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FDA grants accelerated approval to Roche's Tecentriq in combination with Abraxane

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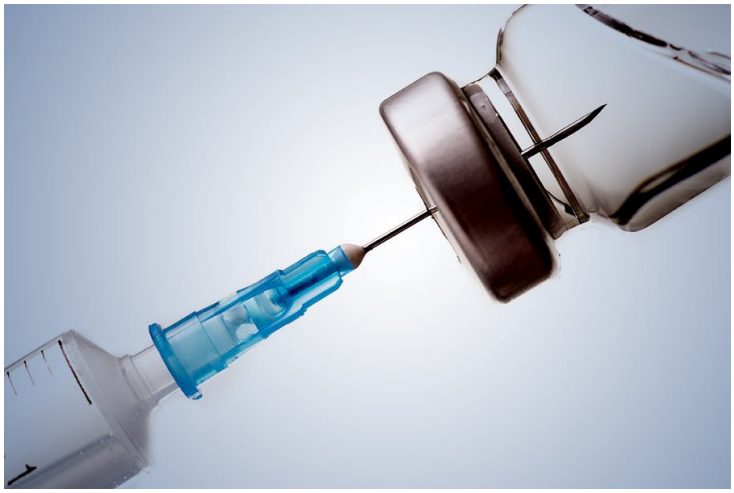
This Tecentriq combination is the first cancer immunotherapy regimen approved for breast cancer



Roche has announced that the US Food and Drug Administration (FDA) has granted accelerated approval to Tecentriq® (atezolizumab) plus chemotherapy (Abraxane® [paclitaxel protein-bound particles for injectable suspension (albumin-bound); nab-paclitaxel]) for the treatment of adults with unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) in people whose tumours express PD-L1, as determined by an FDA-approved test.

This indication is approved under accelerated approval based on progression-free survival (PFS). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). The FDA's Accelerated Approval Programme allows conditional approval of a medicine that fills an unmet medical need for a serious or life-threatening disease or condition.

Sandra Horning, Roche's Chief Medical Officer and Head of Global Product Development said, "The FDA approval of this Tecentriq combination is an important treatment advance for people with PD-L1-positive, metastatic triple-negative breast cancer, a disease with high unmet medical need. This Tecentriq combination is the first cancer immunotherapy regimen to be approved in breast cancer, representing a meaningful step forward in the understanding of this disease."

This accelerated approval is based on data from the Phase III IMpassion130 study, which demonstrated that Tecentriq plus nab-paclitaxel significantly reduced the risk of disease worsening or death (PFS) by 40% compared with nab-paclitaxel alone.

Tecentriq is a monoclonal antibody designed to bind with a protein called PD-L1 expressed on tumour cells and tumour-infiltrating immune cells, blocking its interactions with both PD-1 and B7.1 receptors. By inhibiting PD-L1, Tecentriq may enable the activation of T cells. Tecentriq has the potential to be used as a foundational combination partner with cancer immunotherapies, targeted medicines and various chemotherapies across a broad range of cancers.

Tecentriq is already approved in the European Union, United States and more than 85 countries for people with previously treated metastatic non-small cell lung cancer (NSCLC) and for certain types of untreated or previously treated metastatic urothelial carcinoma (mUC). Tecentriq was also recently approved in the United States for the initial treatment of people with

metastatic non-squamous NSCLC with no EGFR or ALK genomic tumour aberrations.