# Clinical Trials Data BRAF - Document 38

# Vemurafenib in Combination With Everolimus or Temsirolimus With Advanced Cancer

## Clinical Trial: https://clinicaltrials.gov/study/NCT01596140

"eligibilityCriteria": "Inclusion Criteria:\n\n1. Confirmation of BRAF mutation-positive malignancy is required for selection of patients for vemurafenib therapy\n2. Measurable or non-measurable disease by RECIST 1.1.\n3. Patients with advanced cancer should be refractory to standard therapy, relapsed after standard therapy, or have no standard therapy available that improves survival by at least three months.\n4. Patients must be at least 3 weeks past receiving cytotoxic therapy and at least 5 half-lives after their previous treatment or 3 weeks, whichever is shorter, after biologic therapy. Patients may receive palliative radiotherapy immediately or during treatment provided that not all target lesions are radiated.\n5. ECOG performance status \\</= 2 (Karnofsky \\>/= 60%; Lansky Score \\>/= 50).\n6. Patients must have normal organ and marrow function defined as: absolute neutrophil count \\>/=1,000/mL; platelets \\>/=50,000/mL; creatinine \\< 2.0; total bilirubin \\< 2.0; ALT(SGPT) \\</= 3 X ULN; Exception for patients with liver metastasis: ALT(SGPT) \\</= 5 X ULN.\n7. Women of childbearing potential and men must agree to use adequate contraception (hormonal or barrier method of birth control; abstinence) prior to study entry, for the duration of study participation, and for 30 days after the last dose.\n8. Ability to understand and the willingness to sign a written informed consent document.\n\nExclusion Criteria:\n\n1. Patients with uncontrolled concurrent illness, including but not limited to: ongoing or active infection requiring hospitalization; psychiatric illness/social situations that would limit compliance with study requirements.\n2. Exclusion of patients with creatinine \\>2.0 and bilirubin \\> 2.0.\n3. Pregnant or lactating women.\n4. Patients with a history of bone marrow transplant within the previous two years.\n5. Patients with a known hypersensitivity to any of the components of the drug products.\n6. Patients with major surgery within 30 days prior to entering the study.\n7. Patients with a baseline QTc \\> 500 ms.\n8. Patients who are unable to swallow pills.",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
"stdAges": [  
"CHILD",  
"ADULT",  
"OLDER\_ADULT"  
]

Question:  
Based on the following clinical trial information, would a patient with a BRAF gene mutation be eligible for the clinical trial?

Answer:  
Yes, a patient with a BRAF mutation-positive malignancy would be \*\*potentially eligible\*\* for this clinical trial. The first inclusion criteria specifically states that confirmation of a BRAF mutation is \*required\*.  
  
However, simply having the BRAF mutation is not enough. The patient must \*also\* meet \*all\* of the other inclusion criteria and \*none\* of the exclusion criteria to be eligible. For example, they must have adequate organ function, an acceptable ECOG performance status, and not have any of the listed exclusionary conditions (uncontrolled illness, pregnancy, etc.).