# Clinical Trials Data BRAF - Document 54

# A Phase Ib/II Study of LGX818 in Combination With MEK162 in Adult Patients With BRAF Dependent Advanced Solid Tumors

## Clinical Trial: https://clinicaltrials.gov/study/NCT01543698

"eligibilityCriteria": "Inclusion Criteria:\n\nHistologically confirmed diagnosis of locally advanced or metastatic melanoma (stage IIIB to IV per American Joint Committee on Cancer \\[AJCC\\]), or confirmed diagnosis of non-resectable advanced metastatic colorectal cancer (mCRC), or any other indication upon agreement with the Sponsor, whose disease has progressed despite previous antineoplastic therapy or for whom no further effective standard therapy is available\n\n\* Written documentation of BRAF V600E mutation, or any other BRAF V600 mutation\n\* Evidence of measurable disease as determined by RECIST v1.1\n\* World Health Organization (WHO) Performance Status \u2264 2\n\* Negative serum pregnancy test within 72 hours prior to the first study dose in all women of childbearing potential\n\nExclusion Criteria:\n\nProgressive disease following prior treatment with RAF-inhibitors in combination with MEK-inhibitors\n\n\* Symptomatic or untreated leptomeningeal disease\n\* Symptomatic brain metastases. Patients are not permitted to receive enzyme inducing anti-epileptic drugs\n\* Known acute or chronic pancreatitis\n\* History or current evidence of retinal disease, retinal vein occlusion or ophthalmopathy\n\* Clinically significant cardiac disease\n\* Patients with abnormal laboratory values at Screening/baseline\n\* Impairment of gastrointestinal (GI) function or GI disease that may significantly alter the absorption of oral LGX818/MEK162\n\* Previous or concurrent malignancy\n\* Pregnant or nursing (lactating) women\n\* For addition of LEE011 in the triple combination, congenital long QT syndrome or family history of unexpected sudden cardiac death and/or hypokalemia CTCAE Grade \u2265 3, brain metastases at baseline, abnormal coagulation results PT/INR \\>1.5 x ULN or aPTT \\>1.5 x ULN.\n\nOther protocol-defined inclusion/exclusion criteria may apply",  
 "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 eligibility criteria, a patient with a BRAF gene mutation, specifically a BRAF V600E mutation or any other BRAF V600 mutation, would be eligible for the clinical trial, assuming they also meet all other inclusion criteria and do not fall under any of the exclusion criteria. The inclusion criteria explicitly require "written documentation of BRAF V600E mutation, or any other BRAF V600 mutation" as one of the factors for selection.   
  
However, the exclusion criteria must also be considered. The patient should not have progressive disease following prior treatment with RAF-inhibitors in combination with MEK-inhibitors and must not have any other listed conditions or factors such as significant cardiac disease, symptomatic brain metastases, or other outlined in the exclusion list.  
  
If the patient meets the inclusion criteria and none of the exclusion criteria apply, then they would be eligible for participation in this clinical trial.