

DCGI approves Roche's Atezolizumab for breast cancer treatment

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Atezolizumab in combination with nab-Paclitaxel can now be used as a first-line treatment for TNBC patients



Roche India has announced the launch of Atezolizumab for the treatment of metastatic triple-negative breast cancer (TNBC) in India.

Atezolizumab (cancer immunotherapy drug) in combination with nab-Paclitaxel (Chemotherapy) can now be used as a first-line treatment for TNBC patients.

This approval from the Drug Controller General of India (DCGI) is based on the data from phase III IMpassion130 study according to which Atezolizumab is proven to significantly reduce the risk of disease worsening or death (PFS) in the intention-to-treat and PD-L1 positive population with metastatic or unresectable locally advanced triple-negative breast cancer (TNBC).

Additionally, it has shown an encouraging overall survival (OS) in the PD-L1 positive population at this interim analysis.

V. Simpson Emmanuel, General Manager, Roche Products (India) Pvt. Ltd said, "Atezolizumab is the first immunotherapy drug to be approved globally and in India for triple negative breast cancer, an aggressive disease with very limited treatment options. Roche has been at the forefront of improving the lives of patients diagnosed with breast cancer. This launch further strengthens our commitment to provide better outcomes for patients with unresectable locally advanced and metastatic triple-negative breast cancer in India."

Breast cancer is the most common cancer amongst women across the world impacting 2.1 million women each year. According to Globocan 2018, over 160,000 new cases of breast cancer were in India. TNBC is a rare type of breast cancer that experiences rapid progression and it is defined by the lack of expression and/or amplification of the targetable receptors for oestrogen, progesterone and HER2 amplification. Triple negative breast cancer represents 31% of all breast cancers and is more common in women under the age of 50, compared with other forms of breast cancer.

Atezolizumab in combination with nab-paclitaxel, is indicated for the treatment of patients with unresectable locally advanced or metastatic TNBC- whose tumors have PD-L1 expression $\geq 1\%$, and who have not received prior chemotherapy for metastatic disease.

Previously, Atezolizumab has been approved either alone or in combination with targeted therapies and/or chemotherapies in various forms of Non-Small cell Lung Cancer (NSCLC) and Small Cell Lung Cancer (ES-SCLC) and for certain types of untreated or previously treated metastatic Urothelial Carcinoma (mUC) with improved survival outcomes, comparable safety profile and improved quality of life.

Roche has been developing medicines with the goal to redefine treatment in oncology and investing more in bringing innovative treatment options that help a person's own immune system fight cancer.