Tecentriq® (atezolizumab) – New orphan indication

- On December 9, 2022, the FDA announced the approval of Genentech's Tecentriq (atezolizumab), as a single agent, for the treatment of adult and pediatric patients 2 years of age and older with unresectable or metastatic alveolar soft part sarcoma (ASPS).

- Tecentriq is also approved for non-small cell lung cancer, small cell lung cancer, hepatocellular carcinoma, and melanoma.

- The approval of Tecentriq for the new indication was based on ML39345, an open-label, single-arm study in 49 adult and pediatric patients aged 2 years and older with unresectable or metastatic ASPS. Patients received Tecentriq once every 21 days until disease progression or unacceptable toxicity. The major efficacy outcomes were overall response rate (ORR) and duration of response (DOR).

    — The ORR was 24% (95% CI: 13, 39).
    — The median DOR was not estimable (95% CI: 17.0 months, not estimable).

- For adults, the recommended dose of Tecentriq for the treatment of ASPS is 840 mg intravenously every 2 weeks or 1200 mg every 3 weeks or 1680 mg every 4 weeks, until disease progression or unacceptable toxicity.

- For pediatric patients 2 years of age and older, the recommended dose of Tecentriq for the treatment of ASPS is 15 mg/kg (up to a maximum 1200 mg) every 3 weeks, until disease progression or unacceptable toxicity.

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