

AstraZeneca's Enhertu gets regulatory approval in India for first-line HER2-positive breast cancer

AstraZeneca Pharma India has secured approval from India's drug regulator for its smart chemotherapy drug Enhertu. This allows for its import, sale, and distribution for an additional use. The drug will now be available as a first-line treatment for certain types of advanced breast cancer. This development expands treatment options for oncologists and patients facing HER2-positive breast cancer.



AstraZeneca Pharma India Ltd on Thursday said it has received approval from India's national drug regulatory body to import, sell and distribute its smart chemo-therapy brand

Enhertu for an additional indication.

The approval was granted by the Central Drugs Standard Control Organisation (CDSCO), under the Directorate General of Health Services (DGHS), Ministry of Health & Family Welfare (MoHFW), Government of India on June 10, the company said in information to the exchanges.

This further allows the use of Enhertu (Trastuzumab deruxtecan 100 mg/5mL) to be used, in combination with pertuzumab, as a first-line treatment for adults with unresectable or metastatic HER2-positive (IHC3+ or ISH+) breast cancer.

HER2-positive breast cancer is a subtype where tumor cells overexpress the HER2 protein. It is generally considered faster-growing than the other types. In about 1 of every 5 breast cancer patients, the cancer cells have extra copies of the gene that makes the HER2 protein, accounting for a significant proportion of breast cancer cases globally. But, treatments that specifically target HER2 are considered effective. Therefore, this move is expected to strengthen the available treatment options to oncologists and patients alike.

AstraZeneca shares were trading almost flat at Rs 8,312.00 apiece on the BSE as of 11.33 AM on Thursday.

News Source:

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