

## AstraZeneca secures CDSCO approval for expanded use of Trastuzumab Deruxtecan in HER2-positive solid tumours

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AstraZeneca Pharma India has received approval from the Central Drugs Standard Control Organisation (CDSCO) to import, market, and distribute Trastuzumab Deruxtecan (100mg/5mL vial lyophilised powder for concentrate for solution for infusion) for an additional indication in India.

With this approval, Trastuzumab Deruxtecan is now indicated for the treatment of adult patients with unresectable or metastatic HER2-positive (IHC3+) solid tumours who have received prior systemic therapy and have no satisfactory alternative treatment options. This marks the first and only antibody drug conjugate (ADC) in India with a tumour-agnostic indication, representing a significant advancement in precision oncology.

HER2 overexpression, which can occur across a range of solid tumors—including breast, gastric, biliary tract, bladder, pancreatic, and gynecological cancers—is associated with aggressive disease, poor prognosis, and limited benefit from chemotherapy. While HER2-directed therapy has improved outcomes in some cancers, patients with other HER2-expressing tumors often progress on standard therapy and face poor outcomes.

Trastuzumab Deruxtecan is already approved in India for the treatment of metastatic breast cancer (HER2-positive, HER2-low, and HER2-ultralow) and locally advanced or metastatic gastric cancer. The tumour-agnostic approval further broadens its potential to benefit patients across a range of advanced HER2-positive cancers.