# Clinical Trials Data KRAS - Document 37

# Vemurafenib, Cetuximab, and Irinotecan Hydrochloride in Treating Patients With Solid Tumors That Are Metastatic or That Cannot Be Removed by Surgery

## Clinical Trial: https://clinicaltrials.gov/study/NCT01787500

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Patients must have histologically confirmed malignancy that is metastatic or unresectable\n\* Cancers with positive BRAF V600 mutation detected by a Clinical Laboratory Improvement Act (CLIA)-certified laboratory\n\* Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2\n\* Life expectancy of greater than 3 months\n\* Patients must have measurable disease per Response Evaluation Criteria in Solid Tumors (RECIST) 1.1 criteria\n\* Patients must have a K-RAS wild-type (WT) tumor\n\* Absolute neutrophils count \\>= 1500/mcl (within 14 days)\n\* Platelets \\>= 100000/mcl (within 14 days)\n\* Hemoglobin (Hb) \\>= 9 mg/dl (within 14 days)\n\* Total bilirubin =\\< 1.5 mg/dl (within 14 days)\n\* Aspartate aminotransferase (AST)/alanine aminotransferase (ALT) =\\< 5 x upper limit of normal if liver metastases present; otherwise, then =\\< 2.5 x upper limit (within 14 days)\n\* Estimated creatinine clearance by Cockcroft-Gault equation \\> 30 mL/min (within 14 days)\n\* Current treatment may cause harm to the developing human fetus; for this reason women of child-bearing age must have a negative pregnancy test at screening and both women of child-bearing potential and men must agree to use adequate contraception (hormonal or barrier method of birth control; abstinence) prior to study entry and for the duration of study participation, and for 6 months after last dose; should a woman become pregnant or suspect she is pregnant while she or her partner is participating in this study, she should inform her treating physician immediately\n\* Signed informed consent approved by the Institutional Review Board prior to patient entry\n\* Expansion cohort: We propose a final expansion cohort for this study in a subset of interest utilizing the recommended dosing of combination; this cohort will include patients harboring characteristics that may predict response of combination or with clinical features that proved to derive most benefit of the study combination during preclinical studies; cancers with positive BRAF (V600) mutation detected by a CLIA-certified laboratory\n\nExclusion Criteria:\n\n\* Patient receiving any concurrent chemotherapy\n\* Concurrent severe and/or uncontrolled medical disease including, but not limited to, ongoing or active infection requiring intravenous antibiotics, bowel obstruction\n\* Symptomatic congestive heart failure (New York Heart Association \\[NYHA\\] class III or IV), or unstable angina pectoris\n\* Patients who have had a myocardial infarction, transient ischemic attack, unstable angina, or cardiovascular symptoms (CVS) within 6 months before treatment\n\* Presence of symptomatic pleural and/or pericardial effusion not appropriately treated\n\* Prolonged corrected QT (QTc) interval (\\>= 450 msec) as calculated by Bazett's formula, or patients with a history of congenital long QT syndrome or uncorrectable electrolyte abnormalities\n\* Medical and/or psychiatric problems of sufficient severity to limit full compliance with the study or expose patients to undue risk\n\* Known anaphylactic or severe hypersensitivity to the study drugs or their analogs\n\* Patient has failed to recover from any prior surgery within 4 weeks of study entry\n\* Patient is pregnant, lactating, or breastfeeding\n\* Patient has had any treatment specific for tumor control within 3 weeks of dosing with investigational drugs and cytotoxic agents, or within 2 weeks of cytotoxic agent given weekly, or within 6 weeks of nitrosoureas or mitomycin C, or within 5 half-lives of biological targeted agents with half-lives and pharmacodynamic effects lasting less than 5 days\n\* Patient is not able to swallow oral medication\n\* Patients receiving any medications or substances that are strong inhibitors or inducers of cytochrome P450, family 3, subfamily A, polypeptide 4 (CYP3A4) complex are ineligible\n\* Patients with known K-RAS mutant (codon 12 or 13) detected by a Food and Drug Administration (FDA)-approved test in a CLIA-certified laboratory\n\* Patients with BRAF WT cancers",  
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"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:  
No. The inclusion criteria specifically require patients to have a K-RAS wild-type (WT) tumor. The exclusion criteria further specify that patients with known K-RAS mutations (codon 12 or 13) are ineligible. Therefore, a patient with a KRAS mutation would \*not\* be eligible for this trial.