# Clinical Trials Data ERBB2 - Document 43

# Pilot Trial of CRLX101 in Treatment of Patients With Advanced or Metastatic Stomach, Gastroesophageal, or Esophageal Cancer That Cannot be Removed by Surgery

## Clinical Trial: https://clinicaltrials.gov/study/NCT01612546

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Patients must have histologically confirmed advanced or metastatic squamous adenocarcinoma of the esophagus, GEJ, or stomach\n\* Patients must have primary tumor and adjacent normal tissue accessible via endoscopic biopsy\n\* Patients must have received at least one prior chemotherapy regimen for their unresectable or metastatic disease, not including treatment administered in the adjuvant and/or neoadjuvant setting for curative intent\n\* Patients must have measurable or evaluable disease\n\* Absolute neutrophil count \\>= 1500 cells/uL\n\* Platelets \\>= 100,000 cells/uL\n\* Total bilirubin =\\< 1.5 times the upper limit of normal (ULN)\n\* Aspartate aminotransferase (AST)/alanine aminotransferase (ALT) =\\< 2.5 x ULN\n\* AST/ALT =\\< 5 x ULN if liver metastasis is present\n\* Serum creatinine =\\< 1.5 mg/dL or a measured creatinine clearance \\>= 50 mL/min\n\* Prothrombin time (PT)/partial thromboplastin time (PTT) =\\< 1.5 x ULN\n\* Subjects with an Eastern Cooperative Oncology Group (ECOG) performance status of =\\< 2\n\* Subjects with a life expectancy \\>= 12 weeks\n\* Women of child-bearing potential and men must agree to use adequate contraception (hormonal or barrier method of birth control or abstinence) prior to study entry and for six months following duration of study participation; should a woman become pregnant or suspect that she is pregnant while participating on the trial, she should inform her treating physician immediately and be discontinued on study; subjects should be instructed to notify the investigator if it is determined after completion of the study that they became pregnant during the treatment phase of the study; the anticipated date or birth or termination of the pregnancy should be provided at the time of the initial report; whenever possible, a pregnancy should be followed to term, any premature terminations reported, and the status of the mother and the child should be reported to the study monitor after delivery; if the outcome of the pregnancy meets any severe adverse events (SAE) classification criterion, the investigator must follow the procedures for reporting SAEs; any neonatal death occurring =\\< 30 days after birth must also be reported as a SAE\n\* Subjects must have an electrocardiogram without evidence of clinically significant conduction abnormalities or active ischemia as determined by the investigator and an acceptable QTc interval\n\* All subjects must have the ability to understand and the willingness to sign a written informed consent\n\* Subjects must not have received prior chemotherapy or radiation within \\< 4 weeks prior to first dose of study drug\n\* Subjects may be entered if they have received prior radiation therapy involving =\\< 30% of the bone marrow; any prior radiation therapy must have been administered \\>= 4 weeks prior to first dose of study drug and the subject must be recovered from the acute toxic effects of the treatment prior to first dose of study drug (defined as a return to baseline or a severity of =\\< grade 1)\n\* Subjects may be enrolled with a history of treated brain metastases that are clinically stable for \\>= 4 weeks prior to the first dose of study drug; subjects may not be currently receiving dexamethasone\n\nExclusion Criteria:\n\n\* Female subjects who are pregnant or nursing\n\* Subjects who have had chemotherapy or radiotherapy within 4 weeks (6 weeks for nitrosoureas or mitomycin C) prior to first dose of study drug or those who have not had adverse events return to baseline severity level or a severity of grade 1 due to agents administered more than 4 weeks prior to first dose of study drug\n\* Subjects with a history of congestive heart failure (CHF) requiring medical therapy\n\* Subjects with serum amylase or lipase \\> 1.5 ULN\n\* Subjects with previous high dose chemotherapy with autologous stem cell rescue bone marrow transplantation\n\* History of organ or allogeneic bone marrow transplant\n\* Use of any investigational agent or device within 4 weeks prior to first dose of study drug\n\* Metastatic disease to the central nervous system (CNS) requiring treatment or radiation therapy\n\* Subjects with known untreated brain metastases or treated brain metastases that have not been stable \\>= 4 weeks prior to first dose of study drug\n\* Uncontrolled intercurrent illness including, but not limited to ongoing or active infection (including human immunodeficiency virus \\[HIV\\] not stable on antiretroviral therapy), symptomatic congestive heart failure, hypertension, unstable angina pectoris, cardiac arrhythmia, or psychiatric illness/social situations that would limit compliance with study requirements, as determined by the investigator\n\* History of prior malignancy not cured by excision; patients with non-melanoma skin cancer or carcinoma in situ of the cervix are not excluded, but patients with other prior malignancies must have had at least 2-year disease free interval\n\* Concurrent therapeutic anticoagulation: PTT less than or equal to 1.5 x ULN or low dose aspirin and low-molecular weight heparin only are allowed; Coumadin will be allowed on a case by case basis if use is chronic and approved by the study medical monitors\n\* Any major surgery =\\< 4 week prior to first dose of study drug\n\* Concurrent use of filgrastim (G-CSF) or growth factors at the time of initiation of study drug\n\* History of allergic reactions attributed to compounds of similar chemical or biologic composition to CRLX101 and camptothecins\n\* Subjects with marked baseline prolongation of QT/QTc interval (for females QTc interval \\>= 470 msec and for males QTc interval \\>= 450 msec)\n\* Subjects, who in the opinion of the investigator, may not be able to comply with the safety monitoring requirements of the study",  
 "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:  
This trial is for squamous adenocarcinoma of the esophagus, GEJ, or stomach. The eligibility criteria do \*\*not\*\* mention anything about ERBB2 gene mutation status. Therefore, having an ERBB2 mutation would \*not\* automatically exclude a patient, but they would still need to meet all other inclusion criteria and not have any of the exclusion criteria.