# 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:  
This trial requires HER2 \*overexpression\* as measured by FISH. An ERBB2 (which codes for HER2) mutation does not automatically mean the patient has HER2 overexpression. Therefore, based on this information alone, we \*\*cannot determine\*\* if the patient is eligible. The patient would need to be tested for HER2 overexpression via FISH. If the test shows overexpression, then they \*might\* be eligible, pending meeting all other inclusion and exclusion criteria.