# Clinical Trials Data KRAS - Document 26

# Efficacy of FOLFOX Versus FOLFOX Plus Aflibercept in K-ras Mutant Patients With Resectable Liver Metastases

## Clinical Trial: https://clinicaltrials.gov/study/NCT01646554

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Histologically proven CRC with 1 to 8 metachronous or synchronous liver metastases considered to be completely resectable\n\* Primary tumor (or liver metastasis) of CRC must be KRAS status \"mutant\"\n\* Patients must have undergone complete resection (R0) of the primary tumor at least 4 weeks before randomization. Or for patients with synchronous metastases the primary tumor can be resected (R0) at the same time as the liver metastases if: the patient has a non-obstructive primary tumor and is able to receive preoperative chemotherapy (3-4 months) before surgery1.\n\* Measurable hepatic disease by RECIST version 1.1\n\* Patients must be 18 years old or older\n\* A World Health Organization (WHO) performance status of 0 or 1\n\* Previous adjuvant chemotherapy for primary CRC is allowed if completed at least 12 months before inclusion in this study\n\* All the following tests should be done within 4 weeks prior to randomization:\n\* Hematological status: neutrophils (ANC) = 1.5x10 9/L; platelets = 100x10 9/L; haemoglobin = 9g/dL\n\* Serum creatinine = 1.5 times the upper limit of normal (ULN)\n\* Proteinuria \\< 2+ (dipstick urinalysis) or =1g/24hour.\n\* Liver function: serum bilirubin = 1.5 x upper normal limit (ULN), alkaline phosphatase \\< 5xULN\n\* Magnesium \u2265 lower limit of normal (LLN)\n\* Patients with a buffer range from the normal values of +/- 5% for hematology and +/- 10% for biochemistry are acceptable. This will not apply for Renal Function, including Creatinine.\n\* Women of child bearing potential (WOCBP) must have a negative serum (or urine) pregnancy test within 14 days prior to the first dose of study treatment.\n\* Patients of childbearing / reproductive potential should use adequate birth control measures, as defined by the investigator, during the study treatment period and for at least 6 months after the last study treatment. A highly effective method of birth control is defined as those which result in low failure rate (i.e. less than 1% per year) when used consistently and correctly.\n\* Female subjects who are breast feeding should discontinue nursing prior to the first dose of study treatment and until 6 months after the last study treatment.\n\* Absence of any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule; those conditions should be discussed with the patient before registration in the trial\n\* Patient should be willing and able to comply with protocol requirements\n\* Before patient registration/randomization, written informed consent must be given according to ICH/GCP, and national/local regulations.\n\nExclusion Criteria:\n\n\* Evidence of extra-hepatic metastasis (of CRC)\n\* Previous chemotherapy for metastatic disease or surgical treatment (e.g. surgical resection or radiofrequency ablation) for liver metastasis. Radiotherapy alone is allowed if given pre or post protocol treatment\n\* Previous exposure to VEGF/VEGFR targeting therapy within the last 12 months\n\* Major surgical procedure, open biopsy, or significant traumatic injury within 4 weeks prior to randomization\n\* Gilbert's syndrome\n\* History of myocardial infarction and/or stroke within 6 months prior to randomization\n\* Uncontrolled hypertension (defined as systolic blood pressure \\>150 mmHg and/or diastolic blood pressure \\> 100 mmHg), or history of hypertensive crisis, or hypertensive encephalopathy\n\* History or evidence upon physical examination of CNS metastasis\n\* Bowel obstruction\n\* Uncontrolled hypercalcemia\n\* Pre-existing permanent neuropathy (NCI grade = 2)\n\* Known allergy to any excipient to study drugs",  
 "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 mutant CRC would be \*\*eligible\*\* for this trial, provided they also meet all other inclusion criteria and do not meet any of the exclusion criteria. The inclusion criteria specifically state: "Primary tumor (or liver metastasis) of CRC must be KRAS status "mutant"".