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AstraZeneca Pharma India receives CDSCO approval for HER2-positive stage II or III early breast cancer treatment

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Approval for trastuzumab deruxtecan followed by taxane, trastuzumab, and pertuzumab (THP)



AstraZeneca Pharma India 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 trastuzumab deruxtecan followed by a taxane, trastuzumab, and pertuzumab (THP) indicated for the neoadjuvant treatment of adult patients with HER2-positive (IHC 3+ or ISH+) Stage II or III breast cancer.

In HER2-positive early breast cancer, treatment before surgery plays an important role in shaping the overall care pathway. It provides an opportunity to assess tumour response, guide post-surgical decisions and, where possible, improve longer-term outcomes.

However, with currently used neoadjuvant regimens, pathological complete response (pCR) is achieved in only 39% to 64% of patients, however, these regimens are associated with a range of acute and long-term toxicities. With no new therapies introduced in this setting for more than a decade, there remains a need for neoadjuvant options that can deliver stronger efficacy while reducing treatment burden.

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, in locally advanced or metastatic HER2-positive gastric or gastroesophageal junction adenocarcinoma after an anti-HER-2 based regimen, and in other unresectable or metastatic HER2-positive (IHC3+) solid tumours after prior systemic treatment where no satisfactory alternative treatment options exist.

This approval broadens the role of trastuzumab deruxtecan in India and adds a new option in the neoadjuvant treatment of HER2-positive early breast cancer.