# 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",  
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"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:  
Based on the eligibility criteria provided for the clinical trial, a patient with an ERBB2 gene mutation is potentially eligible for the trial, assuming the mutation results in HER2-positive disease. HER2-positive status is crucial, as HER2 (human epidermal growth factor receptor 2) overexpression or amplification (often associated with ERBB2 gene mutations) is required for this trial. The criteria specify that HER2-positive disease must be documented as either ISH-positive or 3+ by IHC.  
  
Therefore, if the ERBB2 gene mutation in the patient results in HER2-positive breast cancer as defined by these criteria, and if the patient meets all other inclusion and exclusion criteria (such as general safety lab values, prior treatments, and other medical conditions), they would be eligible for the clinical trial.  
  
It's important to verify the HER2 status and ensure all other specific inclusion and exclusion conditions are met before confirming eligibility.