# Clinical Trials Data ERBB2 - Document 14

# Effect of Trastuzumab on Disease Free Survival in Early Stage HER2-Negative Breast Cancer Patients With ERBB2 Expressing Disseminated Tumor Cells

## Clinical Trial: https://clinicaltrials.gov/study/NCT01779050

"eligibilityCriteria": "Pre-Registration Inclusion Criteria:\n\n\* Histologically confirmed HER2-negative primary invasive ductal or invasive lobular breast carcinoma. For patients enrolling for neoadjuvant treatment, diagnosis must be clinical stage II or III; for patients enrolling for adjuvant treatment, diagnosis must be pathologic stage IIA to IIIC. Standard HER2 testing will be performed in the surgical specimen at Washington University according to the standard of care in the Department of Pathology. A HER2-negative primary breast cancer sample from a patient eligible for randomization should have a HER2 IHC score of 0 or 1+ Those patients with IHC score of 2+ should be HER2 FISH-negative in standard testing. Patient will have undergone staging studies including a CT of the chest/abdomen/pelvis and bone scan and/or PET scan either prior to the initiation of treatment or prior to entry into the trial. In addition, patients with non-metastatic, HER2-negative, recurrent tumors who need chemotherapy are eligible.\n\* Planning to receive best practice adjuvant or neoadjuvant chemotherapy according to institutional guidelines. Adjuvant tamoxifen or aromatase inhibitors treatment will be allowed for hormone receptor-positive patients. Patients who have failed neoadjuvant endocrine therapy will also be eligible.\n\* At least 18 years old.\n\* Eastern Cooperative Oncology Group (ECOG) performance status \u2264 1.\n\* Patient (or legally authorized representative) must be able to understand and willing to sign a written informed consent document.\n\nPre-Registration Exclusion Criteria:\n\n\* Prior chemotherapy for this cancer (excluding initiation of best practice chemotherapy to be given as standard of care as described in this protocol, which may be initiated after the pre-registration bone marrow collection but before final confirmation of eligibility and randomization).\n\* Previous treatment with trastuzumab or any other Her2 targeted therapy.\n\* Presence of an uncontrolled intercurrent illness including, but not limited to, ongoing or active infection, symptomatic congestive heart failure, unstable angina pectoris, cardiac arrhythmia, or psychiatric illness/social situations that would limit compliance with study requirements.\n\nRegistration Inclusion Criteria\n\n\* Presence of bone marrow ERBB2 overexpressing DTCs at the time of diagnosis; bone marrow aspiration will be performed in consented patients to evaluate DTCs following pre-registration provided patients meet all eligibility criteria as described in this section.\n\* Eastern Cooperative Oncology Group (ECOG) performance status \u2264 1.\n\* Adequate cardiac function as demonstrated by LVEF of \\>55% performed no more than 4 weeks prior to randomization.\n\* Normal organ and marrow function as defined below:\n\n \* leukocytes \u22653,000/mcL\n \* absolute neutrophil count \u22651,500/mcL\n \* platelets \u2265100,000/mcL\n \* hemoglobin \u2265 10 g/dL\n \* total bilirubin within institutional upper limits of normal unless related to primary disease\n \* AST(SGOT)/ALT(SGPT) \u22642.0 X institutional upper limit of normal\n \* Creatinine \u2264 1.5 institutional upper limits of normal OR creatinine clearance \u226560 mL/min/1.73 m2 for patients with creatinine levels above institutional normal\n\* If a woman of childbearing potential, patient must use two forms of effective contraception for a minimum of 6 months following trastuzumab. Effective methods of birth control include use of established oral, injected, or implanted hormonal methods of birth control, IUD, IUS, and condoms.\n\nRegistration Exclusion Criteria\n\n\* Evidence of distant metastasis present by CT scan, bone scan, or physical exam.\n\* History of allergic reactions attributed to compounds of similar chemical or biologic composition to trastuzumab.\n\* Prior chemotherapy for this cancer (excluding initiation of best practice chemotherapy to be given as standard of care described in this protocol, which may be initiated after the pre-registration bone marrow collection but before final confirmation of eligibility and randomization).\n\* History of other malignancy \u2264 5 years previous with the exception of basal cell or squamous cell carcinoma of the skin which were treated with local resection only or carcinoma in situ of the cervix.\n\* Pregnant or breastfeeding. Patient must have a negative serum pregnancy test \u2264 7 days from date of registration (if a woman of childbearing potential).\n\* Clinically important history of active liver disease, including viral or other hepatitis or cirrhosis.\n\* Uncontrolled hypocalcemia, hypomagnesemia, hyponatremia, or hypokalemia defined as less than the lower limit of normal for the institution despite adequate electrolyte supplementation.\n\* Symptomatic intrinsic lung disease or extensive tumor involvement of the lungs resulting in dyspnea at rest.",  
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"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 clinical trial eligibility criteria, the focus is on patients with HER2-negative breast cancer, as indicated by a HER2 IHC score of 0 or 1+, or those with an IHC score of 2+ that are HER2 FISH-negative. The eligibility does not specifically exclude patients with an ERBB2 (another name for HER2) gene mutation, but it requires that the primary breast cancer itself should be HER2-negative according to immunohistochemistry (IHC) and fluorescence in situ hybridization (FISH) testing.  
  
Additionally, the registration inclusion criteria mention the presence of bone marrow ERBB2 overexpressing DTCs (disseminated tumor cells) at the time of diagnosis. This suggests that ERBB2 overexpression in bone marrow DTCs is considered separately and does not exclude a patient based solely on the mutation status elsewhere.  
  
In summary, a patient with an ERBB2 gene mutation might still be eligible if their primary breast cancer is classified as HER2-negative per the testing criteria described. Therefore, the ERBB2 mutation by itself does not automatically make the patient ineligible, as long as the specific HER2-negative requirements are met as per the trial's criteria.