ForPatients
by Roche

Breast Cancer HER-2 PositiveCáncer de mamaCáncer de mama Her2+

A study to investigate the effectiveness of trastuzumab emtansine compared with trastuzumab in a type of breast cancer (called HER2 positive breast cancer) for patients who still have signs of tumours after receiving previous treatment and undergoing surgery (KATHERINE)

A Study of Trastuzumab Emtansine Versus Trastuzumab as Adjuvant Therapy in Patients With HER2-Positive Breast Cancer Who Have Residual Tumor in the Breast or Axillary Lymph Nodes Following Preoperative Therapy (KATHERINE)

Trial Status	Trial Runs In	Trial Identifier
Finalizado	28 Countries	NCT01772472 2012-002018-37 BO27938

La información se obtuvo directamente de sitios web de registros públicos, como ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., y no se ha editado.

Official Title:

A Randomized, Multicenter, Open-Label Phase III Study to Evaluate the Efficacy and Safety of Trastuzumab Emtansine Versus Trastuzumab as Adjuvant Therapy for Patients With HER2-Positive Primary Breast Cancer Who Have Residual Tumor Present Pathologically in the Breast or Axillary Lymph Nodes Following Preoperative Therapy

Trial Summary:

This 2-arm, randomized, open-label study will evaluate the efficacy and safety of trastuzumab emtansine versus trastuzumab as adjuvant therapy in patients with HER2-positive breast cancer who have residual tumor present in the breast or axillary lymph nodes following preoperative therapy. Eligible patients will be randomized to receive either trastuzumab emtansine 3.6 mg/kg or trastuzumab 6 mg/kg intravenously every 3 weeks for 14 cycles. Radiotherapy and/or hormone therapy will be given in addition if indicated.

Hoffmann-La Roche	Phase 3
Sponsor	Phase

NCT01772472 2012-002018-37 BO27938
Trial Identifiers

Eligibility Criteria:

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Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Adult patient, >/= 18 years of age
- HER2-positive breast cancer
- Histologically confirmed invasive breast carcinoma
- Clinical stage T1-4/N0-3/M0 at presentation (patients with T1a/bN0 tumors will not be eligible)
- Completion of preoperative systemic chemotherapy and HER2-directed treatment consisting of at least 6 cycles of chemotherapy with a total duration of at least 16 weeks, including at least 9 weeks of trastuzumab and at least 9 weeks of taxane-based therapy
- Adequate excision: surgical removal of all clinically evident disease in the breast and lymph nodes as specified in protocol
- Pathological evidence of residual invasive carcinoma in the breast or axillary lymph nodes following completion of preoperative therapy
- An interval of no more than 12 weeks between the date of surgery and the date of randomization
- Known hormone-receptor status
- Eastern Cooperative Oncology Group (ECOG) performance status 0 or 1
- Adequate hematologic, renal and liver function
- Screening Left ventricular ejection fraction (LVEF) >/= 50% on echocardiogram (ECHO) or multiple-gated acquisition (MUGA) after receiving neoadjuvant chemotherapy and no decrease in LVEF by more than 15% absolute points from the pre-chemotherapy LVEF. Or, if pre-chemotherapy LVEF was not assessed, the screening LVEF must be >/= 55% after completion of neoadjuvant chemotherapy.
- For women who are not postmenopausal or surgically sterile: agreement to remain abstinent or use single or combined contraceptive methods that result in a failure rate of < 1% per year during the treatment period and for at least 7 months after the last dose of study drug
- Documentation of hepatitis B virus and hepatitis C virus serology is required

Exclusion Criteria:

- Stage IV (metastatic) breast cancer
- History of any prior (ipsi- or contralateral breast cancer except lobular carcinoma in situ
- Evidence of clinically evident gross residual or recurrent disease following preoperative therapy and surgery
- Progressive disease during preoperative systemic therapy
- Treatment with any anti-cancer investigational drug within 28 days prior to commencing study treatment
- History of other malignancy within the last 5 years except for appropriately treated carcinoma in situ of the cervix, non-melanoma skin carcinoma, Stage I uterine cancer, or other non-breast malignancies with a similar outcome to those mentioned above
- Patients for whom radiotherapy would be recommended for breast cancer treatment but for whom it is contraindicated because of medical reasons
- Current NCI CTCAE (Version 4.0) Grade >/= 2 peripheral neuropathy
- History of exposure to the following cumulative doses of anthracyclines: Doxorubicin > 240 mg/m2; Epirubicin or Liposomal Doxorubicin-Hydrochloride (Myocet®) > 480 mg/m2; For other anthracyclines, exposure equivalent to doxorubicin > 240 mg/m2
- Cardiopulmonary dysfunction as defined by protocol
- Prior treatment with trastuzumab emtansine
- Current severe, uncontrolled systemic disease
- Pregnant or lactating women

- Any known active liver disease, e.g. due to HBV, HCV, autoimmune hepatic disorders, or sclerosing cholangitis
- Concurrent serious uncontrolled infections requiring treatment or known infection with HIV
- History of intolerance, including Grade 3 to 4 infusion reaction or hypersensitivity to trastuzumab or murine proteins or any components of the product