Tecentriq® (atezolizumab) – Expanded indication

- On May 18, 2020, Genentech announced the FDA approval of Tecentriq (atezolizumab), as a single agent, 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%]), as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations.
    - This is the fourth approval for Tecentriq across NSCLC, including as a single agent or in combination with targeted therapies and/or chemotherapies.
- Tecentriq is also approved for urothelial cancer, triple-negative breast cancer, and small cell lung cancer.
- The approval of Tecentriq for the expanded indication was based on IMpower110, a randomized, open-label study in patients with stage IV NSCLC whose tumors express PD-L1, and who had received no prior chemotherapy for metastatic disease. Patients received Tecentriq or platinum-based chemotherapy. The major efficacy outcome measure was overall survival (OS) sequentially tested in the following subgroups of patients, excluding those with EGFR or ALK genomic tumor aberrations: TC ≥ 50% or IC ≥ 10%; TC ≥ 5% or IC ≥ 5%; and TC ≥ 1%, or IC ≥ 1%.
    - The trial demonstrated a statistically significant improvement in OS for patients with high PD-L1 expression (TC ≥ 50% or IC ≥ 10%) at the time of the OS interim analysis. Median OS was 20.2 months vs. 13.1 months for Tecentriq and platinum-based chemotherapy, respectively (hazard ratio: 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) showed a HR of 0.63 (95% CI: 0.45, 0.88), with median PFS of 8.1 months in the Tecentriq arm and 5 months in the platinum-based chemotherapy arm.
    - The objective response rate was 38% (95% CI: 29, 48) in the Tecentriq arm and 29% (95% CI: 20, 39) in the platinum-based chemotherapy arm.
- The recommended dose of Tecentriq, when used as a single agent for NSCLC, is 840 mg every 2 weeks or 1200 mg every 3 weeks or 1680 mg every 4 weeks. Tecentriq is administered intravenously over 60 minutes until disease progression or unacceptable toxicity.
- Refer to the Tecentriq drug label for dosing for all its other indications.