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ASIA EDITION

CHMP recommends approval of Roche's Tecentriq in combination with Abraxane

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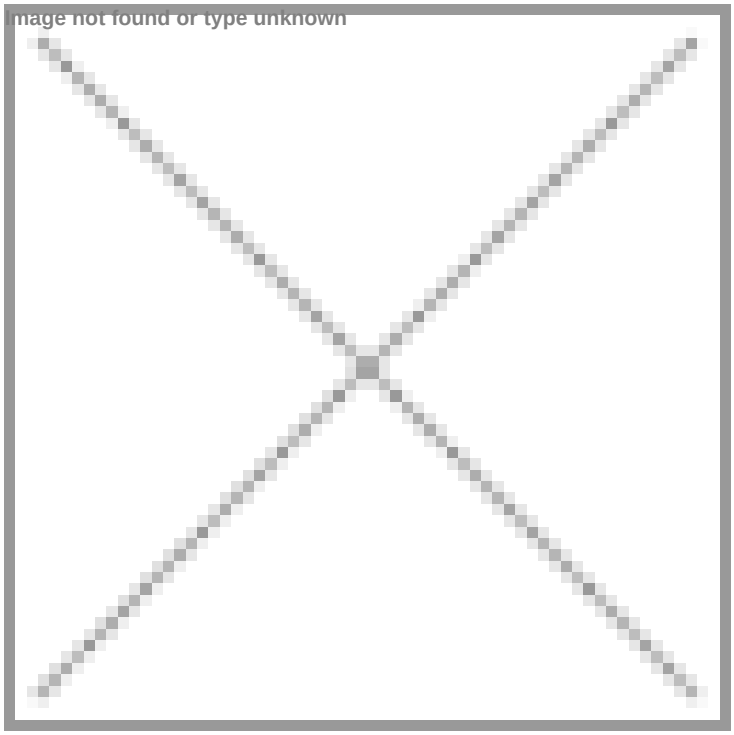

Roche has announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has recommended the approval of Tecentriq (atezolizumab) plus chemotherapy (Abraxane; nab-paclitaxel) for the treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) whose tumours have PD-L1 expression (? 1%) and who have not received prior chemotherapy for metastatic disease.

"This CHMP recommendation marks a breakthrough in the treatment of triple-negative breast cancer, an aggressive type of breast cancer with high unmet medical need," said Sandra Horning, MD, Roche's Chief Medical Officer and Head of Global Product Development. "With today's announcement, we hope that people living with PD-L1-positive metastatic triple-negative breast cancer in Europe will soon have a new treatment option with the Tecentriq combination."

The CHMP recommendation 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 (progression-free survival; PFS) by 38% compared with nab-paclitaxel alone (median PFS=7.5 vs 5 months; HR=0.62, 95% CI: 0.49–0.78, p<0.0001) in people who were tested positive for PD-L1 expression on tumour-infiltrating immune cells (IC). The Tecentriq combination showed a clinically meaningful overall survival (OS) improvement of seven months vs nab-paclitaxel alone in the PD-L1-positive population (median OS=25.0 vs 18.0 months; HR=0.71, 95% CI: 0.54–0.93). OS results in the PD-L1-positive population

were not formally tested due to the hierarchical design of the study, as statistical significance was not met for OS in the intention-to-treat (ITT) population (median OS=21.0 vs 18.7 months; HR=0.86, 95% CI: 0.72–1.02, p=0.078). The study will continue until the next planned analysis.

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

Safety in the Tecentriq plus nab-paclitaxel arm appeared consistent with the known safety profiles of the individual study medicines or underlying disease, and no new safety signals were identified with the combination. Serious adverse events (SAEs) were reported in 23% of people receiving Tecentriq plus nab-paclitaxel, compared with 18% of people receiving chemotherapy alone. Grade 3–4 AEs were reported in 49% of people receiving Tecentriq plus nab-paclitaxel, compared with 42% of people receiving chemotherapy alone.

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