# Clinical Trials Data ERBB2 - Document 61

# Trastuzumab Emtansine in Treating Patients With HER2-Positive Metastatic or Locally Advanced Breast Cancer That Cannot Be Removed by Surgery

## Clinical Trial: https://clinicaltrials.gov/study/NCT01816035

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Signed study-specific informed consent form\n\* Histologically or cytologically documented breast cancer\n\* Metastatic or unresectable locally advanced/recurrent breast cancer\n\* HER2-positive disease documented as in situ hybridization (ISH)-positive and/or 3+ by immunohistochemistry (IHC) on previously collected tumor tissue\n\* Absolute neutrophil count (ANC) \\> 1500 cells/mm\\^3\n\* Platelet count \\> 100,000/mm\\^3\n\* Hemoglobin \\> 9.0 g/dL (patients are allowed to receive transfused red blood cells \\[RBC\\] to achieve this level)\n\* Total bilirubin =\\< 1.5 \u00d7 upper limit of normal (ULN), except in patients with previously documented Gilbert's syndrome, in which case the direct bilirubin should be less than or equal to the ULN\n\* Serum glutamic oxaloacetic transaminase (SGOT) (aspartate aminotransferase \\[AST\\]) and serum glutamate pyruvate transaminase (SGPT) (alanine aminotransferase \\[ALT\\]) =\\< 2.5 \u00d7 ULN\n\* Alkaline phosphatase =\\< 2.5 \u00d7 ULN (patients with hepatic and/or bone metastases: alkaline phosphatase =\\< 5 \u00d7 ULN)\n\* Serum creatinine \\< 1.5 \u00d7 ULN\n\* International normalized ratio (INR) \\< 1.5 \u00d7 ULN\n\* Eastern Cooperative Oncology Group (ECOG) performance status of 0, 1, or 2\n\* Left ventricular ejection fraction (LVEF) \\>= 50% by either echocardiogram (ECHO) or multigated acquisition scan (MUGA)\n\* Negative results of serum pregnancy test for premenopausal women of reproductive capacity and for women \\< 12 months after entering menopause\n\* For women of childbearing potential and men with partners of childbearing potential, agreement by the patient and/or partner to use a highly effective, non-hormonal form of contraception or two effective forms of non-hormonal contraception; female patients of childbearing potential must agree to use two effective forms of non-hormonal contraception; effective methods of contraception include: intrauterine device (IUD); female condom; male condom; diaphragm with spermicide; cervical cap; or a sterile sexual partner; male patients with partners of childbearing potential must use barrier contraception; in addition, male patients should also have their partners use another method of contraception from the time of informed consent through the duration of study activity\n\* Willingness and ability to comply with scheduled visits, treatment plans, laboratory tests, and other study procedures, including thrombokinetic studies and platelet function studies\n\nExclusion Criteria:\n\nCANCER-RELATED CRITERIA\n\n\* Known platelet disorder, such as von Willebrand's disease or baseline platelet count of \\< 100,000/mm\\^3\n\* Chemotherapy =\\< 21 days before first study treatment\n\* Trastuzumab =\\< 21 days before first study treatment\n\* Lapatinib =\\< 14 days before first study treatment\n\* Investigational therapy or any other therapy =\\< 28 days before first study treatment\n\* Any prior ado-trastuzumab emtansine\n\* Previous radiotherapy for the treatment of unresectable, locally advanced/recurrent or metastatic breast cancer is not allowed if:\n\n \* The last fraction of radiotherapy has been administered within 14 days of first on-study thormbokinetic study\n \* The patient has not recovered from any resulting acute toxicity (to grade =\\< 1) prior to first on-study thormbokinetic study\n\* Brain metastases that are untreated or symptomatic, or require any radiation, surgery, or steroid therapy to control symptoms from brain metastases within 14 days of first on-study thrombokinetic study; for patients with newly diagnosed brain metastases or unequivocal progression of brain metastases on screening scans, localized treatment (i.e., surgery, radiosurgery, and/or whole brain radiotherapy) is required before study enrollment; subjects with known brain metastases must have clinically controlled neurologic symptoms, defined as surgical excision and/or radiation therapy followed by 14 days of stable neurologic function prior to the first thrombokinetic procedure; patients with small brain metastases not symptomatic and deemed requiring treatment by managing clinicians or study investigators may be permitted to enroll on study\n\* History of intolerance (including grade 3 or 4 infusion reaction) or hypersensitivity to trastuzumab or murine proteins\n\* Current peripheral neuropathy of grade \\>= 3 per the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) v. 4.0\n\* Current use of any platelet functioning inhibitors (including aspirin) within 14 days of first on-study thrombokinetic study\n\nCARDIOPULMONARY FUNCTION CRITERIA\n\n\* Current unstable ventricular arrhythmia requiring treatment\n\* History of symptomatic congestive heart failure (CHF) (New York Heart Association \\[NYHA\\] classes II-IV)\n\* History of myocardial infarction or unstable angina within 6 months of enrollment\n\* History of a decrease in LVEF to \\< 40% or symptomatic CHF with previous trastuzumab treatment\n\* Severe dyspnea at rest due to complications of advanced malignancy or requiring current continuous oxygen therapy\n\nGENERAL CRITERIA\n\n\* Current severe, uncontrolled non-cancer systemic disease (e.g., clinically significant cardiovascular, pulmonary, or metabolic disease) resulting in a life expectancy of \\< 6 months\n\* Major surgical procedure or significant traumatic injury within 28 days before enrollment or anticipation of the need for major surgery during the course of study treatment\n\* Current pregnancy or lactation\n\* Current known active infection with human immunodeficiency virus (HIV), hepatitis B, and/or hepatitis C virus; for patients who are known carriers of hepatitis B virus (HBV), active hepatitis B infection must be ruled out based on negative serologic testing and/or determination of HBV deoxyribonucleic acid (DNA) viral load per local guidelines\n\* Assessed by the investigator to be unable or unwilling to comply with the requirements of the protocol",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "18 Years",  
"stdAges": [  
"ADULT",  
"OLDER\_ADULT"  
]

Question:  
Based on the following clinical trial information, would a patient with a ERBB2 gene mutation be eligible for the clinical trial?

Answer:  
This trial requires \*\*HER2-positive\*\* breast cancer. While \*ERBB2\* mutations are often associated with HER2-positive breast cancer, they are not the same thing. The trial specifically requires HER2 positivity to be documented by \*\*ISH-positive and/or 3+ by IHC\*\*. A patient with an \*ERBB2\* mutation would only be eligible \*\*if\*\* their tumor also tested positive by one or both of these specific tests. Just having the \*ERBB2\* mutation is not sufficient for enrollment.