# Clinical Trials Data EGFR - Document 131

# 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 EGFR gene mutation be eligible for the clinical trial?

Answer:  
Based on the provided eligibility criteria for the clinical trial, the presence of an EGFR gene mutation is not explicitly listed as either an inclusion or exclusion factor. The trial primarily focuses on patients with HER-2 positive, metastatic or non-operable locally advanced breast or gastric cancer. Therefore, whether a patient with an EGFR mutation is eligible would depend on other factors related to the trial's criteria, such as HER-2 status and treatment history, rather than the EGFR mutation status itself.  
  
To determine eligibility, it's important to consider the following key inclusion criteria:  
- The patient must have HER-2 positive cancer.  
- The patient must fit within the specified range of prior anti-HER2 treatments.  
- Additional criteria related to measurable lesions, performance status, etc.  
  
And key exclusion criteria, such as:  
- The patient should not have untreated or symptomatic CNS metastases.  
- There should be no prior treatment with anti-HER3 agents.  
  
If the patient meets the inclusion criteria and does not meet any of the exclusion criteria, then the presence of an EGFR mutation alone would not automatically disqualify them from participating in this trial. It would be advisable for the patient's medical team to confirm eligibility with the trial organizers, particularly if there are any specific protocol-defined criteria that have not been detailed here.