

AstraZeneca India receives dual CDSCO approval for Trastuzumab deruxtecan

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Additional indications for treatment of HER2 low breast cancer and HER2 positive gastric / gastro-oesophageal cancer



AstraZeneca Pharma India has received permission to import for sale and distribution of Trastuzumab deruxtecan lyophilised powder for concentrate for solution for infusion 100mg from the Central Drugs Standard Control Organisation (CDSCO), Directorate General of Health Services, Government of India for two additional indications.

The new indications are:

HER2-Low Metastatic Breast Cancer: Trastuzumab deruxtecan is now indicated for the treatment of adult patients with unresectable or metastatic HER2-Low breast cancer who have received a prior chemotherapy in the metastatic setting or developed disease recurrence during or within 6 months of completing adjuvant chemotherapy.

Locally Advanced or Metastatic Gastric Cancer: Trastuzumab deruxtecan is now indicated for the treatment of adult patients with locally advanced or metastatic HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma who have received a prior trastuzumab based regimen.

Trastuzumab deruxtecan was earlier approved by Drug Controller General of India (DCGI), for the treatment of adult patients with unresectable or metastatic HER2-positive breast cancer who have received a prior anti-HER2-based regimen.

According to World Health Organisation, more than 2 million cases of breast cancer were diagnosed in 2020, making it the world's most commonly diagnosed cancer. The incidence of breast cancer is low in India, but it is gradually rising with almost a 40% increase in cases, over the past 25 years. Gastric cancer on the other hand, ranks sixth most prevalent cancer in India affecting men, and poses a considerable challenge with a 5-year survival rate of less than 7% for those diagnosed at an advanced stage.