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FDA nod for Genentech pre-surgical cancer drug

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Singapore: Genentech, a member of the Roche Group, has recieved US FDA approval for Perjeta (pertuzumab) regimen for neoadjuvant treatment (use before surgery) in people with high-risk, HER2-positive early stage breast cancer.

Perjeta is a medicine that targets the HER2 receptor, a protein found on the outside of many normal cells and in high quantities on the outside of cancer cells in HER2-positive cancers.

Herceptin (trastuzumab) and docetaxel chemotherapy had no evidence of tumor tissue detectable at the time of surgery (known as a pathological complete response, or pCR). The Perjeta regimen is the first neoadjuvant breast cancer treatment approved by the FDA and also the first to be approved based on pCR data. It means neoadjuvant treatment may allow a doctor to quickly assess whether a medicine is working, and may also reduce a tumor's size so it is easier to surgically remove.

"A new approval pathway has made Perjeta available to people with HER2-positive early breast cancer several years earlier than previously possible," said Dr Hal Barron, chief medical officer and head, Global Product Development. Genentech. "Together with the FDA, we've charted new territory. We look forward to working with health authorities around the world to explore additional ways to bring promising medicines to patients more quickly."

This new neoadjuvant indication for Perjeta is for use prior to surgery in combination with Herceptin and docetaxel chemotherapy in people with HER2-positive, locally advanced, inflammatory, or early stage (tumor is greater than two centimeters in diameter or node positive) breast cancer. Perjeta should be used as part of a complete treatment regimen for early stage breast cancer.