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ASIA EDITION

Roche gets FDA's accelerated approval to Tecentriq for TNBC

11 March 2019 | News

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.

"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," said Sandra Horning, MD, Roche's Chief Medical Officer and Head of Global Product Development. "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 in PD-L1-positive patients with unresectable locally advanced or metastatic TNBC who had not received prior chemotherapy for metastatic disease.