For immediate release:

Roche's Atezolizumab receives DCGI approval for treatment of metastatic triple-negative breast cancer in India

- Atezolizumbab is the first immunotherapy drug to be approved globally for treatment of unresectable locally advanced and metastatic triple-negative breast cancer
- Provides statistically significant progression-free survival (PFS) with encouraging overall survival (OS) benefit of 25 months for PD-L1 positive population at interim analysis
- Triple-negative breast cancer (TNBC) is the most aggressive form of breast cancer and represents 31% of all breast cancers in India

Mumbai, 08 April 2020: Roche India –today 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.

"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," said **Mr. V. Simpson Emmanuel, General Manager, Roche Products (India) Pvt. Ltd.** *"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. [1] According to Globocan 2018, over 160,000 new cases of breast cancer were in India. [2] 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. [3] 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. [4]

About Atezolizumab

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 ≥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.

About the IMpassion130 study

IMpassion130 study is a phase III multicentre, randomised, double-blind study evaluating the efficacy, safety, and pharmacokinetics of Atezolizumab and nab-paclitaxel compared with placebo in combination with nab- paclitaxel in patients with locally advanced or metastatic TNBC who have not received prior systemic therapy for metastatic breast cancer (mBC). The study enrolled 902 patients who were randomised equally (1:1).

The co-primary endpoints were progression-free survival (PFS) per investigator assessment (RECIST 1.1) and overall survival (OS). PFS and OS were assessed in all randomized participants [intention-to-treat (ITT)] and in those whose disease expressed the PD-L1 protein. Secondary endpoints included objective response rate, duration of response and time to deterioration in Global Health Status/Health-Related Quality of Life.

About Roche in cancer immunotherapy

For more than 50 years, Roche has been developing medicines with the goal to redefine treatment in oncology. Today, we're investing more than ever in our effort to bring innovative treatment options that help a person's own immune system fight cancer.

By applying our seminal research in immune tumor profiling within the framework of the Roche-devised cancer immunity cycle, we are accelerating and expanding the transformative benefits with Atezolizumab to a greater number of people living with cancer. Our cancer immunotherapy development program takes a comprehensive approach in pursuing the goal of restoring cancer immunity to improve outcomes for patients.

To learn more about the Roche approach to cancer immunotherapy please follow this link:
http://www.roche.com/research_and_development/what_we_are_working_on/oncology/cancer-immunotherapy.htm

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