# Clinical Trials Data BRAF - Document 56

# Phase 2 Study of Neoadjuvant Vemurafenib in Melanoma Patients With Untreated Brain Metastases

## Clinical Trial: https://clinicaltrials.gov/study/NCT01781026

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Biopsy proven metastatic melanoma with the B-raf V600E or V600K mutations.\n\* Untreated brain metastases\n\* At least one cerebral metastasis that is not amenable to stereotactic radiosurgery (SRS) or surgical resection based on size or location OR four or more lesions\n\* Patients may be symptomatic at the time of enrollment, but after any necessary local therapy and/or corticosteroids, the patient should be asymptomatic when vemurafenib is initiated.\n\* Age \\>18\n\* Adequate organ function\n\* ECOG performance status \\< 3\n\* No prior therapies with selective inhibitors of mutated BRAF; other prior therapies must have been administered at least 4 weeks before administration of vemurafenib\n\* Life expectancy of at least 3 months\n\* Understanding and willingness to consent\n\* The use of corticosteroids to control cerebral edema or treat symptoms will be allowed\n\* A history of whole brain radiotherapy for brain metastases is allowed, but any stable lesion that was present at the time of WBRT will NOT be considered evaluable. A minimum of 1 week break will be required between prior WBRT and initiation of vemurafenib therapy.\n\nExclusion Criteria:\n\n\* Presence of leptomeningeal disease based on positive CSF cytology.\n\* History or presence of clinically significant ventricular or atrial dysrhythmias \u2265 Grade 2 (NCI CTCAE, v4.0), Corrected QT (QTc) interval \\>450 ms at baseline or history of congenital long QT syndrome\n\* Uncontrolled medical illness, such as uncontrolled infection, congestive heart failure and MI within 2 months.\n\* Second active, untreated malignancy, which is likely to result in the patient's demise prior to death from uncontrolled melanoma CNS metastases. This will be determined on a case by case basis by the PIs.\n\* Unwillingness to undergo monitoring for a secondary malignancy including clinical dermatologic examinations and head and neck examinations and serial CT scans.",  
 "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 information, a patient with a BRAF gene mutation would be eligible for the clinical trial if they meet the following specific inclusion criteria:  
  
- They must have biopsy-proven metastatic melanoma with the B-raf V600E or V600K mutations.  
- They must have untreated brain metastases.  
- They should have at least one cerebral metastasis that is not amenable to stereotactic radiosurgery (SRS) or surgical resection based on size or location, or have four or more lesions.  
- The patient should be asymptomatic following any necessary local therapy and/or corticosteroids when vemurafenib is initiated.  
  
Additionally, the patient must meet other general inclusion criteria, such as:  
  
- Age greater than 18 years.  
- Adequate organ function.  
- An Eastern Cooperative Oncology Group (ECOG) performance status of less than 3.  
- No prior therapies with selective inhibitors of mutated BRAF, and any other prior therapies must have been administered at least 4 weeks before starting vemurafenib.  
- A life expectancy of at least 3 months.  
- The ability to understand and willingness to provide consent.  
- The ability to take corticosteroids to control cerebral edema or treat symptoms as needed.  
- If they received whole brain radiotherapy (WBRT) previously, a stable lesion that was present at the time of WBRT will not be considered evaluable, and there needs to be at least a 1-week break between prior WBRT and venurafenib therapy initiation.  
  
The patient must not meet the exclusion criteria, which include:  
  
- Presence of leptomeningeal disease based on positive CSF cytology.  
- History or presence of significant cardiac dysrhythmias or a corrected QT (QTc) interval over 450 ms at baseline or history of congenital long QT syndrome.  
- Uncontrolled medical illnesses.  
- A second active, untreated malignancy expected to lead to the patient's death before melanoma CNS metastases.  
- Unwillingness to undergo monitoring for a secondary malignancy.  
  
If a patient with a BRAF gene mutation (specifically V600E or V600K) meets all these inclusion criteria and does not meet any exclusion criteria, they would be eligible for participation in this clinical trial.