

# FDA Approves Atezolizumab for Extensive-Stage SCLC

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On 18 March 2019, the US Food and Drug Administration (FDA) approved atezolizumab (TECENTRIQ, Genentech Inc.) in combination with carboplatin and etoposide, for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC).

Approval was based on IMpower133 (NCT02763579), a randomised (1:1), multicentre, double-blind, placebo-controlled trial in 403 patients with ES-SCLC who received no prior chemotherapy for extensive stage disease and had ECOG performance status 0 or 1. Patients were randomised to one of the following:

- atezolizumab 1200 mg and carboplatin AUC 5 mg/mL/min on day 1 and etoposide 100 mg/m<sup>2</sup> intravenously on days 1, 2 and 3 of each 21-day cycle for a maximum of 4 cycles, followed by atezolizumab 1200 mg once every 3 weeks until disease progression or unacceptable toxicity, or
- placebo and carboplatin AUC 5 mg/mL/min on day 1 and etoposide 100 mg/m<sup>2</sup> intravenously on days 1, 2, and 3 of each 21-day cycle for a maximum of 4 cycles, followed by placebo once every 3 weeks until disease progression or unacceptable toxicity.

Major efficacy outcome measures were overall survival (OS) and progression-free survival (PFS) as assessed by investigator per RECIST v1.1 in the intent-to-treat population. Median OS was 12.3 months (10.8, 15.9) for patients receiving atezolizumab with chemotherapy and 10.3 months (9.3, 11.3) for those receiving placebo with chemotherapy (hazard ratio 0.70; 95% CI: 0.54, 0.91; p = 0.0069). Median PFS was 5.2 months (4.4, 5.6) compared with 4.3 months (4.2, 4.5) in the atezolizumab and placebo arms, respectively (HR 0.77; 0.62, 0.96; p = 0.0170).

The most common adverse reactions reported in ≥ 20% of patients who received atezolizumab in IMpower133 were fatigue/asthenia, nausea, alopecia, constipation, and decreased appetite.

The recommended atezolizumab dose for patients with ES-SCLC is 1200 mg intravenously over 60 minutes every 3 weeks. When administered on the same day, atezolizumab should be administered prior to chemotherapy. If the first infusion is tolerated, all subsequent infusions may be delivered over 30 minutes.

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