# Clinical Trials Data KRAS - Document 38

# A Study of MEHD7945A and Cobimetinib in Patients With Locally Advanced or Metastatic Cancers With Mutant KRAS

## Clinical Trial: https://clinicaltrials.gov/study/NCT01986166

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Locally advanced or metastatic solid KRAS-mutant tumors, for which standard therapies do not exist, have proven ineffective or intolerable or are considered inappropriate\n\* Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1\n\* Evaluable disease or disease measurable per modified Response Evaluation Criteria in Solid Tumors version 1.1 (RECIST v1.1)\n\* Consent to provide archival tumor tissue for biomarker testing\n\* Additionally, for patients who are considered for enrollment into the indication specific expansion cohorts in Stage 2, the current cancer must be either KRAS-mutant colorectal cancer (CRC) or KRAS-mutant non-small cell lung cancer (NSCLC)\n\nExclusion Criteria:\n\n\* History of prior significant toxicity from another MEK pathway inhibitor or combination of another MEK and epidermal growth factor receptor (EGFR) inhibitor requiring discontinuation of treatment\n\* Previous treatment with a combination of a MEK inhibitor with an EGFR inhibitor (applies only to the indication specific expansion cohorts in Stage 2)\n\* Allergy or hypersensitivity to components of the cobimetinib formulations\n\* History of severe (Grade 3 or 4) allergic or hypersensitivity reaction to therapeutic antibodies that required discontinuation of therapy\n\* History of interstitial lung disease (ILD)\n\* Known severe ulcer disease\n\* History of or evidence of retinal pathology on ophthalmologic examination that is considered a risk factor for neurosensory retinal detachment, central serous chorioetinopathy (CSCR), retinal vein occlusion (RVO), or neovascular macular degeneration\n\nPatients will be excluded if they currently have either of the following conditions which have been identified as risk factors for CSCR:\n\n\* Uncontrolled glaucoma with intraocular pressure greater than (\\>) 21 millimeters of mercury (mm Hg)\n\* Grade greater than equal to (\\>=) 3 hypertriglyceridemia",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "18 Years",  
"stdAges": [  
"ADULT",  
"OLDER\_ADULT"  
]

Question:  
Based on the following clinical trial information, would a patient with a KRAS gene mutation be eligible for the clinical trial?

Answer:  
Based on the inclusion and exclusion criteria provided, a patient with a KRAS gene mutation would indeed be eligible to participate in the clinical trial, provided that they meet all other specific conditions listed:  
  
- They must have a locally advanced or metastatic solid tumor with a KRAS mutation.  
- Standard therapies must not exist for their condition, or they must have proven ineffective, intolerable, or inappropriate.  
- The patient should have an ECOG performance status of 0 or 1.  
- They must have evaluable or measurable disease according to RECIST v1.1.  
- The patient must consent to provide archival tumor tissue for biomarker testing.  
  
For patients in the indication-specific expansion cohorts in Stage 2, they must have KRAS-mutant colorectal cancer or KRAS-mutant non-small cell lung cancer.   
  
They must not fall under any of the exclusion criteria, such as having a history of significant toxicity to a MEK pathway inhibitor, allergy to treatment components, severe allergic reactions, interstitial lung disease, known severe ulcer disease, specific retinal pathologies, uncontrolled glaucoma, or severe hypertriglyceridemia.  
  
If a patient with a KRAS gene mutation does not meet any of the exclusion criteria and satisfies all inclusion conditions, they would generally be eligible for this clinical trial.