# Clinical Trials Data BRAF - Document 55

# Neoadjuvant Dabrafenib + Trametinib for AJCC Stage IIIB-C BRAF V600 Mutation Positive Melanoma

## Clinical Trial: https://clinicaltrials.gov/study/NCT01972347

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Age \u226518 years\n\* Histologically confirmed AJCC Stage IIIB or IIIC (Tx, T1-4, N1b, N2b, N2c, N3, Mo) cutaneous melanoma or unknown primary determined to be BRAF V600 mutation positive, with sufficient nodal or in-transit disease to enable biopsies prior to surgery.Patients must have disease that is measurable per RECIST version 1.1\n\* Able to swallow and retain oral medication and must not have any clinically significant gastrointestinal abnormalities that may alter absorption\n\* Eastern Cooperative Oncology Group (ECOG) Performance Status of 0-1\n\* Adequate baseline organ function\n\* Women of childbearing potential must have a negative serum pregnancy test within 7 days of first dose of study treatment and agree to use effective contraception from 14 days prior to commencing study treatment, throughout the treatment period and for 4 months after the last dose of study treatment\n\* Men with any female partner of childbearing potential must agree to use effective contraception from 14 days prior to commencing study treatment, throughout the treatment period and for 4 months after the last dose of study treatment\n\nExclusion Criteria:\n\n\* Known mucosal or ocular melanoma or any unresectable in-transit metastases\n\* Evidence of distant metastatic disease on screening evaluation\n\* Prior anti-cancer treatment for melanoma (chemotherapy, immunotherapy, biologic therapy, vaccine therapy, investigational treatment or radiotherapy). Prior surgery for melanoma is allowed.\n\* Taken an investigational drug within 28 days or 5 half-lives, whichever is longer, prior to commencing study treatment.\n\* Current or expected use of a prohibited medication(s)\n\* Known immediate or delayed hypersensitivity reaction or idiosyncrasy to drugs chemically related to the study treatments, their excipients, and/or dimethyl sulfoxide (DMSO)\n\* Known HIV\n\* A history of known glucose-6-phosphate dehydrogenase (G6PD) deficiency\n\* History of another malignancy or a concurrent malignancy except:\n\n 1. Patients who have been disease-free for 3 years and have a life expectancy of \\> 5 years;\n 2. Patients with a history of completely resected non-melanoma skin cancer or successfully treated in situ carcinoma are eligible, for example cervical cancer in situ, atypical melanocytic hyperplasia or melanoma in situ, multiple primary melanomas.\n\* A history or evidence of cardiovascular risk including any of the following: a. QT interval corrected for heart rate using the Bazett's formula \u2265480 msec or \u2265 450 msec for patients with bundle branch block; b. History or evidence of current clinically significant uncontrolled arrhythmias; c. History of acute coronary syndromes (including myocardial infarction or unstable angina), coronary angioplasty, or stenting within 6 months prior to commencement of study treatment; d. History or evidence of current \u2265 Class II congestive heart failure; e. Abnormal cardiac valve morphology documented by echocardiogram which in the opinion of the investigator could interfere with the patient's safety.\n\n f. Treatment refractory hypertension defined as a blood pressure of systolic \\> 140 mm Hg and/or diastolic \\> 90 mm Hg which cannot be controlled by anti-hypertensive therapy.\n\* A history or current evidence/risk of retinal vein occlusion (RVO) or central serous retinopathy (CSR)\n\* Any serious or unstable pre-existing medical conditions (aside from the malignancy exceptions specified above), psychiatric disorders, or other conditions that, in the opinion of the treating clinician, could interfere with the patient's safety, obtaining informed consent, or compliance with study procedures.\n\* Breastfeeding females",  
 "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 V600 mutation \*could\* be eligible for this trial, but it depends on several other factors. The inclusion criteria specifically require a BRAF V600 mutation, which is good. However, they must also meet \*all\* other inclusion criteria and \*none\* of the exclusion criteria.  
  
Here's a breakdown of what else needs to be considered for eligibility:  
  
\*\*Factors that could make the patient INELIGIBLE:\*\*  
  
\* \*\*Stage of Melanoma:\*\* Must be AJCC Stage IIIB or IIIC cutaneous melanoma or unknown primary. Other stages are excluded.  
\* \*\*Measurable Disease:\*\* Must have sufficient nodal or in-transit disease measurable by RECIST 1.1. Unresectable in-transit metastases or distant metastatic disease are excluded.  
\* \*\*Prior Treatment:\*\* No prior anti-cancer treatment for melanoma (except surgery) is allowed.  
\* \*\*Other Medical Conditions:\*\* Several pre-existing conditions are exclusionary, including mucosal or ocular melanoma, specific cardiovascular risks, retinal vein occlusion, central serous retinopathy, HIV, G6PD deficiency, other active malignancies (with some exceptions), and any other condition the clinician deems could interfere with the study.  
\* \*\*Medications:\*\* Must not be taking prohibited medications, have hypersensitivity to study drugs or related compounds, or have recently taken another investigational drug.  
\* \*\*Ability to take oral medication:\*\* Must be able to swallow and retain oral medication and have no GI issues affecting absorption.  
\* \*\*ECOG Performance Status:\*\* Must be 0 or 1.  
\* \*\*Adequate Organ Function:\*\* Baseline organ function must be adequate.  
\* \*\*Reproductive Status:\*\* Women of childbearing potential must have a negative pregnancy test and use effective contraception. Men with partners of childbearing potential must also use contraception. Breastfeeding females are excluded.  
  
In summary, simply having the BRAF V600 mutation is not enough. A thorough review of the patient's medical history and current condition is necessary to determine their eligibility.