# 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:  
This trial is specifically for esophageal squamous cell carcinoma. The eligibility criteria \*\*do not mention EGFR mutations\*\*, neither as an inclusion nor an exclusion criterion. Therefore, having an EGFR mutation wouldn't automatically disqualify a patient, but it also doesn't make them eligible. They would need to meet \*all\* other inclusion criteria and \*none\* of the exclusion criteria to be considered.