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DCGI approves AstraZeneca's drug for metastatic breast cancer treatment

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Approval to import and market trastuzumab deruxtecan for the treatment of select HER-2 positive breast cancer



AstraZeneca Pharma India has received approval from the Drug Controller General of India (DCGI) for the cancer drug trastuzumab deruxtecan for the treatment of metastatic breast cancer.

Trastuzumab deruxtecan is a specifically engineered HER2-directed antibody drug conjugate (ADC) being jointly developed and commercialised by AstraZeneca and Daiichi Sankyo.

AstraZeneca has received import and marketing permission in Form CT-20 from the regulator, and the therapy is indicated for the treatment of adult patients with unresectable or metastatic HER2-positive breast cancer who have received a prior anti-HER2-based regimen.

The India approval is based on a global, head-to-head, randomised, open label, registrational Phase III trial DESTINY Breast 03. Globally, trastuzumab deruxtecan is approved in more than 40 countries, including the US, for the treatment of adult patients with unresectable or metastatic HER2-positive breast cancer.

HER2 is a tyrosine kinase receptor growth-promoting protein expressed on the surface of multiple tumours including breast, gastric, lung and colorectal cancers, and is one of the biomarkers expressed in breast cancer tumours.

Dr. Sanjeev Panchal, Country President and Managing Director, AstraZeneca India, said, “India’s approval of trastuzumab deruxtecan marks a significant clinical advancement allowing us to help more patients across the HER2 spectrum. It also supports our ambition to evolve the way breast cancer is classified and treated in the country, to ultimately improve patient outcomes."