# Clinical Trials Data ERBB2 - Document 49

# Efficacy Study of Single Agent Trastuzumab or Lapatinib to Treat HER2-Overexpressing Breast Cancer

## Clinical Trial: https://clinicaltrials.gov/study/NCT00842998

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Women aged 18-75 years\n\* Histologically or cytologically confirmed metastatic disease.\n\* HER2-Overexpression proven by Fluorescence in Situ Hybridization (FISH).\n\* Availability of paraffin-embedded block of either primitive tumor and/or biopsy of metastases.\n\* No prior chemotherapy for metastatic or locally advanced disease. Patients with hormone receptor (oestrogen and/or progesterone) positive breast cancer can be eligible provided that they had received only ONE line of hormonal therapy for metastatic disease.\n\* For patients undergoing hormonal therapy for metastatic disease, disease progression must be confirmed according to RECIST criteria.\n\* At least 20% increase in the sum of longest diameters, OR\n\* Evidence of new metastatic lesions or progression of pre-existing non-target lesions.\n\* Presence of at least one monodimensionally measurable lesion. Patients without clinically or radiologically proven evidence of disease are not eligible.\n\* Patients with exclusively skin disease are eligible, provided that the disease evolution under treatment can be photographically documented.\n\* Patients with involvement of NCS, besides presence of measurable lesions, are eligible provided that:\n\n \* Brain lesion/s has/have been radically resected;\n \* Brain lesion/s has/have obtained complete remission following radiation therapy. Complete remission must be documented by TC or RMN.\n\* At least 4-week interval from end of radiotherapy, hormono- or immunotherapy and enrollment in this study.\n\* ECOG PS \\</= 2 and life expectancy of at least 6 months.\n\* Liver metastases involving \\< 30% of liver volume.\n\* Adequate hematopoietic, liver and renal function\n\* Written informed consent.\n\* Patients with childbearing potential must have negative pregnancy test and must use adequate contraceptive measures during treatment.\n\* Prior treatment with Trastuzumab as adjuvant therapy is permitted provided that it was completed at least 12 months prior enrollment in this study.\n\nExclusion Criteria:\n\n\* Prior chemotherapy for metastatic disease.\n\* Active pregnancy or breastfeeding.\n\* Previous treatment with Lapatinib.\n\* Previous therapy with mono- or policlonal antibodies for metastatic disease.\n\* Patients with bone involvement or pleural effusion/ascites as unique localization of disease.\n\* Patients with dyspnea due to presence of disease (lymphangitis) or requiring oxygen therapy.\n\* Patients with clinically evident hearth disease and/or active infectious diseases.\n\* Patients with not resected or not irradiated brain and/or leptomeningeal metastases.\n\* Prior or actual concurrent neoplasms, with the exception of adequately treated carcinoma della cervice uterina and basal cell or squamocellular carcinoma of the skin.\n\* Patients with uncontrolled serious illnesses that may compromise the compliance of the patient to the treatment.\n\* Previous allergic reactions towards any excipient in the composition of Trastuzumab or Lapatinib.\n\* Use of any experimental drug within 4 weeks prior initiation of study treatment.\n\* Women with childbearing potential who refuse to use adequate contraceptive measures.\n\* Patients unable to give written informed consent or are not compliant with treatment.\n\* Patients with great tumor involvement (\\> 30% dof hepatic volume, etc).",  
 "healthyVolunteers": false,  
 "sex": "FEMALE",  
 "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:  
Based on the provided eligibility criteria for the clinical trial, the key factors for eligibility include:  
  
1. \*\*HER2 Overexpression\*\*: The inclusion criteria require HER2 overexpression proven by Fluorescence in Situ Hybridization (FISH).  
  
2. \*\*Sex and Age\*\*: The trial is open to women aged 18 to 75 years.  
  
3. \*\*Histologically or cytologically confirmed metastatic disease\*\*.  
  
4. \*\*Other criteria include\*\*: Prior treatment restrictions, health conditions, and specific clinical requirements.  
  
The ERBB2 gene encodes the HER2 protein. A mutation in the ERBB2 gene could potentially influence HER2 protein expression. However, the trial specifically requires HER2 overexpression proven by FISH rather than just an ERBB2 mutation.   
  
Therefore, a patient with an ERBB2 gene mutation could be eligible \*if\* they also have HER2 overexpression confirmed by FISH. Merely having an ERBB2 mutation is not enough for eligibility; the HER2 overexpression must be confirmed via the specified method. If the patient meets all other inclusion criteria and does not meet any exclusion criteria, they may be eligible for this trial.