# Clinical Trials Data ERBB2 - Document 20

# Pertuzumab, Trastuzumab, and Paclitaxel Albumin-Stabilized Nanoparticle Formulation in Treating Patients With HER2-Positive Advanced Breast Cancer

## Clinical Trial: https://clinicaltrials.gov/study/NCT01730833

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Patients must be diagnosed with metastatic cytologically or histologically confirmed adenocarcinoma of the breast with HER2 over-expression or with newly diagnosed locally advanced (including inflammatory) breast cancer (LABC) with stage II-III disease; patients with metastatic (stage IV) disease (MBC) must have measurable lesions\n\* Women of child-bearing potential and men must agree to use adequate contraception (hormonal or barrier method of birth control or abstinence) prior to study entry and for six months following duration of study participation; should a woman become pregnant or suspect that she is pregnant while participating on the trial, she should inform her treating physician immediately\n\* Tumor positive or negative for expression of hormone receptors (\\< 1% or \\> 1%) and overexpressing HER2 by immunohistochemistry (IHC) (3+), or, HER2-amplified by fluorescence in situ hybridization (FISH) or by alternative gene testing\n\* For patients with LABC, no prior therapy is allowed\n\* For patients with MBC, prior adjuvant chemotherapy and trastuzumab more than or equal to 12 months prior to enrollment are allowed\n\* No prior chemotherapy or trastuzumab for treatment of metastatic breast cancer\n\* Left ventricular ejection fraction (LVEF) \\>= 50% (determined by echocardiogram or multigated acquisition scan) within 42 days of treatment\n\* Eastern Cooperative Oncology Group performance status of 0 or 1\n\* Hemoglobin \\>= 9 g/dl\n\* Leukocytes \\>= 3.0 x 10\\^9/L\n\* Absolute neutrophil count \\>= 1.5 x 10\\^9/L\n\* Platelets \\>= 100 x 10\\^9/L\n\* Total bilirubin =\\< 1.3 mg/dl (institutional upper limit of normal)\n\* Aspartate aminotransferase (AST) (serum glutamic oxaloacetic transaminase \\[SGOT\\])/alanine aminotransferase (ALT) (serum glutamate pyruvate transaminase \\[SGPT\\]) =\\< 2 x institutional upper limit of normal\n\* Creatinine within normal institutional limits or creatinine clearance \\> 50 mL/min/1.73 m\\^2 for patients with creatinine levels above institutional normal (using Cockcroft-Gault formula)\n\* All radiology studies (study requiring staging) must be performed within 35 days prior to the start of therapy\n\* No serious medical conditions such as myocardial infarction within 6 months prior to entry, congestive heart failure, unstable ventricular arrhythmia, uncontrolled hypertension, uncontrolled diabetes mellitus, uncontrolled psychotic disorders, serious infections, active peptic ulcer disease, psychiatric illness, or any other medical conditions that might be aggravated by treatment or limit compliance\n\* Currently, no active second malignancy other than non-melanoma skin cancer; note: patients are not considered to have a \"current active\" malignancy if they have completed anti-cancer therapy and are considered by their physicians to have a less than 30% chance of relapse\n\* All patients must have the ability to understand and the willingness to sign an informed consent\n\* Negative serum or urine beta-human chorionic gonadotropin (hCG) pregnancy test at screening for patients of child-bearing potential\n\* No prior therapies (except for anti-estrogen therapy) are allowed for the treatment of the newly diagnosed metastatic breast cancer; patients are allowed to have had prior chemotherapy for breast cancer in the adjuvant setting for at least 12 months prior to enrollment into this study; patients with a prior diagnosis of malignancy treated \\>= 5 years ago are eligible, provided that they have not received prior nab-paclitaxel as part of their prior treatment regimen, and that they meet all eligibility criteria\n\nExclusion Criteria:\n\n\* Known active hepatitis B or C\n\* Known active human immunodeficiency virus (HIV)\n\* Prior breast cancer or other invasive malignancy treated within 5 years\n\* Pregnancy\n\* Neuropathy \\> grade 1\n\* Any other intercurrent medical/psychological problem deemed exclusionary by the treating physician or investigators/principal investigator (PI)\n\* Cumulative dose of doxorubicin or equivalent of \\> 360 mg/m\\^2 during prior adjuvant therapy\n\* LVEF \\< 50% during previous trastuzumab therapy\n\* Central nervous system metastases\n\* Another malignancy excluding basal cell skin cancer\n\* Pregnant women\n\* Subjects will be excluded who, in the opinion of the investigator, may not be able to comply with the safety monitoring requirements of the study",  
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 "minimumAge": "19 Years",  
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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 mention "HER2 over-expression or with newly diagnosed locally advanced...breast cancer with HER2-amplified by fluorescence in situ hybridization (FISH) or by \*\*alternative gene testing\*\*". An ERBB2 mutation is generally what leads to HER2 overexpression. Therefore, if the alternative gene testing confirms that the ERBB2 mutation results in HER2 overexpression or amplification, the patient \*could\* be eligible.  
  
However, simply having an ERBB2 mutation doesn't automatically qualify them. The mutation needs to result in HER2 overexpression or amplification as determined by one of the specified tests (IHC, FISH, or alternative gene testing). Furthermore, the patient must also meet \*all other\* inclusion criteria and \*none\* of the exclusion criteria to be eligible for the trial.