

Tecentriq (atezolizumab) Injection Clinical Update

Clinical Update: FDA Approved Tecentriq as a First-Line Monotherapy for Certain People With Metastatic Non-Small Cell Lung Cancer.

FDA approval date: May 18, 2020

Tecentriq (atezolizumab) is a programmed death-ligand 1 (PD-L1) blocking antibody indicated for use in the treatment of urothelial carcinoma, non-small cell lung cancer (NSCLC), triple-negative breast cancer (TNBC), small cell lung cancer (SCLC), hepatocellular carcinoma and melanoma. Tecentriq is the first and only single-agent cancer immunotherapy with three dosing options, allowing administration every two, three or four weeks.

Genentech's Tecentriq has been approved in the US as a first-line (initial) treatment for adults with metastatic non-small cell lung cancer (NSCLC) whose tumors have high PD-L1 expression (PD-L1 stained $\geq 50\%$ of tumor cells [TC $\geq 50\%$] or PD-L1 stained tumor-infiltrating [IC] covering $\geq 10\%$ of the tumor area [IC $\geq 10\%$]), as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations. This approval is based on an interim analysis from the Phase III IMpower110 study, which showed Tecentriq monotherapy improved overall survival (OS) by 7.1 months compared with chemotherapy (median OS=20.2 versus 13.1 months; hazard ratio [HR]=0.59, 95% CI: 0.40–0.89; $p=0.0106$) in people with high PD-L1 expression (TC3/IC3-wild-type [WT]). Safety for Tecentriq appeared to be consistent with its known safety profile, and no new safety signals were identified. Grade 3–4 treatment-related adverse events (AEs) were reported in 12.9% of people receiving Tecentriq compared with 44.1% of people receiving chemotherapy. IMpower110 is a Phase III, randomized, open-label study evaluating the efficacy and safety of Tecentriq monotherapy compared with cisplatin or carboplatin and pemetrexed or gemcitabine (chemotherapy) in PD-L1-selected, chemotherapy-naïve participants with stage IV non-squamous or squamous NSCLC.

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