Background

Extensive-stage small-cell lung cancer (ES-SCLC) is associated with rapid disease progression and poor prognosis, with a 5-year survival rate of 7%[1,2]. Following over three decades of platinum-etoposide chemotherapy, combination therapy of a programmed death 1 (PD-1) or programmed death ligand 1 (PD-L1) inhibitor with chemotherapy has become the standard of care as first-line treatment for ES-SCLC.

In the IMpower133 and CASPIAN phase 3 studies, addition of PD-L1 inhibitor atezolizumab, and durvalumab to chemotherapy prolonged the median overall survival (OS) by 2.0[3] and 2.7 months[4], respectively. Other PD-(L)1 inhibitors, including adebrelimab, tislelizumab, and toripalimab, have also shown survival benefit in studies conducted in China, prolonging median OS by 2.5[5], 2.0[6], and 1.3 months[7], respectively.

ASTRUM-005 is an international, randomized, double-blind, placebo-controlled phase 3 trial that was the first to show significantly improved OS upon addition of a PD-1 inhibitor, serplulimab, to chemotherapy for first-line treatment of ES-SCLC, with a median OS extension by 4.5 months[8]. An updated analysis at 32-month median follow-up showed sustained survival benefit[9]. Here we present the efficacy and safety findings from the end-of-study analysis of ASTRUM-005 at a median follow-up duration of 42.4 months.

Methods

Previously untreated patients with ES-SCLC were randomized in a 2:1 ratio to receive serplulimab + carboplatin + etoposide (serplulimab group) or placebo + carboplatin + etoposide (placebo group) in 3-week cycles (**Figure 1**).

Figure 1. Study design

Inclusion criteria:

Histologically or cytologically diagnosed with ES-SCLC
No prior systemic therapy for ES-SCLC
At least one measurable lesion as assessed by BICR per RECIST 1.1
ECOG performance status 0/1

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