# 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:  
Based on the provided clinical trial eligibility criteria, a patient with a BRAF gene mutation would be eligible for the clinical trial if they meet the following specific inclusion criteria:  
  
1. The patient is over 18 years of age.  
2. The patient has metastatic melanoma at unresectable stage IIIb-IV, with a histologically confirmed V600 type BRAF mutation.  
3. The patient has measurable disease by RECIST v1.1 standards.  
4. The patient has an ECOG performance status of 0 - 1.  
5. They have successfully completed all secondary side effects from any previous systemic therapy.  
6. They meet the specified hematological, hepatic, and renal function requirements.  
7. If applicable, a negative pregnancy test is required, and effective contraception must be used as outlined.  
8. They do not have any psychological, familial, or social conditions that could affect compliance.  
9. They have signed an informed consent form.  
  
The patient must not meet any of the exclusion criteria, such as having symptomatic brain metastases, a history of other malignant cancer within the last 2 years, recent investigative study treatment involvement, pregnancy, severe medical conditions, and others specified in the exclusion list.  
  
If a patient with a BRAF mutation meets all the inclusion criteria and none of the exclusion criteria, they would be eligible for this clinical trial.