# Clinical Trials Data BRAF - Document 40

# BRAF Inhibitor, Vemurafenib, in Patients With Relapsed or Refractory Hairy Cell Leukemia

## Clinical Trial: https://clinicaltrials.gov/study/NCT01711632

"eligibilityCriteria": "Inclusion Criteria:\n\n\* \u2265 18 years of age\n\* Histologically confirmed classical HCL with one of the following:\n\* Intolerance to purine analogs or considered to be poor candidates for purine analog-based therapy\n\* Failure to achieve any response (CR or PR) to the initial purine analog-based therapy\n\* Relapse \u2264 2 years of purine analog-based therapy\n\* \u2265 2 relapses Histologic confirmation of diagnosis will be performed at MSKCC or a participating site.\n\* Patients who meet the standard treatment initiation criteria, as defined by ANC \u22641.0, Hgb \u2264 10.0 or PLT \u2264100K\n\* ECOG performance status of 0-2\n\* Acceptable pre-study organ function during screening as defined as: Total bilirubin \u2264 1.5 times the upper limit of normal (ULN), aspartate aminotransferase (AST) and alanine aminotransferase (ALT) \u2264 2.5x ULN, and serum creatinine \u2264 1.5x ULN\n\* Electrocardiogram (ECG) without evidence of clinically significant ventricular arrhythmias or ischemia as determined by the investigator and a rate-corrected QT interval (QTc, Bazett's formula) of \\< 480 msec.\n\* For women of childbearing potential, agreement to the use of two acceptable methods of contraception, including one barrier method, during the study and for 6 months after discontinuation of vemurafenib\n\* For men with female partners of childbearing potential, agreement to use a latex condom and to advise their female partner to use an additional method of contraception during the study and for 6 months after discontinuation of vemurafenib\n\* Negative serum pregnancy test within 7 days of commencement of treatment in premenopausal women.\n\* Agreement not to donate blood or blood products during the study and for at least 6 months after discontinuation of vemurafenib; for male partners, agreement not to donate sperm during the study and for at least 6 months after discontinuation of vemurafenib\n\* Ability to understand and willingness to sign a written informed consent document.\n\* Willingness and ability to comply with scheduled visits, treatment plans, laboratory tests, and other study procedures.\n\nExclusion Criteria:\n\n\* Pregnant or breast-feeding\n\* Have had chemotherapy (including purine analogs, rituximab, and other investigational agents) within six weeks prior to entering the study\n\* Major surgery within 4 weeks prior to entering the study\n\* Invasive malignancy within the past 2 years prior to first study drug administration, except for adequately treated (with curative intent) basal or squamous cell carcinoma, melanoma, in situ carcinoma of the cervix, in situ ductal adenocarcinoma of the breast, in situ prostate cancer, or limited stage bladder cancer or other cancers from which the patient has been disease-free for at least 2 years\n\* Refractory nausea or vomiting, malabsorption, external biliary shunt, or history of any type of gastrointestinal surgery that would preclude adequate absorption of study drug\n\* Prior treatment with MEK or BRAF inhibitors\n\* Active HIV, hepatitis B and hepatitis C\n\* Patients with HCL variant (as defined by absence of expression of CD25 or absence of BRAF V600E mutation)",  
 "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 eligibility criteria provided for the clinical trial, it appears that patients with the BRAF V600E mutation are specifically relevant to the trial, particularly in the inclusion and exclusion criteria that list the necessity for diagnosis confirmation and mutation expression.   
  
However, the exclusion criteria specifically mention that patients with "HCL variant (as defined by absence of expression of CD25 or absence of BRAF V600E mutation)" are not eligible for the study. This implies that patients must have the BRAF V600E mutation to participate.   
  
Therefore, a patient with a BRAF V600E mutation would be eligible for this trial if they meet all other inclusion criteria and do not meet any exclusion criteria.