Tecentriq® (atezolizumab) – Indication withdrawal

- On March 8, 2021, Roche announced the voluntary withdrawal of the Tecentriq (atezolizumab) indication for patients with prior-platinum treated metastatic urothelial carcinoma (mUC).

- Roche's decision was made in consultation with the FDA. Roche will work with the FDA over the coming weeks to complete the withdrawal process. 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 in 2016 for the treatment of prior-platinum treated mUC based on the results from the IMvigor210 study. Continued approval for this indication was contingent upon the results of IMvigor211. This study did not meet its primary endpoint of overall survival in the PD-L1 high patient population. Subsequently, the FDA designated the IMvigor130 study as the post marketing requirement which will still continue until the final analysis. However, as the treatment landscape in prior-platinum mUC has rapidly evolved with the emergence of new treatment options, Roche is voluntarily withdrawing this indication.

- Roche is notifying healthcare professionals about this withdrawal. Patients being treated with Tecentriq for prior-platinum treated mUC should discuss their care with their healthcare provider.