# Clinical Trials Data ERBB2 - Document 2

# Tolerability of the Combination of Lapatinib and Trastuzumab in Adults Age 60 or Older With HER2 Positive Locally Advanced or Metastatic Breast Cancer

## Clinical Trial: https://clinicaltrials.gov/study/NCT01273610

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Locally advanced or metastatic Her2/Neu positive breast cancer (defined as immunohistochemistry \\[IHC\\] 3+ or a fluorescence in situ hybridization \\[FISH\\] ratio of \\>= 2.0); this may be on either a primary tumor or a metastatic site, and there is no time limit from the time the specimen was obtained; locally advanced breast cancer (LABC) includes breast cancers with advanced primary tumors, i.e., large diameter (at least 5 cm) or those with skin and/or chest wall involvement, and advanced regional lymph node involvement; it also includes a rare subgroup, inflammatory breast cancer; in the 2010 American Joint Committee on Cancer and the International Union for Cancer Control (AJCC-UICC) TNM breast cancer staging system, locally advanced breast cancer (LABC) includes patients with stage III disease; this comprises:\n\n \* Advanced primary tumors (tumors \\> 5 cm in greatest dimension \\[T3\\]; direct extension to the chest wall and/or to the skin \\[T4\\]: ulceration, skin nodules, and/or edema (including peau d'orange) confined to the same breast, inflammatory breast cancer \\[IBC, T4d\\])\n \* Advanced regional lymph nodes (ipsilateral level I, II axillary lymph nodes that are clinically fixed or matted or clinically detected internal mammary lymph nodes in the absence of axillary lymph node metastases \\[N2\\], ipsilateral infraclavicular \\[level III axillary\\] lymph nodes, ipsilateral internal mammary lymph node\\[s\\] with axillary lymph nodes, or ipsilateral supraclavicular lymph nodes \\[N3\\])\n\* Both measurable and non-measurable disease are allowed\n\* Life expectancy of greater than 12 weeks\n\* Women of child-bearing potential and sexually active men must agree to use adequate contraception prior to study entry for six months following duration of study participation\n\* Eastern Cooperative Oncology Group (ECOG) performance status =\\< 2 (Karnofsky performance status \\>= 60%)\n\* Hemoglobin \\>= 10 g/dL (after transfusion if necessary)\n\* Absolute neutrophil count \\>= 1,500/mcL\n\* Platelets \\>= 100,000/mcL\n\* Total bilirubin within normal institutional limits\n\* Aspartate aminotransferase (AST) (serum glutamic oxaloacetic transaminase \\[SGOT\\])/aspartate aminotransferase (ALT) (serum glutamate pyruvate transaminase \\[SGPT\\]) =\\< 2.5 X institutional upper limit of normal\n\* Creatinine clearance \\>= 30 mL/min as measured using either the Cockcroft-Gault method or 24-hour creatinine clearance\n\* The above tests must be obtained within 14 days of study treatment\n\* Cardiac ejection fraction \\>= 50% as measured by echocardiogram or multiple gated acquisition scan (MUGA) scan\n\* The ability to swallow and retain oral medication\n\* Prior treatment with lapatinib or trastuzumab are allowed, provided that the agents have never been given in combination\n\* Any number of prior cancer treatments, including investigational agents, chemotherapy, hormone therapy, or targeted therapy are allowed\n\* All patients must have the ability to understand and the willingness to sign a written informed consent\n\nExclusion Criteria:\n\n\* Concurrent investigational treatment, chemotherapy, or targeted therapy; prior chemotherapy, hormonal therapy, targeted therapy, and investigational agents are allowed but all toxicities grade \\>= 2 must have resolved by the time of study commencement (except alopecia)\n\* Unstable or symptomatic brain metastases (however, patients with stable or treated brain metastases who do not require steroids at doses above those permitted for control of symptoms may be enrolled)\n\* History of allergic reactions attributed to compounds of similar chemical or biological composition to lapatinib or trastuzumab; however, patients with a history of infusion reaction to trastuzumab which was controlled with premedication on subsequent infusions without a recurring infusion reaction are eligible\n\* Concomitant medications listed are prohibited; inhibitors or inducers of cytochrome P450 3A4 (CYP3A4) not listed can be used with caution\n\* Ongoing or active infection (including human immunodeficiency virus \\[HIV\\]) or psychiatric illness/social situations that would limit compliance with study requirements\n\* Inability to take oral medication\n\* Malabsorption syndrome, (prior surgical procedures affecting absorption), or inflammatory gastrointestinal (GI) disease (e.g., Crohn's, ulcerative colitis) which in the opinion of the study coordinator is likely to limit normal absorption of the drug\n\* Current active 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\* Active cardiac disease, defined as (but not limited to):\n\n \* History of documented congestive heart failure (CHF) or systolic dysfunction (left ventricular ejection fraction \\[LVEF\\] \\< 50%)\n \* High-risk uncontrolled arrhythmias (ventricular tachycardia, high-grade atrio-ventricular \\[AV\\]-block, supraventricular tachycardias which are not adequately rate-controlled)\n \* Angina pectoris requiring antianginal medications\n \* Evidence of transmural infarction on electrocardiogram (ECG)\n \* Clinically significant valvular heart disease\n \* Poorly controlled hypertension (e.g. systolic \\> 180 mm HG or diastolic \\> 100 mm Hg)\n \* Any other cardiac condition, which in the opinion of the treating physician would make this protocol unreasonably hazardous for the patient\n\* Subjects who, in the opinion of the investigator, may not be able to comply with the safety monitoring requirements of the study are not eligible",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "60 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/Neu positive breast cancer, defined as IHC 3+ or FISH ratio >= 2.0. An ERBB2 gene mutation is \*often\* the cause of Her2/Neu positive breast cancer, but not always. Therefore, simply having the ERBB2 mutation doesn't guarantee eligibility.   
  
\*\*The patient needs to have their Her2/Neu status confirmed by IHC or FISH testing to determine eligibility for this trial.\*\* If those tests come back positive as defined in the inclusion criteria, then they would likely be eligible, assuming they also meet all other inclusion criteria and none of the exclusion criteria.