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 ≥ 50% of tumor cells [TC ≥ 50%] or PD-L1 stained tumor-infiltrating immune cells [IC] covering ≥ 10% of the tumor area [IC ≥ 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 ≥ 1% or IC ≥ 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 ≥5% or IC ≥5%; and TC ≥1% or IC ≥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 (≥ 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.

This announcement was originally published on the Food and Drug Administration website on May 18, 2020.
