# Clinical Trials Data KRAS - Document 21

# Trametinib, Fluorouracil, and Radiation Therapy Before Surgery in Treating Patients With Stage II-III Rectal Cancer

## Clinical Trial: https://clinicaltrials.gov/study/NCT01740648

"eligibilityCriteria": "Inclusion Criteria:\n\n\* All prior treatment-related toxicities must be Common Terminology Criteria for Adverse Events (CTCAE) (version 4.0) =\\< grade 1 (except alopecia) at the time of enrollment\n\* Absolute neutrophil count \\>= 1.5 x 10\\^9/L\n\* Hemoglobin \\>= 9 g/dL\n\* Platelets \\>= 100 x 10\\^9/L\n\* Prothrombin time (PT)/international normalized ratio (INR) =\\< 1.5 x upper limit of normal (ULN)\n\* Partial thromboplastin time (PTT) =\\< 1.5 x ULN\n\* Albumin \\>= 2.5 g/dL\n\* Total bilirubin =\\< 1.5 x ULN\n\* Aspartate aminotransferase (AST) and alanine aminotransferase (ALT) =\\< 2.5 x ULN\n\* Creatinine =\\< 1.5 ULN or calculated creatinine clearance \\>= 50 mL/min or 24-hour urine creatinine clearance \\>= 50 mL/min\n\* Left ventricular ejection fraction (LVEF) \\>= lower limit of normal (LLN) by echocardiogram (ECHO) or multi gated acquisition scan (MUGA)\n\* Life expectancy of at least 3 months in the opinion of investigator\n\* Able to swallow and retain orally administered medication and does not have any clinically significant gastrointestinal abnormalities that may alter absorption such as malabsorption syndrome or major resection of the stomach or bowels\n\* Patient has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1\n\* Ability to provide written informed consent obtained prior to participation in the study and any related procedures being performed\n\* Women of child-bearing potential (WOCBP) must have a negative pregnancy test within 14 days of the first administration of study treatment, and counseled on contraception/abstinence while receiving the study treatment; urine human chorionic gonadotropin (HCG) is an acceptable pregnancy assessment\n\* A histologically confirmed rectal cancer with measurable or evaluable disease on imaging or endoscopy\n\* Stage II or III disease by the American Joint Committee on Cancer (AJCC) 7th edition\n\* Specific tumor genetic eligibility criteria include:\n\n \* Presence of KRAS gene mutation (at codon 12, 13, or 61) for patients on expansion cohort.\n \* Presence of V600E BRAF gene mutation, or\n \* Presence of an NRAS mutation at codon 12, 13, or 61\n\nExclusion Criteria:\n\n\* History of another malignancy; exception: subjects who have been disease-free for 5 years, or subjects with a history of completely resected non-melanoma skin cancer or successfully treated in situ carcinoma are eligible\n\* Any serious and/or unstable pre-existing medical disorder (aside from malignancy exception above), psychiatric disorder, or other conditions that could interfere with subject's safety, obtaining informed consent or compliance to the study procedures, in the opinion of the Investigator\n\* Prior chemotherapy treatment unless \\> 5 years ago\n\* Prior treatment with a selective inhibitor of v-raf-1 murine leukemia viral oncogene homolog 1 (RAF) or mitogen-activated protein kinase kinase 1 (MEK)\n\* Prior radiation therapy to the abdomen or pelvis\n\* Have a known immediate or delayed hypersensitivity reaction or idiosyncrasy to drugs chemically related to study drug, or excipients or to dimethyl sulfoxide (DMSO)\n\* Current use of a prohibited medication\n\* History or current evidence / risk of retinal vein occlusion (RVO) or central serous retinopathy (CSR):\n\n \* History of RVO or CSR, or predisposing factors to RVO or CSR (e.g. uncontrolled glaucoma or ocular hypertension, uncontrolled systemic disease such as hypertension, diabetes mellitus, or history of hyperviscosity or hypercoagulability syndromes)\n \* Visible retinal pathology as assessed by ophthalmic exam that is considered a risk factor for RVO or CSR such as:\n\n \* Evidence of optic disc cupping\n \* Evidence of visual field defects\n \* Intraocular pressure \\> 21 mm Hg\n\* Known human immunodeficiency virus (HIV), hepatitis B virus (HBV), or hepatitis C virus (HCV) infection (with the exception of chronic or cleared HBV and HCV infection which will be allowed)\n\* History or evidence of cardiovascular risk including any of the following:\n\n \* Bazett correction QT (QTcB) \\>= 480 msec\n \* History or evidence of current clinically significant uncontrolled arrhythmias; exception: subjects with controlled atrial fibrillation for \\>30 days prior to enrollment are eligible\n \* History of acute coronary syndromes (including myocardial infarction and unstable angina), coronary angioplasty, or stenting within 6 months prior to enrollment\n \* History or evidence of current \\>= class II congestive heart failure as defined by New York Heart Association (NYHA)\n \* Treatment refractory hypertension defined as a blood pressure of systolic \\> 140 mmHg and/or diastolic \\> 90 mm Hg which cannot be controlled by anti-hypertensive therapy\n \* Patients with intra-cardiac defibrillators or permanent pacemakers\n \* Cardiac metastases\n\* Pregnancy or breastfeeding: 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; should a woman become pregnant or suspect she is pregnant while participating in this study, she should inform her treating physician immediately; no breastfeeding while patient is on study",  
 "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:  
Yes, a patient with a KRAS gene mutation (at codon 12, 13, or 61) would be eligible for this clinical trial. Specifically, the inclusion criteria state: "Specific tumor genetic eligibility criteria include...Presence of KRAS gene mutation (at codon 12, 13, or 61) for patients on expansion cohort." However, having the KRAS mutation is not the only requirement. The patient must also meet \*all\* other inclusion criteria and \*none\* of the exclusion criteria.