Tecentriq® (atezolizumab) – New indication approval

- On July 31, 2020, Roche announced the FDA approval of Tecentriq (atezolizumab), in combination with Cotellic® (cobimetinib) and Zelboraf® (vemurafenib) for the treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma.

- Tecentriq is also indicated for the treatment of urothelial carcinoma, non-small cell lung cancer, triple negative breast cancer, small cell lung cancer, and hepatorcellular carcinoma.

- The approval of the new indication for Tecentriq was based on a double-blind study of 514 patients with previously untreated unresectable or metastatic BRAF V600 mutation-positive melanoma. Patients were randomized to Tecentriq plus Cotellic and Zelboraf or placebo plus Cotellic and Zelboraf until disease progression or unacceptable toxicity. The primary efficacy outcome was progression-free survival (PFS).

    - The median PFS was 15.1 months for the Tecentriq plus Cotellic and Zelboraf group vs. 10.6 months for the Cotellic and Zelboraf group (hazard ratio: 0.78; 95% CI: 0.63, 0.97; p = 0.0429).
    - In addition, the overall response rate was seen in 66% (95% CI: 60, 72) of the Tecentriq plus Cotellic and Zelboraf group vs. 65% (95% CI: 59, 71) of the Cotellic and Zelboraf group.
    - The median duration of response was 20.4 months (95% CI: 15.1, NE) for the Tecentriq plus Cotellic and Zelboraf group vs. 12.5 months (95% CI: 10.7, 16.6) for the Cotellic and Zelboraf group.

- The most common adverse reactions (≥ 20%) with Tecentriq in combination with Cotellic and Zelboraf were rash, musculoskeletal pain, fatigue, hepatotoxicity, pyrexia, nausea, pruritus, edema, stomatitis, hypothyroidism, and photosensitivity reaction.

- The recommended dose of Tecentriq is 840 mg administered as an intravenous infusion over 60 minutes every 2 weeks until disease progression or unacceptable toxicity, when administered with Cotellic 60 mg orally once daily (21 days on and 7 days off) and Zelboraf 720 mg orally twice daily.

    - Prior to initiating Tecentriq, patients should receive a 28 day treatment cycle of Cotellic 60 mg orally once daily (21 days on and 7 days off) and Zelboraf 960 mg orally twice daily from days 1-21 and Zelboraf 720 mg orally twice daily from days 22-28.
    - Select patients with unresectable or metastatic melanoma for treatment with Tecentriq in combination with Cotellic and Zelboraf after confirming the presence of a BRAF V600 mutation. Information on FDA-approved tests for the detection of BRAF V600E and V600K mutations in melanoma is available at http://www.fda.gov/CompanionDiagnostics.
    - Consult Cotellic and Zelboraf's drug labels for further dosing information.
    - Consult Tecentriq's drug label for dosing recommendations for all its other indications.