# Clinical Trials Data ERBB2 - Document 34

# Phase I Study LJM716 Combined With Trastuzumab in Patients With HER2 Overexpressing Metastatic Breast or Gastric Cancer

## Clinical Trial: https://clinicaltrials.gov/study/NCT01602406

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Patients with confirmed HER-2 positive, metastatic or non-operable locally advanced breast or gastric cancer\n\* Metastatic breast cancer patients must have received a minimum of 1 and a maximum of 3 prior anti HER2 based regimens with documented progression on the most recent regimen which must contain trastuzumab, ado-trastuzumab emtansine or lapatinib\n\* Metastatic gastric cancer patients must have received a minimum of 1 and a maximum of 2 prior anti HER2 based regimens with documented progression on the most recent regimen which must contain trastuzumab or ado-trastuzumab emtansine\n\* During the dose expansion part of study, all patients must have at least one measurable lesion as defined by RECIST criteria.\n\* Patients must have at least one prior trastuzumab-containing regimen\n\* Eastern Cooperative Oncology Group (ECOG) Performance status \u2264 2\n\nExclusion Criteria:\n\n\* Patients with Central Nervous System (CNS) metastasis which are: symptomatic or require treatment for symptom control and/or growing\n\* Prior treatment with any anti-HER3 (Human Epidermal growth factor Receptor 3) treatment\n\* Impaired cardiac function\n\* Prior to the first dose of study treatment, patients who have received systemic antineoplastic therapy or any investigational therapy within 4 weeks or within 5 half- lives of the therapy prior to starting study treatment, whichever is shorter, or for cyclical therapy, within one cycle length (e.g. 6 weeks for nitrosourea, mitomycin-C).\n\* Patients who have a history of primary malignancy other than that being treated in this study, and currently requires active clinical intervention.\n\* Patients who do not have an archival tumor sample (or sections of it) available or readily obtainable.\n\nOther protocol-defined inclusion/exclusion criteria may apply",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "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:  
Potentially, but more information is needed.  
  
The trial requires HER-2 positive cancer. ERBB2 is the gene that codes for HER2. Therefore, a mutation in ERBB2 \*could\* lead to HER2 positive cancer. However, not all ERBB2 mutations result in HER2 overexpression or positivity as measured by clinical tests. The trial specifically requires \*confirmed\* HER-2 positive status, not just the presence of an ERBB2 mutation.  
  
Therefore, simply having an ERBB2 mutation does not automatically qualify a patient. They would need to undergo testing to confirm if the mutation has resulted in HER-2 positive cancer as defined by the trial's criteria.