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EC approves Roche's Tecentriq in combination with Abraxane

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Approval based on the Phase III IMpassion130 study, which showed that the combination improved outcomes in people with PD-L1-positive metastatic triple-negative breast cancer

Roche has announced that the European Commission has approved Tecentriq® (atezolizumab) plus chemotherapy (Abraxane® [paclitaxel protein-bound particles for injectable suspension (albumin-bound); nab-paclitaxel]) for the treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) whose tumours have PD-L1 expression (?1%) and who have not received prior chemotherapy for metastatic disease. Roche's VENTANA PD-L1 (SP142) Assay is now CE marked and commercially available in the European Union as an aid for identifying patients with TNBC eligible for treatment with the Tecentriq combination.

"For the past 30 years, we have been dedicated to transforming the lives of people with breast cancer. Now, we are pleased to build on this foundation with the news that the first immunotherapy treatment for triple-negative breast cancer is available to people in Europe with PD-L1-positive, metastatic triple-negative breast cancer," said Sandra Horning, MD, Roche's Chief Medical Officer and Head of Global Product Development. "The European approval of this Tecentriq combination represents a significant step forward in the treatment of this aggressive breast cancer, where the unmet medical need is great."

This approval is based on the results from the Phase III IMpassion130 study. Progression-free survival (PFS) results demonstrated a statistically significant benefit for Tecentriq in combination with nab-paclitaxel and showed that Tecentriq plus nab-paclitaxel significantly reduced the risk of disease worsening or death (PFS) by 38% compared with nab-paclitaxel alone.

The assessment of PD-L1 on tumour-infiltrating immune cells is essential for identifying the patients with TNBC benefiting from this Tecentriq combination. PD-L1 expression status in the IMpassion130 study was assessed by the VENTANA PD-L1 (SP142) assay.

Currently, there are seven ongoing Phase III studies investigating Tecentriq in TNBC, including early and advanced stages of the disease.