Tecentriq Hybreza™ (atezolizumab/hyaluronidase-tqjs) – New subcutaneous formulation approval

- On September 12, 2024, Roche announced the FDA approval of Tecentriq Hybreza (atezolizumab/hyaluronidase-tqjs), for all intravenous (IV) indications of Tecentriq® (atezolizumab) approved for adults, including certain types of lung, liver, skin and soft tissue cancer.

- Tecentriq Hybreza is the first subcutaneously (SC) administered programmed death-ligand 1 (PD-L1) blocking antibody. All other drugs in the class are administered via IV infusion.

- The approval of Tecentriq Hybreza was based on IMscin001, an open-label, randomized study in 371 adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC). Patients were randomized to receive either SC administered Tecentriq Hybreza or IV administered Tecentriq until disease progression or unacceptable toxicity. The primary outcome measure was atezolizumab exposure of SC Tecentriq Hybreza as compared to IV Tecentriq. Additional descriptive efficacy outcome measures were overall response rate (ORR), progression-free survival (PFS) and overall survival (OS).

    - The study showed comparable levels of atezolizumab in the blood, when administered SC vs. IV.
    - At the primary analysis, the confirmed ORR was 9% (95% CI: 5, 13) in the SC Tecentriq Hybreza arm and 8% (95% CI: 4, 14) in the IV Tecentriq arm.
    - After further follow up, no notable differences in PFS and OS were observed between patients who received the two formulations.

- Warnings and precautions for Tecentriq Hybreza include severe and fatal immune-mediated adverse reactions; infusion-related reactions; complications of allogeneic hematopoietic stem cell transplant after PD-1/PD-L1 inhibitors; and embryo-fetal toxicity.

- The most common adverse reactions(≥ 10%) with Tecentriq Hybreza as monotherapy in patients with NSCLC were fatigue, musculoskeletal pain, cough, dyspnea, and decreased appetite.

- The safety of Tecentriq Hybreza for its other approved uses and indications was based on safety of IV Tecentriq in these populations. Refer to the drug label for a complete summary of the adverse reactions.

- The recommended dosage of Tecentriq Hybreza is one 15 mL injection (containing 1,875 mg of atezolizumab and 30,000 units of hyaluronidase) administered SC in the thigh over approximately 7 minutes every 3 weeks.

    - Tecentriq Hybreza must be administered by a healthcare professional.
    - Refer to the Tecentriq Hybreza label for complete administration instructions.

- Roche's launch plans for Tecentriq Hybreza are pending. Tecentriq Hybreza will be available as a solution in a single-dose vial containing 1,875 mg atezolizumab and 30,000 units hyaluronidase per 15 mL (125 mg/2,000 units per mL).