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AstraZeneca receives CDSCO approval for Trastuzumab Deruxtecan in combination with Pertuzumab for breast cancer treatment

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AstraZeneca Pharma India Ltd. (AZPIL), a global, science-led biopharmaceutical company, has announced that the Central Drugs Standard Control Organisation (CDSCO) has approved an additional indication for Trastuzumab Deruxtecan 100 mg/5 mL vial lyophilised powder for concentrate for solution for infusion, in combination with Pertuzumab as a first-line treatment for adult patients with unresectable or metastatic HER2-positive (IHC 3+ or ISH+) breast cancer.

Breast cancer remains one of the most common cancers affecting women worldwide, and HER2-positive breast cancer is among its most aggressive forms.

In India, HER2-positive breast cancer, defined by HER2 gene amplification or protein overexpression, is estimated to account for approximately 12% to 19% of breast cancer cases. In the metastatic setting, unmet need remains significant.

Despite advances in care, no new first-line therapies have enhanced outcomes for patients with HER2-positive metastatic breast cancer in recent years. In addition, approximately one-third of patients treated in the first-line setting do not go on to receive second-line therapy, highlighting the importance of using the more effective treatment early in the course of disease.

Praveen Rao Akkinepally, Country President and Managing Director, AstraZeneca Pharma India Limited said, “This approval marks an important step forward for patients with unresectable or metastatic HER2-positive breast cancer in India, where the need for more effective treatment options in the first-line setting remains high."