# Clinical Trials Data ERBB2 - Document 53

# 1303GCC: Trastuzmab & Pertuzumab With Hormonal Therapy or Chemotherapy in Women Aged 60 and Over.

## Clinical Trial: https://clinicaltrials.gov/study/NCT02000596

"eligibilityCriteria": "Inclusion Criteria:\n\n1. Women \u226560 Years of Age.\n2. Histologically confirmed, locally advanced (T4 primary tumor and stage IIIB or IIIC disease) or metastatic breast cancer that progressed after treatment with standard treatment regimens in the adjuvant or neoadjuvant setting.\n3. Prior treatment with trastuzumab and/or lapatinib in the neo-adjuvant or adjuvant setting is allowed but not required. Lapatininb has to be discontinued \\> 21 days before the initiation of the T+P study treatments.\n4. Up to 3 prior chemo regimens for treatment of metastatic disease are allowed as long as the study subject is acceptable for study treatment with chemo required on this study in cohort 2 at progression on T+P.\n5. Patients may have had prior hormonal therapy with any hormonal agents as per section 3.1.5 of this protocol.\n6. Zometa or denosumab can be continued as per standard of care as long as started before the study treatment is started.\n7. HER2 positive breast cancer, as defined in Section 3.3 of this protocol\n8. Must have measurable or evaluable disease according to RECIST 1.1 criteria.\n9. Lab values obtained \u22647 days prior to registration as indicated in 3.1.9 of this protocol.\n10. ECOG Performance Status (PS) of 0, 1 or 2.\n11. LVEF at least 50% as determined by MUGA or ECHO.\n12. Life expectancy \\>3 months.\n13. Written informed consent.\n14. Willingness to return to study site for treatment and follow-up.\n15. Normal QTc interval defined on EKG as QTc \u2264 440 msec.\n16. Postmenopausal women defined in section 3.1.16 of this protocol.\n\nExclusion Criteria:\n\n1. Stage III or IV cancer, other than breast cancer, in \u22645 years prior to registration.\n2. Actively being treated for other malignancy.\n3. New York Heart Association Class III or IV cardiovascular disease.\n4. History of coronary heart failure (CHF)\n5. Current use of drugs known to prolong the QTc interval including Class Ia and III antiarrhythmics or history of congenital long QTc syndrome.\n6. Evidence of active brain metastasis including leptomeningeal involvement.\n7. Major surgery, chemotherapy, hormonal or immunologic therapy \u22643 weeks prior to registration.\n8. Radiotherapy \u22643 weeks prior to registration, except if to a non-target lesion only.\n9. Prior treatment with Pertuzumab, Eribulin, Fulvestrant or Anastrozole.\n10. Uncontrolled illness.\n11. Co-morbid systemic illnesses or other severe concurrent disease. See section 3.2.11.\n12. Currently receiving treatment in a different clinical study in which investigational procedures are performed or investigational therapies are administered.\n13. Immunocompromised patients (other than that related to the use of corticosteroids) including patients known to be HIV positive.\n14. International normalized ratio (INR), activated partial thromboplastin time (aPTT) or partial thromboplastin time (PTT) \\>1.5 \u00d7 ULN (unless on anticoagulation medication)\n15. Receipt of intravenous (IV) antibiotics for infection within 7 days prior to enrollment into the study.\n16. Current chronic daily treatment with corticosteroids. See section 3.2.16 of this protocol.\n17. Known hypersensitivity to any of the study treatments or to excipients of recombinant human or humanized antibodies.\n18. History of receiving any investigational treatment within 28 days prior to enrollment into the study.\n19. Assessed by the investigator to be unable or unwilling to comply with the requirements of the protocol.",  
 "healthyVolunteers": false,  
 "sex": "FEMALE",  
 "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:  
A patient with an ERBB2 (also known as HER2) gene mutation \*could\* be eligible, but more information is needed.  
  
The inclusion criteria specify "HER2 positive breast cancer," which is usually determined by testing for overexpression of the HER2 protein or gene amplification, not specifically by the presence of an ERBB2/HER2 mutation. While some ERBB2 mutations can lead to HER2 overexpression, not all do. Therefore, simply having an ERBB2 mutation doesn't automatically qualify a patient.  
  
The trial protocol's Section 3.3, which defines HER2 positivity for this specific trial, needs to be reviewed to determine if the patient's specific ERBB2 mutation status would be considered HER2-positive according to their criteria. It's possible they use criteria beyond just IHC or FISH testing, but we can't know based on the provided information.