# Clinical Trials Data BRAF - Document 46

# Vemurafenib and Panitumumab Combination Therapy in Patients With BRAF V600E Mutated Metastatic Colorectal Cancer

## Clinical Trial: https://clinicaltrials.gov/study/NCT01791309

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Patient must have metastatic colorectal cancer with a V600E BRAF mutation that has been histologically or cytologically-confirmed at MSKCC and has failed to respond to appropriate standard therapy regimens. There is no limit on the number of prior treatment regimens permitted.\n\* Patient must not have previously received treatment with an anti-EGFR targeting antibody (cetuximab or panitumumab).\n\* Patient must have accessible disease appropriate for tumor biopsy.\n\* Patient is male or female and \u226518 years of age on the day of signing informed consent.\n\* Patient must have a performance status of 0 or 1 on the ECOG Performance Scale.\n\* Patient must have adequate organ function as indicated by the following laboratory values:\n\nHematological:\n\nAbsolute neutrophil count (ANC) \u22651,500/\u03bcL Platelets \u2265100,000/\u03bcL Hemoglobin \u22658g/dL\n\nRenal:\n\nSerum creatinine or calculated creatinine clearance\\\*\n\n\u22641.5 x upper limit of normal (ULN) OR\n\n\u226560mL/min for patients with creatinine levels \\<1.5 x institutional ULN\n\nHepatic:\n\nSerum total bilirubin \u22641.5 x ULN OR direct bilirubin \u2264 ULN for patients with total bilirubin levels \\> 1.5 x ULN AST (SGOT) and ALT (SGPT) \u22643 x ULN or \u22645 x ULN in patients with known liver metastasis\n\n\\\*Creatinine clearance should be calculated using the Cockcroft-Gault method\n\n\* Female patient of childbearing potential who is not surgically sterilized must have a negative serum or urine pregnancy test \u03b2-hCG within 72 hours prior to receiving the first dose of study medication.\n\* Patient, or the patient's legal representative, has voluntarily agreed to participate by giving written informed consent.\n\* Patient is able to swallow capsules and has no surgical or anatomical condition that will preclude the patient from swallowing and absorbing oral medications on an ongoing basis.\n\nExclusion Criteria:\n\nAny patient meeting any of the following criteria is not eligible to participate in this study:\n\n\* Patient who has had chemotherapy, radiotherapy, or biological therapy within 3 weeks (6 weeks for nitrosoureas or mitomycin C), or who has not recovered from the adverse events due to previous agents administered more than 4 weeks prior to study day 1. If the patient has residual toxicity from prior treatment, other than oxaliplatin-related neurotoxicity or bevacizumab-related albuminuria, toxicity must be \u2264 grade 1.\n\* Patient must be at least 4 weeks post major surgical procedure, and all surgical wounds must be adequately healed (in the judgment of the treating investigator).\n\* Patient is currently participating or has participated in a study with an investigational compound or device within 30 days of study day 1.\n\nPatient has evidence of active CNS disease (radiographically unstable, symptomatic lesions). Newly diagnosed, untreated brain metastases are ineligible. However, prior treatment with stereotactic radiosurgery (SRS), whole brain radiotherapy, or surgical resection is allowed if the patient remains without evidence of disease progression in the brain \u2265 6 weeks and has been off corticosteroids for \u2265 3 weeks.\n\n\* Patient has known hypersensitivity to the components of study drug or its analogs.\n\* Patient is, at the time of signing informed consent, a regular user (including \"recreational use\") of any illicit drugs or had a recent history (within the last year) of drug or alcohol abuse.\n\* Patient is breastfeeding or expecting to conceive or father children within the projected duration of the study.\n\* Patient is known to be Human Immunodeficiency Virus (HIV) positive.\n\* Patient who has a known history of interstitial pneumonitis or pulmonary fibrosis.\n\* Patient with mean QTc \u2265450msec on screening EKG.\n\* Patient has a history or current evidence of any condition, therapy, or lab abnormality that might confound the results of the study, interfere with the patient's participation for the full duration of the study, or it is not in the best interest of the patient to participate, in the opinion of the treating investigator.\n\* Patient has known psychiatric or substance abuse disorders that would, in the opinion of the treating investigator, interfere with cooperation with the requirements of the trial.",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "18 Years",  
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"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:  
Based on the provided clinical trial information, a patient with a BRAF gene mutation would be eligible for the clinical trial if they meet the following criteria:  
  
1. \*\*Diagnosis\*\*: The patient must have metastatic colorectal cancer with a V600E BRAF mutation that has been confirmed histologically or cytologically.  
2. \*\*Previous Treatment\*\*: The patient must not have previously received treatment with an anti-EGFR targeting antibody (such as cetuximab or panitumumab) and must have failed to respond to appropriate standard therapy regimens. There is no limit on the number of prior treatment regimens.  
3. \*\*Disease Access\*\*: The patient must have accessible disease appropriate for tumor biopsy.  
4. \*\*Age\*\*: The patient must be 18 years or older.  
5. \*\*Performance Status\*\*: The patient must have a performance status of 0 or 1 on the ECOG Performance Scale.  
6. \*\*Organ Function\*\*: The patient must have adequate organ function based on specified hematological, renal, and hepatic laboratory values.  
7. \*\*Pregnancy\*\*: Female patients of childbearing potential must have a negative pregnancy test prior to starting the study.  
8. \*\*Consent and Medication Intake\*\*: The patient must voluntarily agree to participate and be able to swallow capsules without any condition precluding this.  
  
The patient must also not meet any of the exclusion criteria listed, which include recent chemotherapy, radiotherapy, or biological therapy; evidence of active CNS disease; current participation in another study; hypersensitivity to the study drug; drug or alcohol abuse; current breastfeeding status; being HIV positive; history of certain lung diseases; prolonged QT interval on EKG; and any other condition that might interfere with the study or patient's participation.  
  
Thus, if the patient has the V600E BRAF mutation and meets all the above inclusion criteria without any exclusion criteria, they would be eligible for the trial.