FDA Approves Atezolizumab for the First-Line Treatment of Patients With Metastatic NSCLC and High PD-L1 Expression

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On May 18, the U.S. Food and Drug Administration (FDA) approved atezolizumab (Tecentriq) for the first-line treatment of adult patients with metastatic non–small cell lung cancer (NSCLC) whose tumors have high programmed cell death ligand 1 (PD-L1) expression (PD-L1 stained ≥ 50% of tumor cells or PD-L1–stained tumor-infiltrating immune cells covering ≥ 10% of the tumor area), with no *EGFR* or *ALK* genomic tumor aberrations.

The FDA also approved the VENTANA PD-L1 (SP142) Assay as a companion diagnostic device for selecting patients with NSCLC for treatment with atezolizumab.

IMpower110

Efficacy was evaluated in IMpower110, a multicenter, international, randomized, open-label trial in patients with stage IV NSCLC whose tumors express PD-L1 and who had received no prior chemotherapy for metastatic disease. Patients were randomly assigned 1:1 to receive atezolizumab at 1,200 mg every 3 weeks until disease progression or unacceptable toxicity, or to receive platinum-based chemotherapy. The main efficacy outcome measure was overall survival.

The trial demonstrated a statistically significant improvement in overall survival for patients with high PD-L1 tumor expression receiving atezolizumab compared to those treated with platinum-based chemotherapy. Median overall survival was 20.2 months (95% confidence interval [CI] = 16.5–not evaluable) for patients in the atezolizumab arm compared with 13.1 months (95% CI = 7.4–16.5) in the chemotherapy arm (hazard ratio [HR] = 0.59, 95% CI = 0.40–0.89, *P* = .0106). There was no statistically significant difference in overall survival for the other two PD-L1 subgroups (PD-L1 stained ≥ 5% of tumor cells or PD-L1–stained tumor-infiltrating immune cells covering ≥ 5% of the tumor area; and PD-L1 stained ≥ 1% of tumor cells or PD-L1–stained tumor-infiltrating immune cells covering ≥ 1% of the tumor area) at the interim or final analyses.

Median progression-free survival 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 per investigator was 38% (95% CI = 29%–48%) and 29% (95% CI = 20%–39%), respectively.

The most common adverse reaction reported (≥ 20%) with single-agent atezolizumab was fatigue/asthenia.

The recommended dose of atezolizumab for the treatment of patients with NSCLC is 840 mg every 2 weeks, 1,200 mg every 3 weeks, or 1,680 mg every 4 weeks, administered intravenously over 60 minutes.

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