Tecentriq® (atezolizumab) – Expanded indication

- On October 15, 2021, Roche announced the FDA approval of Tecentriq (atezolizumab), as a single-agent, as adjuvant treatment following resection and platinum-based chemotherapy for adult patients with stage II to IIIA non-small cell lung cancer (NSCLC) whose tumors have PD-L1 expression on ≥ 1% of tumor cells, as determined by an FDA-approved test.

- Tecentriq was previously approved for various other uses in NSCLC and also approved for urothelial carcinoma, small cell lung cancer, hepatocellular carcinoma, and melanoma.

- The approval of Tecentriq for the expanded indication was based on IMpower010, a randomized, open-label study for the adjuvant treatment of patients with NSCLC who had complete tumor resection and were eligible to receive cisplatin-based adjuvant chemotherapy. Patients received Tecentriq every 3 weeks for 16 cycles, unless disease recurrence or unacceptable toxicity occurred, or best supportive care (BSC). The primary endpoint was disease-free survival (DFS). The primary efficacy analysis population (N = 476) was patients with stage II – IIIA NSCLC with PD-L1 expression on ≥ 1% of tumor cells.

    — In the efficacy analysis population, median DFS was not reached with Tecentriq vs. 35.3 months with BSC (hazard ratio 0.66, 95% CI: 0.50, 0.88; p = 0.004).

- The recommended intravenous dose of Tecentriq for adjuvant treatment of NSCLC is 840 mg every 2 weeks, 1200 mg every 3 weeks, or 1680 mg every 4 weeks for up to one year, unless there is disease recurrence or unacceptable toxicity.

    — Refer to the Tecentriq drug label for dosing for all its other uses and indications.