

Tecentriq[®] (atezolizumab) – Expanded indication

- On December 4, 2019, Roche announced the FDA approval of Tecentriq (atezolizumab), in combination with Abraxane (paclitaxel protein-bound) and carboplatin, for the first-line treatment of adult patients with metastatic non-squamous non-small cell lung cancer (NSCLC) with no EGFR or ALK genomic tumor aberrations.
 - Tecentriq was previously approved for this same indication in combination with <u>Avastin[®]</u> (<u>bevacizumab</u>), <u>paclitaxel</u>, and carboplatin and as a single-agent for the treatment of adult patients with metastatic NSCLC who have disease progression during or following platinum-containing chemotherapy.
- Tecentriq is also approved for the treatment of urothelial carcinoma, locally advanced or metastatic triple-negative breast cancer, and small cell lung cancer.
- The approval of Tecentriq for the expanded indication was based on IMpower130, a randomized, open-label study in patients with stage IV non-squamous NSCLC. Patients received Tecentriq plus chemotherapy (Abraxane and carboplatin) or chemotherapy alone (Abraxane and carboplatin). Major efficacy outcome measures were progression-free survival (PFS) and overall survival (OS) in the subpopulation of patients (N = 681) evaluated for and documented to have no EGFR or ALK genomic tumor aberrations.
 - Median OS was 18.6 months and 13.9 months for Tecentriq plus chemotherapy vs.
 chemotherapy alone, respectively (hazard ratio [HR] 0.80; 95% CI: 0.64, 0.99; p = 0.0384).
 - Median PFS was 7.2 months and 6.5 months for Tecentriq plus chemotherapy vs. chemotherapy alone, respectively (HR 0.75; 95% CI: 0.63, 0.91; p = 0.0024).
- The recommended dose of Tecentriq (when used in combination with platinum-based chemotherapy) for the treatment of NSCLC is 1200 mg intravenously (IV) every 3 weeks until disease progression or unacceptable toxicity.
 - Refer to the drug labels for the chemotherapy agents administered in combination with Tecentriq for recommended dosing information.
 - Refer to the Tecentriq drug label for dosing for all its other indications.



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