# Clinical Trials Data BRAF - Document 35

# Vemurafenib Plus Cobimetinib Plus PEG-interferon in Advanced Melanoma Patients Harboring the V600BRAF Mutation

## Clinical Trial: https://clinicaltrials.gov/study/NCT01959633

"eligibilityCriteria": "Inclusion Criteria:\n\n1. Patients over 18\n2. Untreated and pretreated (no more than 1 treatment) patients with metastatic melanoma at stage unreseactable IIIb-IV, histologically confirmed, that show V600 type BRAF mutations. Patients eligible for Phase I may have been pretreated with the investigational study treatments.\n3. Patient with measurable disease by RECIST v 1.1\n4. Eastern Cooperative Oncology Group (ECOG) performance status (PS) 0 - 1\n5. Patients who have successfully completed all the secondary side effects to previous systemic therapy\n6. Patients with an appropriate hematologic, hepatic and renal functionality, assessed in the 7 days preceding the start of therapy, as well as:\n\n \* Absolute neutrophil count (ANC)\\> 1.5 X 109 / L\n \* Absolute platelet count \\> 100 X 109 / L\n \* Hemoglobin \\> 9 g/dl\n \* Serum creatinine \\< 1.5 times the normal maximum values or Creatinine Clearance \\> 50 mL/hr (Cockroft-Gault formula)\n \* Transaminase level (AST and ALT) \\< 2.5 times the normal maximum values\n \* Serum bilirubin \\< 1.5 times the normal maximum values\n7. Negative pregnancy test performed within 7 days before beginning therapy (premenopausal women)\n8. Patients of childbearing age (or with partners of childbearing age) must use effective contraception during therapy and for at least 6 months after the effective treatment\n9. Absence of any psychological, familiar or social condition that may affect compliance with study protocol and scheduled follow-up\n10. Dated and signed informed consent before any study procedure\n\nExclusion Criteria:\n\n1. Presence of symptomatic brain metastases\n2. Previous malignant cancer during the 2 years preceding the signing of informed consent\n3. Investigational study treatment within 28 days or 5 half-lives, whichever is longer, preceding the first dose of study treatments in this study\n4. Pregnancy and/or breast feeding;\n5. Nausea and vomit refractory to therapy, malabsorption, external biliary shunt, previous bowel resection, which could impair an adequate absorption\n6. Any of these conditions occurring in the 6 months before the start of Vemurafenib therapy: heart attack, unstable angina and/or severe degree, congestive heart failure, cerebrovascular accident or transient ischemic attack, pulmonary embolism, arterial hypertension not adequately controlled\n7. History of atrial or ventricular arrhythmia, symptomatic\\> grade 2 (NCI CTCAE)\n8. Hystory of retinopathy\n9. Correct QT interval \\> 450msec to baseline history of congenital long QT syndrome\n10. Uncontrolled medical condition among which endocrine disorders (such as hypothyroidism, hyperthyroidism and diabetes mellitus)\n11. Other severe medical or psychiatric conditions or abnormalities of laboratory tests that may increase the risk associated with study participation or the assumption of Vemurafenib, or that may interfere with the interpretation of study results, which in the judgment of the Investigator can make the patient not eligible for the study\n12. Unwillingness to practice adequate contraception\n13. Prior systemic treatment with BRAFi or MEKi, or interferon alpha",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "18 Years",  
"stdAges": [  
"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:  
A patient with a BRAF V600 mutation \*could\* be eligible for this trial, but more information is needed. While the inclusion criteria specify "V600 type BRAF mutations," there are several other requirements they must also meet. Here's a breakdown:  
  
\*\*Factors that suggest potential eligibility:\*\*  
  
\* \*\*BRAF V600 mutation:\*\* The patient has the required mutation.  
\* \*\*Age:\*\* The patient is over 18.  
  
\*\*Factors requiring further clarification:\*\*  
  
\* \*\*Metastatic melanoma stage IIIb-IV:\*\* The patient's melanoma stage needs to be confirmed as unresectable IIIb-IV.  
\* \*\*Prior treatment:\*\* The patient must have received no more than one prior treatment for metastatic melanoma (unless eligible for Phase I, which has different criteria). \*What prior treatments, if any, has the patient received?\* This is crucial. Specifically, they \*cannot\* have received prior BRAFi, MEKi, or interferon alpha.  
\* \*\*Measurable disease:\*\* Confirmation is needed that the patient has measurable disease according to RECIST v1.1 criteria.  
\* \*\*ECOG Performance Status:\*\* The patient's ECOG PS must be 0 or 1.  
\* \*\*Resolved side effects:\*\* The patient must have recovered from side effects of any previous systemic therapy.  
\* \*\*Lab values:\*\* Recent blood tests (within 7 days of starting therapy) must meet the specified criteria for ANC, platelet count, hemoglobin, creatinine, transaminases, and bilirubin.  
\* \*\*Pregnancy status/Contraception:\*\* If the patient is a premenopausal woman, a recent negative pregnancy test is required. Patients of childbearing potential must agree to use effective contraception.  
\* \*\*Brain metastases:\*\* The patient \*cannot\* have symptomatic brain metastases.  
\* \*\*Prior cancer:\*\* The patient cannot have had another malignant cancer within the past two years.  
\* \*\*Recent investigational treatments:\*\* The patient cannot have received other investigational treatments within a specific timeframe.  
\* \*\*Other exclusion criteria:\*\* The patient must be free of the other listed exclusionary conditions (e.g., uncontrolled hypertension, cardiac issues, retinopathy, etc.).  
  
In short, having the BRAF V600 mutation is necessary but not sufficient for eligibility. A thorough review of the patient's medical history and current status is needed to determine if they meet \*all\* inclusion criteria and \*none\* of the exclusion criteria.