

FDA Approves Tecentriq for First-Line Treatment of Metastatic Lung Cancer

Initial treatment with atezolizumab led to longer overall survival in people with high biomarker levels.

May 21, 2020 By [Food and Drug Administration \(FDA\)](#)

FDA approves atezolizumab for first-line treatment of metastatic NSCLC with high PD-L1 expression

On May 18, 2020, the Food and Drug Administration approved atezolizumab (TECENTRIQ, Genentech Inc.) for the first-line treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have high PD-L1 expression (PD-L1 stained $\geq 50\%$ of tumor cells [TC $\geq 50\%$] or PD-L1 stained tumor-infiltrating immune cells [IC] covering $\geq 10\%$ of the tumor area [IC $\geq 10\%$]), with no EGFR or ALK genomic tumor aberrations.

Today, the FDA also approved the VENTANA PD-L1 (SP142) Assay (Ventana Medical Systems, Inc.) as a companion diagnostic device for selecting patients with NSCLC for treatment with atezolizumab.

Efficacy was evaluated in IMpower110 (NCT02409342), a multicenter, international, randomized, open-label trial in patients with stage IV NSCLC whose tumors express PD-L1 (TC $\geq 1\%$ or IC $\geq 1\%$), who had received no prior chemotherapy for metastatic disease. Patients were randomized (1:1) to receive atezolizumab 1200 mg every 3 weeks until disease progression or unacceptable toxicity or platinum-based chemotherapy. The main efficacy outcome measure was overall survival (OS).

The trial demonstrated a statistically significant improvement in OS for patients with high PD-L1 tumor expression receiving atezolizumab compared to those treated with platinum-based chemotherapy. Median OS was 20.2 months (95% CI: 16.5, NE) for patients in the atezolizumab arm compared with 13.1 months (95% CI: 7.4, 16.5) in the chemotherapy arm (HR 0.59; 95% CI: 0.40, 0.89; $p=0.0106$). There was no statistically significant difference in OS for the other two PD-L1 subgroups (TC $\geq 5\%$ or IC $\geq 5\%$; and TC $\geq 1\%$ or IC $\geq 1\%$) at the interim or final analyses.

Median progression-free survival (PFS) per investigator was 8.1 months (95% CI: 6.8, 11.0) in the atezolizumab arm and 5.0 months (95% CI: 4.2, 5.7) in the platinum-based chemotherapy arm (HR 0.63; 95%CI: 0.45, 0.88). Confirmed overall response rate (ORR) per investigator was 38% (95%

CI: 29, 48) and 29% (95% CI: 20, 39), respectively.

The most common adverse reaction ($\geq 20\%$) with atezolizumab as a single-agent in IMpower110 was fatigue/asthenia.

The recommended atezolizumab dose for treatment of NSCLC is 840 mg every 2 weeks, 1200 mg every 3 weeks, or 1680 mg every 4 weeks, administered intravenously over 60 minutes.

[View full prescribing information for TECENTRIQ.](#)

This review used the [Assessment Aid](#), a voluntary submission from the applicant to facilitate the FDA's assessment. This application was approved one month prior to the FDA goal date.

This application was granted 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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