Tecentriq® (atezolizumab) – Indication withdrawal

- On November 28, 2022, Genentech announced that it is voluntarily withdrawing the indication for Tecentriq (atezolizumab) for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma who:
  - are not eligible for cisplatin-containing chemotherapy and whose tumors express PD-L1 (PD-L1 stained tumor-infiltrating immune cells covering ≥ 5% of the tumor area), as determined by an FDA-approved test, or
  - are not eligible for any platinum-containing chemotherapy regardless of PD-L1 status.
- Genentech made this decision following consultation with the FDA, in accordance with the requirements of the FDA's Accelerated Approval Program. The Phase 3 IMvigor130 trial was the designated post-marketing requirement to convert the accelerated approval to regular approval, and it did not meet the co-primary endpoint of overall survival for Tecentriq plus chemotherapy compared with chemotherapy alone.
- This decision does not affect other approved indications for Tecentriq. Tecentriq is also approved for non-small cell lung cancer, small cell lung cancer, hepatocellular carcinoma, and melanoma.
- Genentech will work with the FDA over the coming weeks to complete the withdrawal process and notify healthcare professionals about this withdrawal.
- Patients being treated with Tecentriq for previously untreated metastatic urothelial carcinoma should discuss their care with their healthcare provider.