# 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:  
A patient with a BRAF V600E mutation \*could\* be eligible for this trial, but more information is needed. The inclusion criteria specify having this mutation (or any other BRAF V600 mutation) as a requirement. However, there are many other inclusion and exclusion criteria that must also be met.  
  
Here's why more information is needed:  
  
\* \*\*Other Conditions:\*\* The patient's overall health status must be considered. Do they have any of the exclusionary conditions (e.g., brain metastases, cardiac disease, pancreatitis, retinal issues, abnormal lab values, GI issues, prior malignancy)?  
\* \*\*Prior Treatment:\*\* Has the patient received prior treatment with RAF-inhibitors in combination with MEK-inhibitors? If so, they would be excluded.  
\* \*\*Disease Status:\*\* The patient needs to have a histologically confirmed diagnosis of one of the specified cancers (melanoma, mCRC, or other approved indication) and measurable disease per RECIST v1.1. The cancer must also have progressed despite prior therapy or have no further standard therapy available.  
\* \*\*Performance Status:\*\* The patient must have a WHO Performance Status of 2 or less.  
\* \*\*Additional Exclusion Criteria for LEE011:\*\* If the trial involves the triple combination with LEE011, there are further exclusions related to long QT syndrome, family history of sudden cardiac death, hypokalemia, brain metastases, and abnormal coagulation results.  
  
In short, having the BRAF V600E mutation is a necessary but not sufficient condition for eligibility. A full medical evaluation is required to determine if the patient meets \*all\* the inclusion criteria and \*none\* of the exclusion criteria.