# Clinical Trials Data ERBB2 - Document 4

# A Study to Assess the Efficacy and Safety of Enzalutamide With Trastuzumab in Patients With Human Epidermal Growth Factor Receptor 2 Positive (HER2+), Androgen Receptor Positive (AR+) Metastatic or Locally Advanced Breast Cancer

## Clinical Trial: https://clinicaltrials.gov/study/NCT02091960

"eligibilityCriteria": "Inclusion Criteria:\n\n\* The subject has histologically or cytologically proven adenocarcinoma of the breast that is HER2+\n\* The subject has AR+ breast cancer\n\* The subject has metastatic disease or has locally advanced disease that is not amendable to curative treatment\n\* The subject has measurable disease or nonmeasurable, evaluable disease per RECIST 1.1. (NOTE: pleural effusions, ascites or other third fluid space are not evaluable diseases per RECIST 1.1).\n\* The subject has received at least 1 line of therapy in the metastatic or locally advanced disease setting. The subject has been documented to have progressed by determination of the investigator on a regimen containing an anti-HER2 agent as the most recent regimen or the most recent anti-HER2 regimen was discontinued for any toxicity, with the exception of a cardiotoxicity.\n\* The subject has adequately recovered from toxicities due to prior therapy.\n\* The subject has an Eastern Cooperative Oncology Group performance (ECOG) status \u2264 1 at Screening and Day 1\n\* The subject has available at the site a representative, formalin-fixed, paraffin-embedded, tumor specimen that enabled the definitive diagnosis of breast cancer with adequate viable tumor cells in a tissue block (preferred) or \u2265 10 (20 preferred) freshly cut, unstained, serial slides and the associated pathology report\n\nExclusion Criteria:\n\n\* The subject has a severe concurrent disease, infection, or comorbidity that would make the subject inappropriate for enrollment.\n\* The subject has current or previously treated brain metastasis or active leptomeningeal disease. Brain imaging is required during screening in all subjects to exclude the presence of unequivocal central nervous system disease.\n\* The subject has a history of a non-breast cancer malignancy with the following exceptions:\n\n \* The subject with a previous history of a non-invasive carcinoma is eligible if he/she has had successful curative treatment any time prior to Screening.\n \* For all other malignancies, the subject is eligible if they have undergone potentially curative therapy and they have been considered disease free for at least 5 years prior to Screening.\n\* The subject has a history of seizure or any condition that may predispose to seizure (e.g., prior cortical stroke, significant brain trauma).\n\* The subject has a history of loss of consciousness, cerebrovascular accident, or transient ischemic attack within 12 months before the Day 1 visit.\n\* The subject has had a hypoglycemic episode requiring medical intervention while on insulin (or other anti-diabetic) treatment within 12 months before Day 1.\n\* The subject had a major surgical procedure, substantial open biopsy, or significant traumatic experience within 28 days before the Day 1 visit, or anticipation of need for major surgical procedure during the course of the study.\n\* The subject has had palliative radiation therapy to bone metastases within 14 days prior to the Day 1 visit (side effects from radiation must be resolved).\n\* The subject has received chemotherapy, immunotherapy, or any other systemic anticancer therapy, with the exception of anti-HER2 therapy (e.g., trastuzumab), within 14 days prior to the Day 1 visit.",  
 "healthyVolunteers": false,  
 "sex": "FEMALE",  
 "minimumAge": "18 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:  
Based on the provided clinical trial eligibility criteria, a patient with an ERBB2 gene mutation (commonly associated with HER2+ breast cancer) would indeed be eligible, given they meet other relevant criteria listed. More explicitly, the inclusion criteria specify that the subject must have adenocarcinoma of the breast that is HER2-positive. HER2 positivity in breast cancer typically corresponds to amplification or overexpression of the ERBB2 gene.  
  
However, to conclude definitively, the patient must also fulfill additional criteria, such as having AR+ breast cancer, being female, having metastatic or locally advanced disease, having measurable or evaluable disease per RECIST 1.1, previously receiving at least one line of treatment for their condition, and having adequate recovery from prior therapy among others.  
  
In short, having an ERBB2 gene mutation aligns with this trial’s requirement for HER2+ breast cancer, potentially making the patient eligible, but all other criteria (both inclusion and exclusion) must also be assessed.