# 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:  
Based on the eligibility criteria for the clinical trial, a patient with an ERBB2 gene mutation may be eligible if the mutation indicates HER-2 positivity.   
  
The inclusion criteria specifically mention patients with confirmed HER-2 positive breast or gastric cancer. The ERBB2 gene encodes the HER2 protein, and mutations or amplifications in this gene can lead to HER-2 positive cancer. Therefore, if the ERBB2 mutation results in HER-2 overexpression, the patient could qualify under the HER-2 positive criteria.  
  
Additionally, other factors such as the number of prior anti-HER2 regimens and other inclusion/exclusion criteria mentioned above must also be considered to determine complete eligibility. For instance, metastatic breast cancer patients must have received between one and three prior HER2-based regimens, and all patients must have received at least one prior trastuzumab-containing regimen. The patient should also not have any conditions listed in the exclusion criteria.  
  
It is essential for the treating physician to assess the patient's entire profile against all study criteria to conclude final eligibility.