Tecentriq® (atezolizumab) – New indication

- On March 8, 2019, Genentech announced the FDA approval of Tecentriq (atezolizumab), in combination with Abraxane® (paclitaxel protein-bound), for the treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) whose tumors express PD-L1 (PD-L1 stained tumor-infiltrating immune cells of any intensity covering ≥ 1% of the tumor area), as determined by an FDA-approved test.
    - This indication is approved under accelerated approval based on progression free survival. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).
- Tecentriq is also approved for the treatment of patients with locally advanced or metastatic urothelial carcinoma and metastatic non-small cell lung cancer.
    - The indication for urothelial carcinoma is also approved under accelerated approval.
- According to the American Cancer Society, approximately 271,000 people in the U.S. will be diagnosed with breast cancer, and more than 42,000 will die from the disease in 2019. In TNBC, tumor cells lack hormone receptors and do not have excess HER2 protein. Approximately 15% of breast cancers are triple-negative based on the results of diagnostic tests.
    - TNBC is an aggressive form of the disease with few treatment options.
- The approval of Tecentriq's new indication was based on IMpassion130, a double-blind study in 902 unresectable locally advanced or metastatic TNBC patients that had not received prior chemotherapy for metastatic disease. Patients received Abraxane and were randomized to receive either Tecentriq or placebo. The major efficacy outcomes were progression free survival (PFS) in the intent-to-treat (ITT) and PD-L1 expressing patient population and overall survival (OS) in the ITT population. However, OS data were immature with 43% deaths in the ITT population.
    - Median PFS in patients with PD-L1 expression ≥ 1% was 7.4 months (95% CI: 6.6, 9.2) for Tecentriq plus Abraxane vs. 4.8 months (95% CI: 3.8, 5.5) for placebo plus Abraxane (Hazard Ratio [HR]: 0.60; 95% CI: 0.48, 0.77; $p < 0.0001$).
    - In addition, the objective response rate in patients with PD-L1 expression ≥ 1% was 53% (95% CI: 45.5, 60.3) for Tecentriq plus Abraxane vs. 33% (95% CI: 26.0, 40.1) for placebo plus Abraxane.
    - The median duration of response was 9.2 months (95% CI: 7.5, 11.9) for Tecentriq plus Abraxane vs. 6.2 months (95% CI: 5.5, 8.8) for placebo plus Abraxane.
- The most common adverse reactions (≥ 20%) with Tecentriq in combination with Abraxane were alopecia, peripheral neuropathies, fatigue, nausea, diarrhea, anemia, constipation, cough, headache, neutropenia, vomiting, and decreased appetite.
- The recommended dosage of Tecentriq for TNBC is 840 mg administered as an intravenous (IV) infusion over 60 minutes, followed by 100 mg/m^2 IV Abraxane.
    - For each 28 day cycle, Tecentriq is administered on days 1 and 15, and Abraxane is administered on days 1, 8, and 15 until disease progression or unacceptable toxicity.

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    - Refer to the drug label for Abraxane for additional dosing recommendations.
- Refer to the Tecentriq drug label for dosing recommendations for other indications.