Tecentriq® (atezolizumab) – Expanded indication

- On December 6, 2018, Genentech announced the FDA approval of Tecentriq (atezolizumab), in combination with Avastin® (bevacizumab), paclitaxel, and carboplatin, for the first-line treatment of patients with metastatic non-squamous non-small cell lung cancer (NSq NSCLC) with no EGFR or ALK genomic tumor aberrations.
    - Tecentriq was previously approved for the treatment of patients with metastatic NSCLC who have disease progression during or following platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for NSCLC harboring these aberrations prior to receiving Tecentriq.
- Tecentriq is also approved for the treatment of patients with locally advanced or metastatic urothelial carcinoma who: (1) are not eligible for cisplatin-containing chemotherapy and whose tumors express PD-L1, as determined by an FDA-approved test; or (2) are not eligible for any platinum-containing chemotherapy regardless of PD-L1 status; or (3) have disease progression during or following any platinum-containing chemotherapy, or within 12 months of neoadjuvant or adjuvant chemotherapy.
- According to the American Cancer Society, it is estimated that more than 234,000 Americans will be diagnosed with lung cancer in 2018, and NSCLC accounts for 85% of all lung cancers. It is estimated that approximately 60% of lung cancer diagnoses in the U.S. are made when the disease is in the advanced stages.
- The approval of Tecentriq's expanded indication was based on IMpower150, an open-label study in 1202 patients with metastatic NSq NSCLC. Patients were randomized to receive Tecentriq plus carboplatin and paclitaxel (Arm A), or Tecentriq and Avastin plus carboplatin and paclitaxel (Arm B), or Avastin plus carboplatin and paclitaxel (Arm C, control arm). The major efficacy outcome measures for comparison of Arms B and C were progression free survival (PFS) and overall survival (OS) in the intention-to-treat wild type (ITT-WT) subpopulation.
    - Median PFS was 8.5 months (95% CI: 7.3, 9.7) for Tecentriq in combination with Avastin and chemotherapy vs. 7.0 months (95% CI: 6.3, 7.9) for Avastin and chemotherapy (HR 0.71; 95% CI: 0.59 to 0.85; p = 0.0002).
    - OS was 19.2 months (95% CI: 17.0, 23.8) for Tecentriq in combination with Avastin and chemotherapy vs. 14.7 months (95% CI: 13.3, 16.9) for Avastin and chemotherapy (HR 0.78; 95% CI: 0.64 to 0.96; p = 0.016).
    - The trial did not demonstrate a significant difference between Arms A and C based on the PFS or OS analyses.
    - In addition, the objective response rate and duration of response was 55% and 10.8 months, respectively, for Tecentriq in combination with Avastin and chemotherapy vs. 42% and 6.5 months, respectively, for Avastin and chemotherapy.
- The most common adverse reactions (≥ 20%) with Tecentriq in combination with Avastin, paclitaxel, and carboplatin use were fatigue/asthenia, alopecia, nausea, diarrhea, constipation, decreased appetite, arthralgia, hypertension, and peripheral neuropathy.
- The recommended dosage of Tecentriq is 1200 mg intravenously (IV) over 60 minutes followed by Avastin, paclitaxel, and carboplatin, on day 1 of each 21-day cycle for a maximum of 4 to 6 cycles of chemotherapy.
    - After completion of chemotherapy, administer Tecentriq 1200 mg IV, followed by Avastin on day 1 of each 21-day cycle until disease progression or unacceptable toxicity.

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    - — Refer to the drug labels for Avastin, paclitaxel, and carboplatin for additional recommended dosing information

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