# Clinical Trials Data ERBB2 - Document 12

# Afatinib in Advanced Refractory Urothelial Cancer

## Clinical Trial: https://clinicaltrials.gov/study/NCT02122172

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Patients must have locally advanced or metastatic urothelial cancer that is not amenable to surgical treatment\n\* Patients must have histologically or cytologically confirmed urothelial tract carcinoma; patients with urothelial carcinoma of the bladder, upper tract, or urethra are eligible\n\* Patients must have measurable disease, defined as at least one lesion that can be accurately measured in at least one dimension (longest diameter to be recorded) as \\>= 20 mm with conventional techniques or as \\>= 10 mm with spiral computed tomography (CT) scan for the evaluation of measurable disease (Response Evaluation Criteria in Solid Tumors version 1.1 \\[RECIST v1.1\\])\n\* Patients must have evidence of disease progression prior to enrollment\n\* All patients must have received a prior platinum-based chemotherapy regimen for treatment of urothelial cancer and must now be considered refractory to platinum-based chemotherapy; patients may have received the platinum-containing regimen either in the peri-operative or metastatic setting\n\* Patients may have received up to one line of prior systemic chemotherapy for recurrent/metastatic disease; if a platinum-based regimen was received both in the peri-operative setting and again in the metastatic setting, this will be considered 1 line of chemotherapy\n\* Eastern Cooperative Oncology Group (ECOG) performance status 0-1\n\* Absolute neutrophil count \\>= 1,000/mcL\n\* Platelets \\>= 100,000/mcL\n\* Hemoglobin \\>= 8.5g/dL\n\* Total bilirubin =\\< 1.5 institutional upper limit of normal (IULN)\n\* Aspartate aminotransferase (AST) (serum glutamic oxaloacetic transaminase \\[SGOT\\])/alanine aminotransferase (ALT)(serum glutamate pyruvate transaminase \\[SGPT\\]) =\\< 2.5 X IULN\n\* Calculated creatinine clearance \\>= 30 mL/min by the modified Cockcroft and Gault Formula OR glomerular filtration rate \\>= 30 mL/min/body surface area (BSA) by Modification of Diet in Renal Disease or Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) formula\n\* Women and men of child-bearing potential must agree to use adequate contraception (hormonal or barrier method of birth control; abstinence) prior to study entry and for the duration of study participation; should a woman become pregnant or suspect she is pregnant while participating in this study, she should inform her treating physician immediately\n\* Patients must have the ability to understand and the willingness to sign a written informed consent document\n\nExclusion Criteria:\n\n\* Patients may not be receiving any other investigational agents\n\* Patients with untreated known brain metastases, or treated brain metastases that are clinically unstable\n\* Uncontrolled intercurrent illness including, but not limited to, ongoing or active infection, symptomatic congestive heart failure, unstable angina pectoris, or psychiatric illness/social situations that would limit compliance with study requirements\n\* Women known to be pregnant\n\* Women who are breastfeeding and who are unwilling to stop breastfeeding prior to study entry\n\* Patients with known prior human immunodeficiency virus (HIV)-positive status on combination antiretroviral therapy are ineligible; known prior HIV-positive patients with CD4+ =\\< 500/mm\\^3 are ineligible (HIV testing is not required as part of this study)\n\* Pre-existing interstitial lung disease\n\* Inability to take oral medications\n\* Prior therapy with afatinib",  
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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 eligibility criteria for the clinical trial, there is no mention of ERBB2 gene mutation status as a criterion for inclusion or exclusion. Therefore, the mutation in the ERBB2 gene is not listed as a factor that would determine eligibility for this trial.   
  
Eligibility is dependent on factors such as having locally advanced or metastatic urothelial cancer, a history of platinum-based chemotherapy, measurable disease, specific lab values, ECOG performance status, and several exclusion criteria mostly related to other health conditions and treatments.  
  
As long as the patient meets all the other inclusion criteria and none of the exclusion criteria apply, an ERBB2 gene mutation would not make the patient ineligible for this trial. However, it would be best to discuss specific cases with the trial team for a definitive eligibility determination.