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Chugai gets Japanese nod cancer drug Kadcyla

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Singapore: The Japanese Ministry of Health, Labour and Welfare has approved Oncology specializing pharmaceutical firm Chugai Pharmaceutical's anti-cancer agent Kadcyla, for HER2-positive inoperable or recurrent breast cancer.

The firm had filed a new drug application for approval for HER2-positive inoperable or recurrent breast cancer based on results from a Japanese phase II clinical trial and a global phase III clinical trial (EMILIA trial) in January this year. The ministry is said to have provided the approval based on data from these clinical trials.

The EMILIA trial is an international phase III study comparing Kadcyla alone to lapatinib in combination with capecitabine in patients with HER2-positive metastatic or unresectable locally advanced breast cancer who had previously been treated with trastuzumab (Herceptin) and a taxane.

One of the primary points of focus was the Progression free survival (PFS), and patients who received Kadcyla experienced a 35 percent reduction in the risk of disease progression or death compared to those who received lapatinib plus capecitabine.

The number of patients newly diagnosed with breast cancer in Japan has been continuing to rise each year and is estimated to become approximately 60,000 during 2015-2019 on annual average. Overexpression of HER2 has been observed in approximately 20 per cent of breast cancer patients.