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AstraZeneca receives CDSCO approval of additional indication for trastuzumab deruxtecan

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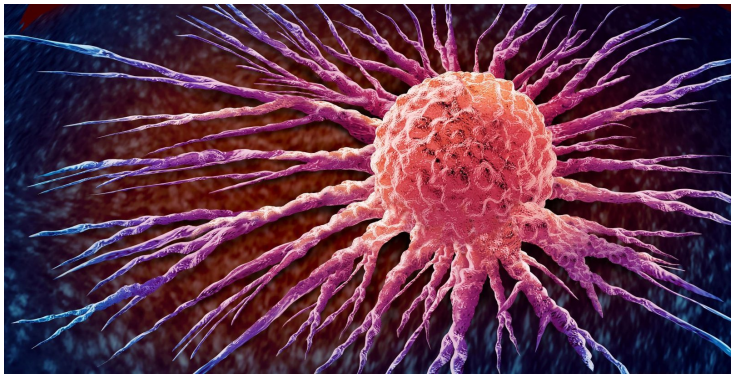
For adults with HER2-positive early breast cancer and residual invasive disease after neoadjuvant treatment



AstraZeneca Pharma India Ltd. (AZPIL) has announced that the Central Drugs Standard Control Organisation (CDSCO) has approved an additional indication for trastuzumab deruxtecan 100 mg/5 mL vial lyophilised powder for concentrate for solution for infusion.

The approval is for the adjuvant treatment of adult patients with HER2-positive (IHC 3+ or ISH+) breast cancer who have residual invasive disease following neoadjuvant trastuzumab (with or without pertuzumab) and taxane-based treatment.

HER2-positive breast cancer affects approximately 21% of patients with breast cancer. In the early-stage setting, this includes Stage I-III disease confined to the breast and/or regional lymph nodes and characterised by HER2 overexpression or amplification. For patients who do not achieve pathological complete response (pCR) after neoadjuvant treatment, the risk of recurrence remains a major clinical concern.

Although adjuvant T-DM1 is recommended for high-risk patients with residual disease following neoadjuvant treatment and surgery, unmet need remains, particularly among patients with advanced locoregional disease or positive nodal status.

The approval is supported by results from the DESTINY-Breast05 trial. Trastuzumab deruxtecan is also approved in India for use in specified settings in metastatic HER2-positive breast cancer, including in combination with pertuzumab in the first-line setting, in HER2-low and HER2-ultralow metastatic breast cancer, for neoadjuvant treatment of early breast cancer, in locally advanced or metastatic HER2-positive gastric or gastroesophageal junction adenocarcinoma, and in other unresectable or metastatic HER2-positive (IHC3+) solid tumours after prior systemic treatment where no satisfactory alternative treatment options exist.

This approval expands the available treatment options for patients with HER2-positive breast cancer in India across earlier and advanced stages of disease.