# Clinical Trials Data EGFR - Document 55

# BKM120 in Esophageal Squamous Cell Carcinoma After Failure of First Line Chemotherapy

## Clinical Trial: https://clinicaltrials.gov/study/NCT01806649

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Patient has provided a signed Informed Consent Form (ICF) obtained prior to any screening procedure.\n\* Age \u2265 18 years old\n\* Histologically confirmed diagnosis of esophageal squamous cell carcinoma and available archival tissue for evaluation of further studies.\n\* Metastatic or unresectable disease\n\* Received one prior chemotherapy or biological therapy regimen for unresectable or metastatic disease\n\* More than 30 days since prior chemotherapy, surgery, radiotherapy, or investigational agents\n\* Measurable disease in at least 1 diameter by CT scan or MRI as per RECIST 1.1 criteria\n\* No evidence of brain metastasis\n\* ECOG \u2264 2\n\* Patient has adequate bone marrow and organ function\n\n \* Absolute Neutrophil Count (ANC) \u2265 1.5 x 109/L\n \* Platelets \u2265 100 x 109/L\n \* Hemoglobin \u2265 9.0 g/dL\n \* INR \u2264 2\n \* Potassium, calcium, magnesium within normal limits for the institution\n \* Serum Creatinine \u2264 1.5 x ULN or Creatinine clearance \\> 60 mL\n \* AST and ALT not more than 2.5 times ULN (not more than 5.0 times ULN if there is liver metastasis)\n \* Serum bilirubin within normal range (or \u2264 1.5 x ULN if liver metastases are present; or total bilirubin \u2264 3.0 x ULN with direct bilirubin within normal range in patients with well documented Gilbert Syndrome)\n \* Fasting serum glucose \\< 1.5 times ULN\n\nExclusion Criteria:\n\n\* Patient has received previous treatment with PI3K inhibitors\n\* Patient has symptomatic CNS metastases\n\* Patients with controlled and asymptomatic CNS metastases may participate in this trial. As such, the patient must have completed any prior treatment for CNS metastases \\> 28 days (including radiotherapy and/or surgery) prior to enrollment in this study and should not be receiving chronic corticosteroid therapy for the CNS metastases.\n\* Patient has a concurrent malignancy or has a malignancy within 5 years of study enrollment, (with the exception of nonmelanoma skin cancer or cervical carcinoma in situ.\n\* Patient has any of the following mood disorders as judged by the Investigator or a Psychiatrist, or meets the cut-off score of \u2265 10 in the PHQ-9 or a cut-off of \u2265 15 in the GAD-7 mood scale, respectively, or selects a positive response of '1, 2, or 3' to question number 9 regarding potential for suicidal thoughts ideation in the PHQ-9 (independent of the total score of the PHQ-9)\n\* Medically documented history of or active major depressive episode, bipolar disorder (I or II), obsessive-compulsive disorder, schizophrenia, a history of suicidal attempt or ideation, or homicidal ideation (immediate risk of doing harm to others) \u2265 CTCAE grade 3 anxiety\n\* Patient is concurrently using other approved or investigational antineoplastic agent\n\* Patient has had major surgery within 28 days prior to starting study drug or has not recovered from major side effects of the surgery\n\* Patient has poorly controlled diabetes mellitus(HbA1c \\> 8 %)\n\* Patient has active cardiac disease including any of the following:\n\n \* LVEF \\< 50%\n \* QTc \\> 480 msec on screening ECG (using the QTcF formula)\n \* Angina pectoris that requires the use of anti-anginal medication\n \* Ventricular arrhythmias except for benign premature ventricular contractions\n\* Supraventricular and nodal arrythmias requiring a pacemaker or not controlled with medication\n\* Conduction abnormality requiring a pacemaker\n\* Valvular disease with documented compromise in cardiac function\n\* Symptomatic pericarditis\n\* Patient has a history of cardiac dysfunction including any of the following;\n\n \* Myocardial infarction within the last 6 months, documented by persistent elevated cardiac enzymes or persistent regional wall abnormalities on assessment of LVEF function\n \* History of documented congestive heart failure (New York Heart Association functional classification III-IV)\n\* Documented cardiomyopathy\n\* Patient is currently receiving treatment with QT prolonging medication known to have a risk to induce Torsades de Pointes, and the treatment cannot be discontinued or switched to a different medication prior to starting study drug\n\* Inability to swallow, impaired gastrointestinal (GI) function, or GI disease that would significantly alter the absorption of study drugs or preclude the use of oral medications\n\* Patient has other concurrent severe and/or uncontrolled medical condition that would, in the investigator's judgment contraindicate her participation in the clinical study (e.g.,chronic pancreatitis, active chronic hepatitis etc.)\n\* Patient is currently being treated with drugs known to be moderate and strong inhibitors or inducers of isoenzyme CYP3A, and the treatment cannot be discontinued or switched to a different medication prior to starting study drug.",  
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]

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 inclusion and exclusion criteria for the clinical trial, there is no specific mention of restrictions related to an EGFR gene mutation. Therefore, having an EGFR mutation alone would not automatically make a patient ineligible for this trial.   
  
Eligibility will be determined by whether the patient meets all the inclusion criteria and does not fall under any of the exclusion criteria listed. Since there is no mention of EGFR mutations as either an inclusion or exclusion factor, an EGFR gene mutation should not impact eligibility in this case.  
  
However, it is always recommended for patients to discuss their specific medical conditions and eligibility with the trial investigator, as there may be additional considerations or clarifications provided during the screening process that are not explicitly detailed in the criteria provided.