# Clinical Trials Data BRAF - Document 52

# Vemurafenib and White Blood Cell Therapy for Advanced Melanoma

## Clinical Trial: https://clinicaltrials.gov/study/NCT01585415

"eligibilityCriteria": "-INCLUSION CRITERIA:\n\n1. Measurable metastatic melanoma that expresses the VtoE BRAF mutation and VtoK BRAF mutation assessed in a CLIA certified laboratory.\n2. Patients with 3 or less brain metastases that are less than 1 cm in diameter and asymptomatic are eligible. Lesions that have been treated with stereotactic radiosurgery must be clinically stable for 1 month after treatment for the patient to be eligible. Patients with surgically resected brain metastases are eligible.\n3. Greater than or equal to 18 and less than or equal to 66 years of age.\n4. Patients of both genders must be willing to practice birth control from the time of enrollment on the study and for four months after treatment.\n5. Life expectancy of greater than three months\n6. Women of child-bearing potential must have a negative pregnancy test because of the potentially dangerous effects of the treatment on the fetus.\n7. Willing to sign a durable power of attorney.\n8. Able to understand and sign the Informed Consent Document\n9. Clinical performance status of ECOG 0 or 1.\n10. Hematology:\n\n \* Absolute neutrophil count greater than 1000/mm(3)\n \* Hemoglobin greater than 8.0 g/dl\n \* Platelet count greater than 100,000/mm(3)\n11. Serology:\n\n \* Seronegative for HIV antibody. (The experimental treatment being evaluated in this protocol depends on an intact immune system. Patients who are HIV seropositive can have decreased immune competence and thus be less responsive to the experimental treatment and more susceptible to its toxicities.)\n \* Seronegative for hepatitis B antigen, or hepatitis C antibody or antigen.\n12. Chemistry:\n\n \* Serum ALT/AST less than three times the upper limit of normal.\n \* Calculated creatinine clearance (eGFR) \\> 50 ml/min.\n \* Total bilirubin less than or equal to 2 mg/dl, except in patients with Gilbert s Syndrome who must have a total bilirubin less than 3 mg/dl.\n13. More than four weeks must have elapsed since any prior systemic therapy at the time of treatment, and patients toxicities must have recovered to a grade 1 or less (except for alopecia or vitiligo). Patients must have stable or progressing disease after prior treatment.\n\n Note: Patients may have undergone minor surgical procedures within the past 3 weeks, as long as all toxicities have recovered to grade 1 or less or as specified in the eligibility criteria in Section 2.1.1.\n14. Six weeks must have elapsed from the time of any antibody therapy that could affect an anti cancer immune response, including anti-CTLA4 antibody therapy at the time the patient receives the preparative regimen to allow antibody levels to decline.\n\n Note: Patients who have previously received ipilimumab and have documented GI toxicity must have a normal colonoscopy with normal colonic biopsies.\n15. EKG with mean QTc interval \\< 450 msec.\n\nEXCLUSION CRITERIA:\n\n1. Prior cell transfer therapy which included a myeloablative chemotherapy regimen (i.e. 1200 TBI or 200 TBI plus chemotherapy).\n2. Previous treatment with Vemurafenib.\n3. Women of child-bearing potential who are pregnant or breastfeeding because of the potentially dangerous effects of the treatment on the fetus or infant.\n4. Systemic steroid therapy requirement.\n5. Active systemic infections, coagulation disorders or other active major medical illnesses of the cardiovascular, respiratory or immune system, as evidenced by a positive stress thallium or comparable test, myocardial infarction, cardiac arrhythmias, obstructive or restrictive pulmonary disease.\n6. Any form of primary immunodeficiency (such as Severe Combined Immunodeficiency Disease and AIDS).\n7. Opportunistic infections (The experimental treatment being evaluated in this protocol depends on an intact immune system. Patients who have decreased immune competence may be less responsive to the experimental treatment and more susceptible to its toxicities.)\n8. History of severe immediate hypersensitivity reaction to any of the agents used in this study.\n9. History of coronary revascularization or ischemic symptoms.\n10. Any patient known to have an LVEF less than or equal to 45 percent.\n11. In patients \\> 60 years old, documented LVEF of less than or equal to 45 percent.",  
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 "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:  
The patient having a BRAF gene mutation \*\*might\*\* be eligible, but more information is needed. The trial specifies needing "Measurable metastatic melanoma that expresses the \*\*VtoE BRAF mutation and VtoK BRAF mutation\*\* assessed in a CLIA certified laboratory." Simply having \*a\* BRAF mutation isn't sufficient; it must specifically be \*both\* the VtoE and VtoK mutations. If the patient has these specific mutations, then they could be eligible provided they also meet all other inclusion criteria and none of the exclusion criteria.