# Clinical Trials Data BRAF - Document 32

# A Study of Sorafenib in Patients With Chemonaive Metastatic Uveal Melanoma

## Clinical Trial: https://clinicaltrials.gov/study/NCT01377025

"eligibilityCriteria": "Inclusion criteria:\n\n1. Signed and dated written informed consent before the start of specific protocol procedures\n2. Metastatic uveal melanoma with histological or cytological confirmation of liver metastasis\n3. By means of whole body MRI documented disease according to RECIST version 1.1 with at least one unidimensional measurable lesion \u2265 10 mm\n4. Eastern Cooperative Oncology Group (ECOG) performance status of 0, 1, or 2\n5. Male or female patients \u2265 18 years of age\n6. Estimated life-expectancy more than 5 months\n7. Hematologic function, as follows:\n\n \* Absolute neutrophil count (ANC) \u2265 1.5 x 109/L\n \* Platelet count \u2265 100 x 109/L\n \* Hemoglobin \u2265 9 g/dL\n8. Renal function, as follows\n\n -Creatinine \u2264 1.5 x upper limit of normal (ULN)\n9. Hepatic function, as follows\n\n \* Aspartate aminotransferase (AST) \u2264 2.5 x ULN\n \* Alanine aminotransferase (ALT) \u2264 2.5 x ULN\n \* Total bilirubin \u2264 3 mg/dl\n \* Alkaline phosphatase \u2264 4.0 x ULN\n10. PT-INR/PT \\< 1.5 x ULN\n11. Females of childbearing potential (FCBP) must have a negative pregnancy test within 7 days of the first application of study treatment and must agree to use effective contraceptive birth control measures\n12. Males must agree to use barrier birth control measures (condoms) during the course of the trial.\n\nExclusion criteria:\n\n1. Previous or concurrent tumor other than uveal melanoma with the exception of cervical cancer in situ, adequately treated basal cell carcinoma, superficial bladder tumors (Ta, Tis, and T1) or any curatively treated tumors \\> 3 years prior to enrollment\n2. History of cardiac disease: congestive heart failure \u2265 NYHA class 2; active coronary artery disease (\\[CAD\\], myocardial infarction more than 6 months prior to study entry is allowed), cardiac arrhythmias requiring antiarrhythmic therapy (only beta blockers or digoxin are permitted)\n3. QT/QTc-interval prolongation (QTc\\> 450 msec) on ECG, known Long QT syndrome or known Long QT syndrome in relatives\n4. Known HIV infection\n5. Known chronic infection with hepatitis B or C\n6. Hypokalemia, hypocalcemia, hypomagnesemia or patients under actual treatment against hypokalemia, hypocalcemia, hypomagnesemia\n7. Active infection requiring systemic antibiotic/antiviral/antifungal treatment or any uncontrolled infection \\> Grade 2 NCI-CTCAE\n8. Symptomatic brain or meningeal tumors (unless patient is \\> 6 months from definitive therapy, had a negative imaging study within 4 weeks of study entry and is clinically stable with respect to the tumor at the time of study enrollment)\n9. Patients with seizure disorder requiring medication (such as steroids or antiepileptics)\n10. History of organ allograft\n11. Patients with evidence or history of bleeding diathesis\n12. Thrombotic or embolic events within the last 6 months\n13. Serious non-healing wound, ulcer or fracture\n14. Uncontrolled arterial hypertension with systolic blood pressure \\>150 mm Hg and/ or diastolic blood pressure \\> 90 mg Hg despite optimal treatment, determined twice within one week\n15. Pregnant or breast-feeding patients\n16. Marked claustrophobia\n17. Cardiac pacemaker, cochlea implants or other implanted metal devices, residual metal splinters\n18. Known allergy to the used study drug sorafenib or to any of its excipients\n19. Known hypersensitivity to gadolinium based contrast agents\n20. Subject unwilling or unable to comply with study requirements\n21. Substance abuse, medical, psychological or social conditions that may interfere with the patient's participation in the study or evaluation of the study results\n22. Participation in any clinical study or treatment with an experimental drug or experimental therapy within 28 days prior to study enrollment or during study participation",  
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 "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:  
This trial is specifically for \*\*uveal melanoma\*\* with liver metastasis. The eligibility criteria do \*\*not\*\* mention anything about BRAF mutation status. Therefore, having a BRAF mutation would \*not\* automatically exclude a patient, but they would still need to meet all other inclusion criteria and not have any of the exclusion criteria.