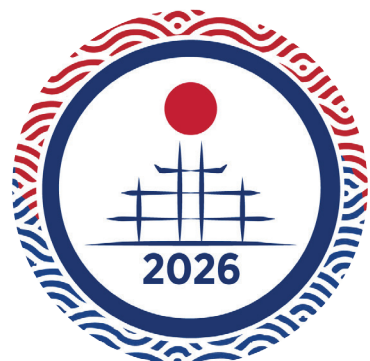


P3.317: First-line Maintenance with Serplulimab for Extensive-Stage Small Cell Lung Cancer: A Post-hoc Analysis and Meta-analysis



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INTRODUCTION

- The phase 3 ASTRUM-005 trial demonstrated a significant overall survival (OS) benefit with the addition of serplulimab to first-line chemotherapy in patients with extensive-stage small cell lung cancer (ES-SCLC).¹⁻³
- However, the efficacy and safety of serplulimab monotherapy as maintenance treatment remain unclear.
- To address this question, we conducted a post-hoc analysis of ASTRUM-005 and a meta-analysis comparing several maintenance regimens, including serplulimab, atezolizumab, and atezolizumab plus lurbinectedin.^{4,5}

METHODS

- This study included patients in the serplulimab group of ASTRUM-005 who had not discontinued the study treatment or withdrawn from the trial upon completing induction therapy and had at least one dose of serplulimab monotherapy as maintenance therapy.
- OS, blinded independent central review (BICR)-assessed progression-free survival (PFS), and the incidence of grade ≥3 treatment-related adverse events (TRAEs) during the maintenance phase were compared between the ASTRUM-005 and IMforte phase 3 trials.
- Matching-adjusted indirect comparison (MAIC) analyses were performed for OS and PFS comparisons, with adjustment for sex, performance status at maintenance baseline, and liver metastasis at induction baseline.

CONCLUSIONS

This inter-trial comparison showed that serplulimab was associated with more favorable OS and PFS than atezolizumab and with more favorable OS and safety than atezolizumab plus lurbinectedin.

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RESULTS

Post-hoc analysis of ASTRUM-005

- The post-hoc analysis of the ASTRUM-005 trial included 323 patients, of whom 278 patients had achieved an objective response or stable disease during induction therapy based on BICR assessment and had at least one response evaluation during the maintenance phase, and were included in the response-evaluable set for efficacy analysis.
- As of May 7, 2024, the median follow-up was 40.2 months (interquartile range, 36.8–42.3). The median age at maintenance baseline was 62 years (range 28–76). Most patients were male (83.0%) or had performance status 1 (80.8%) (**Table 1**).

Table 1: Baseline demographic and disease characteristics

	Overall population (n = 323)	Overall population (n = 323)
Age ^a , median (range), years	62 (28–76)	
<65 years, n (%)	202 (62.5)	
≥65 years, n (%)	121 (37.5)	
Sex, n (%)		
Male	268 (83.0)	
Female	55 (17.0)	
Race		
Asian	221 (68.4)	
Non-Asian ^b	102 (31.6)	
Smoking history, n (%)		
Never	68 (21.1)	
Current	77 (23.8)	
Former	178 (55.1)	
Performance status ^c , n (%)		
0	62 (19.2)	
1	261 (80.8)	
Liver metastasis ^a , n (%)	77 (23.8)	
Brain metastasis ^a , n (%)	39 (12.1)	
BICR-assessed response to induction therapy, n (%)		
Complete or partial response	281 (87.0)	
Stable disease	36 (11.1)	
Progressive disease ^d	3 (0.9)	
Not evaluable	3 (0.9)	

Efficacy

- From the maintenance baseline, the median OS with serplulimab was 15.6 months (95% confidence interval [CI], 14.0–17.9), and the median PFS was 4.1 months (95% CI, 2.8–5.2) (**Table 2**).
- The objective response rate (ORR) was 22.3% (95% CI 17.6%–27.7%). Among the 62 patients who achieved objective response, median duration of response (DOR) was not reached (NR; 95% CI 14.7 months–not evaluable).

Table 2: Survival outcomes

Endpoint	Response-evaluable set (n = 278)	Tumor response, n (%)	Response-evaluable set (n = 278)
OS (95% CI), months ^e	15.6 (14.0–17.9)	Complete response	9 (3.2)
1-y OS rate (95% CI), %	62.8 (56.7–68.3)	Partial response	53 (19.1)
PFS (95% CI), months ^e	4.1 (2.8–5.2)	Stable disease	146 (52.5)
1-y PFS rate (95% CI), %	30.4 (24.6–36.4)	Progressive disease	70 (25.2)
		DOR (95% CI), months	NR (14.7–NE)

Safety

- A summary of treatment-emergent adverse events (TEAEs) is provided in **Table 3**. Treatment-related adverse events (TRAEs) were reported in 209 patients (64.7%; grade ≥3, 51 patients, 15.8%).

Table 3: Summary of TEAEs

Adverse event, n (%)	Overall population (n = 323)	Adverse event, n (%)	Overall population (n = 323)
TEAE	290 (89.8)	TRAE	209 (64.7)
Grade ≥3	124 (38.4)	Grade ≥3	51 (15.8)
Grade 3–4	119 (36.8)	Grade 3–4	49 (15.2)
Serious	64 (19.8)	Serious	34 (10.5)
Leading to death	11 (3.4)	Leading to death	2 (0.6)
Leading to study treatment discontinuation	28 (8.7)		

^a At induction baseline. ^b All non-Asian patients were White. ^c At maintenance baseline. ^d These patients had progressive disease according to assessments by the BICR but not by the investigator and received serplulimab beyond the induction phase. ^e Since maintenance baseline. RECIST, Response Evaluation Criteria in Solid Tumors; TRAE, treatment-related adverse event; y, year.

Meta-analysis

- After adjusting for sex, performance status and liver metastasis, compared with **atezolizumab**, serplulimab was associated with **more favorable OS (hazard ratio [HR], 0.63; 95% CI, 0.48–0.81) and PFS (HR, 0.62; 95% CI, 0.49–0.80) (Table 4; Figures 1A & 1B)**.
- Compared with **atezolizumab plus lurbinectedin**, serplulimab was associated with **improved OS (HR, 0.74; 95% CI, 0.57–0.97), similar PFS (HR, 1.01; 95% CI, 0.77–1.31), and lower risk of grade ≥3 TRAEs (risk ratio, 0.52; 95% CI, 0.38–0.72) (Table 4; Figures 1C & 1D)**. Consistent findings were observed without the baseline factor adjustment (**Table 4**).

Figure 1: Survival curves of (A & C) OS and (B & D) PFS after adjusting for sex, performance status at maintenance baseline, and liver metastasis at induction baseline using MAIC

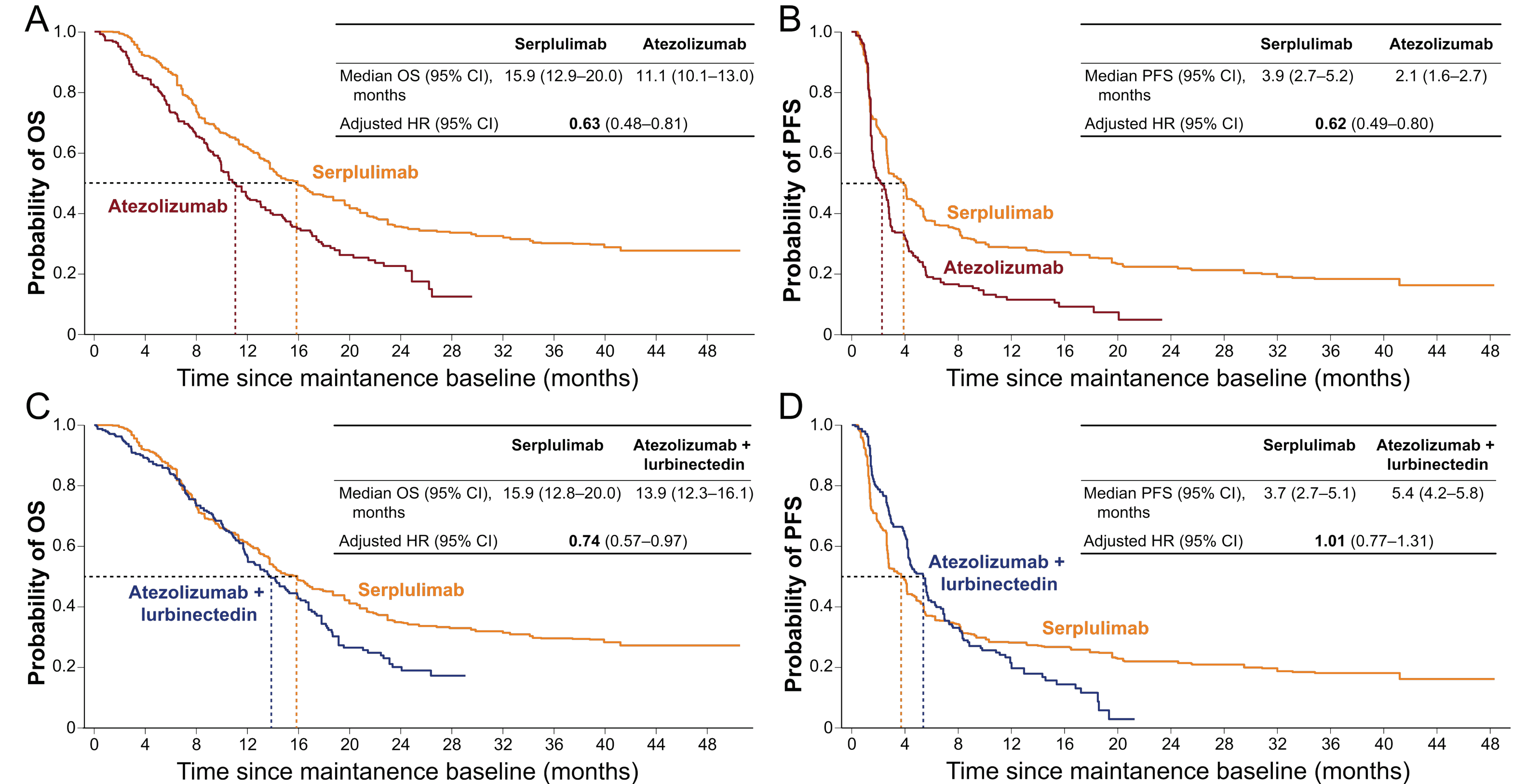


Table 4: Meta-analysis of efficacy and safety between first-line maintenance regimens

	Serplulimab versus atezolizumab		Serplulimab versus atezolizumab + lurbinectedin	
	Serplulimab (n = 278)	Atezolizumab (n = 240)	Serplulimab (n = 278)	Atezolizumab + lurbinectedin (n = 242)
Efficacy				
OS (95% CI), months	15.6 (14.0–17.9)	11.1 (10.1–13.0)	15.6 (14.0–17.9)	13.9 (12.3–16.1)
Hazard ratio (95% CI)	0.62 (0.50–0.77)		0.72 (0.58–0.90)	
Adjusted ^a	15.9 (12.9–20.0)	11.1 (10.1–13.0)	15.9 (12.8–20.0)	13.9 (12.3–16.1)
Hazard ratio (95% CI)	0.63 (0.48–0.81)		0.74 (0.57–0.97)	
PFS (95% CI), months	4.1 (2.8–5.2)	2.1 (1.6–2.7)	4.1 (2.8–5.2)	5.4 (4.2–5.8)
Hazard ratio (95% CI)	0.58 (0.48–0.72)		0.94 (0.76–1.16)	
Adjusted ^a	3.9 (2.7–5.2)	2.1 (1.6–2.7)	3.7 (2.7–5.1)	5.4 (4.2–5.8)
Hazard ratio (95% CI)	0.62 (0.49–0.80)		1.01 (0.77–1.31)	
Safety				
Grade ≥3 TRAE, n (%)	51 (15.8)	17 (7.1)	51 (15.8)	73 (30.2)
Risk ratio (95% CI)	2.23 (1.32–3.76)		0.52 (0.38–0.72)	
Grade 3–4 TRAE, n (%)	49 (15.2)	16 (6.7)	49 (15.2)	71 (29.3)
Risk ratio (95% CI)	2.28 (1.33–3.90)		0.52 (0.37–0.71)	

^a The sample size of the serplulimab group was 146 for comparison with atezolizumab and 138 for comparison with atezolizumab plus lurbinectedin after adjusting for sex, performance status at maintenance baseline, and liver metastasis at induction baseline. TRAE, treatment-related adverse event.

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