

Tecentriq® (atezolizumab) - Indication withdrawal

- On November 28, 2022, <u>Genentech announced</u> that it is voluntarily withdrawing the indication for <u>Tecentriq (atezolizumab)</u> for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma who:
 - are not eligible for cisplatin-containing chemotherapy and whose tumors express PD-L1 (PD-L1 stained tumor-infiltrating immune cells covering ≥ 5% of the tumor area), as determined by an FDA-approved test, or
 - are not eligible for any platinum-containing chemotherapy regardless of PD-L1 status.
- Genentech made this decision following consultation with the FDA, in accordance with the
 requirements of the FDA's Accelerated Approval Program. The Phase 3 IMvigor130 trial was the
 designated post-marketing requirement to convert the accelerated approval to regular approval,
 and it did not meet the co-primary endpoint of overall survival for Tecentriq plus chemotherapy
 compared with chemotherapy alone.
- This decision does not affect other approved indications for Tecentriq. Tecentriq is also approved for non-small cell lung cancer, small cell lung cancer, hepatocellular carcinoma, and melanoma.
- Genentech will work with the FDA over the coming weeks to complete the withdrawal process and notify healthcare professionals about this withdrawal.
- Patients being treated with Tecentriq for previously untreated metastatic urothelial carcinoma should discuss their care with their healthcare provider.



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