# 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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"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 description \*\*does not mention ERBB2 gene status\*\* as either an inclusion or exclusion criterion. Therefore, having an ERBB2 mutation \*would not automatically disqualify\* a patient, but it also \*doesn't guarantee eligibility\*. The patient would still need to meet all other inclusion criteria and not have any of the exclusion criteria.