

AstraZeneca India receives CDSCO approval for sale, distribution of Trastuzumab deruxtecan

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



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Bangalore: AstraZeneca Pharma India Limited has received permission to import for sale and distribution of Trastuzumab deruxtecan lyophilized 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.

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

It is also 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 the 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 (WHO), more than two 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 per cent 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 per cent for those diagnosed at an advanced stage.

Dr Sanjeev Panchal, Country President and Managing Director, AstraZeneca India, said, “The approval of Trastuzumab deruxtecan signifies a pivotal moment in addressing unmet medical needs by introducing life-changing therapies to Indian patients. With this approval, we have the potential to significantly enhance outcomes for patients battling advanced or metastatic low HER-2 & HER-positive gastric cancers, especially those who have exhausted standard treatment options.”

Dr Anil Kukreja, Vice-President, Medical Affairs and Regulatory, AstraZeneca India, said, “Trastuzumab deruxtecan has demonstrated significantly improved overall survival and progression-free survival outcomes in patients with HER2-low metastatic breast cancer in DESTINY Breast 04 trial. The DESTINY Gastric 02 trial showed efficacy of Trastuzumab deruxtecan as second-line therapy in patients with HER2-positive advanced gastric or gastro-oesophageal junction cancer.”

News source:

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