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ASIA EDITION

European Commission approves Roche's breast cancer drug

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Kadcyla in early breast cancer represents a new option after neoadjuvant treatment for this group of patients who are known to have a worse prognosis



Roche has announced that the European Commission has approved Kadcyla® (trastuzumab emtansine) for the adjuvant (after surgery) treatment of adult patients with HER2-positive early breast cancer (eBC) who have residual invasive disease in the breast and/or lymph nodes after neoadjuvant (before surgery) taxane-based and HER2-targeted therapy.

“Optimal treatment is vital for every patient with early-stage breast cancer, a setting where cures are possible,” said Levi Garraway, M.D., Ph.D., Roche’s Chief Medical Officer and Head of Global Product Development. “This approval of Kadcyla will allow many more women with HER2-positive early breast cancer to be given a transformative treatment that may cut the risk of their disease returning or progressing."

The goal of neoadjuvant treatment is to shrink tumours in order to help improve surgical outcomes. Adjuvant treatment aims to eliminate any remaining cancer cells in the body to help reduce the risk of the cancer returning. People who have residual disease after neoadjuvant treatment have a worse prognosis than those with no detectable disease.

The approval of Kadcyla in Europe is based on results from the phase III KATHERINE study, which showed that Kadcyla significantly reduced the risk of invasive breast cancer recurrence or death from any cause (invasive disease-free survival; iDFS) by 50% (HR=0.50, 95% CI 0.39-0.64, p<0.001) compared to Herceptin® (trastuzumab) as an adjuvant treatment in people with HER2-positive eBC who have residual invasive disease after neoadjuvant taxane and Herceptin-based treatment. At three years, 88.3% of people treated with Kadcyla did not have their breast cancer return compared to 77.0% treated with Herceptin, an absolute improvement of 11.3%. The safety profile of Kadcyla was consistent with that observed in previous studies.

The impact of adjuvant treatment with Kadcyla has already been seen in the US where thousands of women are already being given this treatment following US Food and Drug Administration approval in May. Kadcyla in this setting is now approved in 27 countries worldwide and the use of Kadcyla in eBC has been recommended by multiple treatment guidelines, including those from the St Gallen International Breast Cancer Conference, the AGO and the NCCN.