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AstraZeneca receives CDSCO approval for additional indication to manage HER2- low & ultra-low breast cancer in India

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AstraZeneca India Pharma, a global, science-led, patient focused pharmaceutical company has announced a Central Drugs Standard Control Organisation (CDSCO) approval to import for sale and distribution of Trastuzumab deruxtecan concentrate for solution for infusion 100 mg for an additional indication.

The medicine is now indicated as a monotherapy for the treatment of adult patients with unresectable or metastatic HER2- low (IHC 1+ and IHC 2+/ISH-) or HER2- ultralow (IHC0 with membrane staining) breast cancer, who have received at least one endocrine therapy in metastatic setting.

The global burden of breast cancer, identified by the World Health Organization (WHO) as the most diagnosed cancer, exceeded 2 million cases in 2020. In India, the incidence of breast cancer has surged by a significant 40% over the past 25 years. Addressing a critical medical need, Trastuzumab deruxtecan is a beacon of hope for patients confronting HER2 directed metastatic breast cancer.

Dr Sandeep Arora, Director Medical Affairs, AZPIL said, “This approval is based on results of DESTINY Breast06 trial and paves way for new approach to diagnose and treat metastatic breast cancer patients in India with Trastuzumab deruxtecan. Now it will be critical to test unresectable or metastatic breast cancer tumours for any IHC staining to identify patients with HR-positive, HER2-low or HER2-ultralow disease after progression on at least one line of endocrine therapy and improve clinical outcomes."

Dr Sanjeev Panchal, Country President & Managing Director AZPIL said, “Our focus is on some of the most challenging cancers, and it is through persistent innovation that AstraZeneca has built one of the most diverse portfolios and pipelines in the industry globally, with the potential to catalyse changes in the practice of medicine and transform the patient experience.”

This antibody drug conjugate (ADC) was first introduced in India in the year 2024 and is approved for use in three indications in breast and gastric cancer by regulatory authorities presenting vast opportunities to significantly boost the survival rates for breast cancer patients, given the efficacy observed. DESTINY Breast06 trial compared Trastuzumab deruxtecan with Investigator’s choice of chemotherapy in hormone receptor–positive, HER2-low or HER2-ultralow metastatic breast cancer who had received one or more lines of endocrine-based therapy and no previous chemotherapy in metastatic setting.