FDA Approves Atezolizumab for Extensive-Stage Small-Cell Lung Cancer

Progression-free and overall survival improved in patients treated with Tecentriq plus chemotherapy.

March 18, 2019 By Food and Drug Administration (FDA)

On March 18, 2019, the Food and Drug Administration 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 randomized (1:1), multicenter, 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 randomized to one of the following:

- atezolizumab 1200 mg and carboplatin AUC 5 mg/mL/min on day 1 and etoposide 100 mg/m2 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/m2 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 1.1 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.

View full prescribing information for TECENTRIQ.

FDA granted this application priority review. A description of FDA expedited programs is in the Guidance for Industry: Expedited Programs for Serious Conditions-Drugs and Biologics.

Healthcare professionals should report all serious adverse events suspected to be associated with the use of any medicine and device to FDA's MedWatch Reporting System or by calling 1-800-FDA-1088.

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