# Clinical Trials Data ERBB2 - Document 19

# Capecitabine, Cyclophosphamide, Lapatinib Ditosylate, and Trastuzumab in Treating Patients With HER2-Positive Metastatic Breast Cancer

## Clinical Trial: https://clinicaltrials.gov/study/NCT01873833

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Histologically confirmed HER2-positive metastatic breast cancer\n\* HER2 overexpression of tumor by either immunohistochemistry (IHC) or fluorescence in situ hybridization (FISH); tumors tested by IHC must be 3+ positive; tumors tested by FISH must have a ratio of HER2: chromosome enumeration probe (CEP)17 \\> 2.0; when both tests are performed, the FISH result must be positive\n\* Prior trastuzumab use in the adjuvant or metastatic setting\n\* No more than two prior cytotoxic chemotherapeutic regimens for metastatic breast cancer. In addition, prior Trastuzumab emtansine (TDM-1, Kadcyla) is allowed.\n\* Eastern Cooperative Oncology Group (ECOG) performance status of =\\< 2\n\* Absolute neutrophil count (ANC) \\>= 1500/mm\\^3\n\* Platelets \\>= 100,000/mm\\^3\n\* Hemoglobin \\>= 9 g/dL\n\* Bilirubin =\\< 1.5 x upper limit of normal (ULN)\n\* Serum creatinine =\\< 1.5 x ULN or calculated creatinine clearance \\>= 60 ml/min\n\* Alanine aminotransferase (ALT) and aspartate aminotransferase (AST) =\\< 2.5 x ULN\n\* Fully recovered from toxicity due to prior therapy\n\* Capable of understanding the informed consent and complying with the protocol and signed the informed consent document prior to any study-specific screening procedures or evaluations being performed\n\* Must be able to swallow pills\n\* May have either measurable or non-measurable disease by Response Evaluation Criteria in Solid Tumors (RECIST) 1.1 criteria\n\* Sexually active participants must agree to use a medically accepted barrier method of contraception (i.e. male condom or female condom) during the course of the study and for 3 months following discontinuation of study treatments; for participants of childbearing potential, a barrier method and a second method of contraception must be used\n\* Participants of childbearing potential must have a negative pregnancy test at screening and enrollment; participants of childbearing potential are defined as premenopausal females capable of becoming pregnant, i.e. females who have had any evidence of menses in the past 12 months with the exception of those who had prior hysterectomy (oophorectomy or surgical sterilization); however, women who have been amenorrheic for \\>= 12 months are still considered to be of childbearing potential if the amenorrhea is possibly due to any other cause including prior chemotherapy, antiestrogens, or ovarian suppression\n\nExclusion Criteria:\n\n\* Prior treatment with capecitabine or lapatinib\n\* Radiation therapy within 2 weeks before the first dose of study treatment\n\* Hormonal therapy within 2 weeks before the first dose of study treatment\n\* Cytotoxic chemotherapy (including investigational cytotoxic chemotherapy) within 3 weeks before the first dose of study treatment\n\* Biologic therapy (including antibodies \\[other than trastuzumab\\], immune modulators, cytokines) within 4 weeks before the first dose of study treatment; Note: there is no washout period required for trastuzumab\n\* Any other type of investigational agent within 4 weeks before the first dose of study treatment\n\* Major surgery, or not recovered from major surgery within 4 weeks before the first dose of study treatment\n\* Untreated, symptomatic, or progressive brain metastases; participants must have no radiographic or other signs of progression in the brain for \\>= 1 month after completion of local therapy; any corticosteroid use for brain metastases must have been discontinued without the subsequent appearance of symptoms for \\>= 4 weeks prior to first study treatment\n\* Uncontrolled significant intercurrent illness that would preclude the patient from study participation per investigator assessment\n\* Left ventricular ejection fraction (LVEF) =\\< 50% as documented by multi gated acquisition scan (MUGA) or echocardiogram performed within 28 days prior to the first study treatment\n\* Currently receiving anticoagulation with therapeutic doses of warfarin (low-molecular weight heparin is permitted)\n\* Pregnant or breastfeeding\n\* Known to be positive for the human immunodeficiency virus (HIV) (a test for HIV at screening is not required)\n\* Have acute or currently active/requiring anti-viral therapy hepatic or biliary disease (with the exception of patients with Gilbert's syndrome, asymptomatic gallstones, liver metastases or stable chronic liver disease per investigator assessment)\n\* Previously identified allergy or hypersensitivity or intolerance to components of the study treatment formulation (cyclophosphamide, capecitabine, lapatinib \\[lapatinib ditosylate\\], trastuzumab)\n\* Any other diagnosis of malignancy or evidence of malignancy (except non-melanoma skin cancer, in-situ carcinoma of the cervix) within 2 years prior to screening for this study\n\* Unable or unwilling to abide by the study protocol or cooperate fully with the investigator or designee",  
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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:  
The eligibility criteria specify "HER2-positive metastatic breast cancer" with specific requirements for HER2 overexpression determined by IHC or FISH. While ERBB2 mutations are often associated with HER2-positive breast cancer, the trial explicitly requires HER2 overexpression confirmation via IHC or FISH, \*\*not\*\* the presence of an ERBB2 mutation itself.  
  
Therefore, simply having an ERBB2 mutation does \*not\* automatically qualify a patient. They would need to meet the IHC 3+ or FISH ratio > 2.0 criteria in addition to the other inclusion and exclusion criteria.