# Clinical Trials Data BRAF - Document 33

# A Study of Vemurafenib Adjuvant Therapy in Participants With Surgically Resected Cutaneous BRAF-Mutant Melanoma

## Clinical Trial: https://clinicaltrials.gov/study/NCT01667419

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Histologically confirmed melanoma of cutaneous origin\n\* Participants with BRAFV600 mutation-positive, cutaneous melanoma (either pathologic Stage IIC or Stage III according to AJCC Staging Criteria version 7 that has been completely resected\n\* BRAF V600 mutation status of the current primary tumor or involved lymph node determined to be positive using the cobas BRAF V600 mutation test\n\* Surgically rendered free of disease within 90 days of randomization\n\* Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1\n\* Life expectancy of at least 5 years\n\* Fully recovered from the effects of any major surgery or significant traumatic injury prior to the first dose of study treatment\n\* Adequate hematologic, hepatic, and renal function\n\nExclusion Criteria:\n\n\* History of any systemic or local therapy (e.g., chemotherapy, biologic or targeted therapy, hormonal therapy, or photodynamic therapy) for the treatment or prevention of melanoma, including interferon alpha-2b and pegylated interferon alpha-2b\n\* History of limb perfusion therapy\n\* History of radiotherapy for the treatment of melanoma\n\* Invasive malignancy other than melanoma at the time of enrollment or within 5 years prior to first dose of study treatment\n\* Family history of inherited colon cancer syndromes\n\* Known personal history of \\>3 adenomatous colorectal polyps or a personal history of adenomatous colorectal polyp(s) \\>2 centimeters (cm) in size\n\* History of or current clinical, radiographic, or pathologic evidence of in-transit metastases, satellite, or microsatellite lesions\n\* History of or current clinical, radiographic, or pathologic evidence of recurrent lymph node involvement after resection of a primary melanoma with lymph node involvement at any time in the past\n\* History of local and/or regional and/or distant melanoma recurrence\n\* History or current radiographic or pathologic evidence of distant metastases\n\* History of clinically significant cardiac or pulmonary dysfunction\n\* Major surgical procedure or significant traumatic injury within 4 weeks prior to first dose of study treatment\n\* Infection with human immunodeficiency virus (HIV), hepatitis B, or hepatitis C virus",  
 "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 eligibility criteria provided for the clinical trial, a patient with a BRAF V600 gene mutation would be eligible for the trial given the inclusion requirement for such a mutation. The relevant inclusion criteria state:  
  
- Participants with BRAFV600 mutation-positive, cutaneous melanoma (...) have been completely resected, and  
- The BRAF V600 mutation status of the current primary tumor or involved lymph node determined to be positive using the cobas BRAF V600 mutation test.  
  
Therefore, if the patient meets these specific criteria regarding the BRAF mutation, and assuming they also meet all other inclusion criteria and none of the exclusion criteria, they would be eligible for this clinical trial.