Tecentriq® (atezolizumab) – Indication withdrawal

- On August 27, 2021, Roche announced the voluntary withdrawal of the Tecentriq (atezolizumab) indication for use in combination with paclitaxel protein-bound, for the treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) whose tumors express PD-L1 (PD-L1 stained tumor-infiltrating immune cells of any intensity covering ≥ 1% of the tumor area), as determined by an FDA-approved test.

- Roche made this decision following consultation with the FDA, based on the agency's assessment of the current metastatic TNBC treatment landscape and in accordance with the requirements of the accelerated approval program.

    — Roche will work with the FDA over the coming weeks to complete the withdrawal process.

- Roche is notifying healthcare professionals about this withdrawal. Patients being treated with Tecentriq for PD-L1-positive metastatic TNBC should discuss their care with their healthcare provider.

- This decision does not affect other approved indications for Tecentriq.

    — Refer to the Tecentriq drug label for information regarding its other indications.

- Tecentriq was granted accelerated approval by the FDA for the TNBC indication in March 2019. Approval was based on the progression-free survival (PFS) results of the Phase 3 IMpassion130 study. Continued approval was contingent upon the results of IMpassion131, the post-marketing requirement (PMR). This study did not meet its primary endpoint of PFS for the initial (first-line) treatment of people with metastatic TNBC in the PD-L1-positive population.

    — The results of both studies were discussed at the FDA Oncology Drugs Advisory Committee, which voted 7 to 2 on April 27, 2021 in favor of maintaining the accelerated approval of Tecentriq in combination with nab-paclitaxel for the treatment of people with PD-L1-positive metastatic TNBC.
    — Since then, Roche has been working with the FDA on a possible alternative PMR. However, due to the recent changes in the treatment landscape, the FDA no longer considers it appropriate to maintain the accelerated approval. This led to the decision to voluntarily withdraw the indication.

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