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AstraZeneca Pharma India receives CDSCO approval for oncology drug Datopotamab Deruxtecan

18 December 2025 | News

Potential launch timeline in India will be shared post all necessary approvals are obtained

AstraZeneca Pharma India Ltd. (AZPIL), has announced that the Central Drugs Standard Control Organisation (CDSCO) has granted regulatory approval to import, sell, and distribute Datopotamab Deruxtecan (Dato-DXd) in India.

The approval reflects AstraZeneca's focus on bringing to life-changing medicines at a rapid pace and marks its second antibody–drug conjugate (ADC) approval in India after trastuzumab deruxtecan (T-DXd). Further information on potential launch timeline in India will be shared post all necessary approvals are obtained.

Dato-DXd is a novel, TROP2-directed antibody drug conjugate (ADC) developed for the treatment of adult patients with unresectable or metastatic hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (IHC 0, IHC 1+, or IHC 2+/ISH-) breast cancer who have received prior endocrine-based therapy and chemotherapy for unresectable or metastatic disease.

Breast cancer is now the most diagnosed cancer globally, with over 2.3 million cases recorded in 2022 according to the World Health Organization (WHO). In India, the burden continues to grow rapidly, incidence rates have risen by nearly 40% over the past 25 years, making breast cancer the most prevalent cancer among Indian women. Many patients are diagnosed at an advanced stage, where treatment options remain limited and outcomes often poor.

Dato-DXd is a specifically engineered antibody drug conjugate that targets TROP2, a protein frequently overexpressed in breast cancer. It combines a humanized anti-TROP2 IgG1 monoclonal antibody with a topoisomerase I inhibitor payload (DXd) via a cleavable linker. This design aims to enhance targeted delivery while minimizing systemic toxicity.