# Clinical Trials Data BRAF - Document 48

# Study Of Zelboraf (Vemurafenib) in Patients With Locally-Advanced, Unresectable, Stage IIIc Or Metastatic Melanoma and Activating Exon 15 BRAF Mutations Other Than V600E

## Clinical Trial: https://clinicaltrials.gov/study/NCT01586195

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Eastern Cooperative Oncology Group (ECOG) Performance Status 0-2\n\* Histologically-confirmed metastatic melanoma (unresectable Stage IIIc or IV) with an activating BRAF mutation other than V600E, as detected by DNA sequencing of exon 15 performed at a centralized laboratory\n\* Measurable disease (as defined by RECIST, v1.1)\n\* Adequate recovery from most recent systemic or local treatment for cancer\n\* Adequate organ function within 28 days prior to initiation of treatment\n\* For women of childbearing potential, agreement to the use of two acceptable methods of contraception, including one barrier method, during the study and for 6 months after discontinuation of vemurafenib\n\* For men with female partners of childbearing potential, agreement to use a latex condom and to advise their female partner to use an additional method of contraception during the study and for 6 months after discontinuation of vemurafenib\n\* Negative serum pregnancy test within 7 days of commencement of treatment in premenopausal women. Women who are either surgically sterile or have been post-menopausal for at least 1 year are eligible to participate in this study\n\* Agreement not to donate blood or blood products during the study and for at least 6 months after discontinuation of vemurafenib; for male participants, agreement not to donate sperm during the study and for at least 6 months after discontinuation of vemurafenib\n\* Signed informed consent form (prior to study entry and before performing any study-related procedures)\n\nExclusion Criteria:\n\n\* Invasive malignancy other than melanoma at the time of enrollment and within 2 years prior to first study drug administration, except for adequately treated (with curative intent) basal or squamous cell carcinoma, in situ carcinoma of the cervix, in situ ductal adenocarcinoma of the breast, in situ prostate cancer, or limited stage bladder cancer or other cancers from which the patient has been disease-free for at least 2 years\n\* Pregnant or breast-feeding\n\* Inability to swallow pills\n\* Concurrent anti-tumor therapy (e.g., chemotherapy, other targeted therapy, radiation therapy, including participation in an experimental drug study)\n\* Radiation therapy \\</= 1 week prior to first administration of vemurafenib and stereotactic radiotherapy \\</= 1 day prior to first administration of vemurafenib\n\* Prior treatment with a BRAF or MEK inhibitor\n\* Either a concurrent condition (including medical illness, such as active infection requiring treatment with IV antibiotics or the presence of laboratory abnormalities) or history of a prior condition that places the patient at unacceptable risk if he/she were treated with the study drug or confounds the ability to interpret data from the study\n\* History of congenital long QT syndrome or a corrected QT (QTc) interval \\> 450 ms at baseline\n\* Ongoing cardiac dysrhythmia \\>/= Grade 2\n\* Unwillingness to practice effective birth control\n\* Inability to comply with other requirements of the protocol",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "16 Years",  
"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:  
A patient with \*any\* BRAF mutation \*other than\* V600E would be eligible. The inclusion criteria specifically states the patient must have "an activating BRAF mutation \*other than\* V600E". A patient with a V600E BRAF mutation would be excluded.