# 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:  
A patient with a BRAF gene mutation \*might\* be eligible, but more information is needed. The criteria specify:  
  
\* \*\*BRAFV600 mutation-positive cutaneous melanoma:\*\* The trial requires a \*specific type\* of BRAF mutation (V600). Just having \*any\* BRAF mutation isn't enough. The patient's specific BRAF mutation needs to be confirmed.  
\* \*\*Stage IIC or III melanoma:\*\* The melanoma must be of a specific stage and completely resected.  
\* \*\*Confirmed by cobas test:\*\* The BRAF V600 mutation status must be determined using a specific test (the cobas BRAF V600 mutation test). Other tests confirming the mutation might not be accepted.  
\* \*\*Other criteria:\*\* The patient also needs to meet \*all other\* inclusion criteria (e.g., ECOG performance status, adequate organ function) and \*none\* of the exclusion criteria (e.g., no prior systemic therapy for melanoma, no history of recurrence).  
  
Therefore, simply having a BRAF mutation is not sufficient for eligibility. The specific type of mutation, stage of melanoma, test used for confirmation, and other inclusion/exclusion criteria must all be considered.