Tecentriq® (atezolizumab) – Expanded indication

- On April 17, 2017, Genentech announced the FDA approval of Tecentriq (atezolizumab) injection, to expand its use to patients with locally advanced or metastatic urothelial carcinoma (UC) who are not eligible for cisplatin chemotherapy.
    - Tecentriq was already approved for the treatment of patients with locally advanced or metastatic UC who have disease progression during or following platinum-containing chemotherapy or have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.
- Tecentriq is also approved for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) who have disease progression during or following platinum-containing chemotherapy.
    - Patients with epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving Tecentriq.
- Tecentriq's expanded indication was granted based on an open-label, single-arm trial in 119 patients with locally advanced or metastatic UC who were ineligible for cisplatin-containing chemotherapy or were either previously untreated or had disease progression at least 12 months after neoadjuvant or adjuvant chemotherapy. The primary endpoints were objective response rate (ORR), duration of response (DoR), and overall survival (OS).
    - Overall, the ORR was 23.5% (95% CI: 16.2, 32.2). Among patients with programmed death ligand-1 (PD-L1) expression ≥ 5%, the ORR was 28.1% (95% CI: 13.8, 46.8). Among those with PD-L1 expression < 5%, the ORR was 21.8% (95% CI: 13.7, 32.0).
    - At the time of analysis, the DoR was not reached.
    - The OS data are not reported in the drug label.
- The recommended dose of Tecentriq for all approved indications, including locally advanced or metastatic UC and metastatic NSCLC, is 1,200 mg by intravenous infusion every 3 weeks until disease progression or toxicity.