# Clinical Trials Data KRAS - Document 11

# Study of AUY922 and Cetuximab in Patients With KRAS Wild-Type Metastatic Colorectal Cancer

## Clinical Trial: https://clinicaltrials.gov/study/NCT01294826

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Histologically or cytologically confirmed colorectal cancer\n\* KRAS wild type metastatic colorectal cancer\n\* Progression of disease on at least 2 prior therapy to have included 5FU, or oxaliplatin or bevacizumab or irinotecan\n\* Prior treatment with cetuximab is allowed (full dose tolerated), provided that the patient never required a dose reduction due to toxicities\n\* Must have at least one measurable lesion\n\* Must be 18 years of age or older\n\* ECOG performance status 0-1\n\* Life expectancy must be greater than 12 weeks\n\* For women of childbearing potential, a negative pregnancy blood test must be obtained less than 3 days prior to the first AUY922 infusion\n\nExclusion Criteria:\n\n\* Colorectal cancer with a KRAS mutation or in which the KRAS genotype status is unknown\n\* Metastasis to the CNS\n\* Prior treatment with any Hsp90 inhibitor compounds\n\* Patients who received systemic anti-cancer treatment prior to the first dose of AUY922 within the following time frames:\n\n \* Radiotherapy, conventional chemotherapy: within 2 weeks\n \* Palliative radiotherapy: within 2 weeks\n \* Nitrosoureas, monoclonal antibodies, such as trastuzumab and mitomycin: within 6 weeks\n \* Any continuous-dosing (i.e. daily dosing, every-other-day dosing, Monday-Wednesday-Friday dosing, weekly etc.) of systemic anti-cancer treatment for which the recover period is not known, or investigational drugs (i.e. targeted agents) within a duration of \u2264 5 half lives of the agent and their active metabolites (if any)\n\* Treatment of therapeutic doses of coumadin-type anticoagulants. \\[Maximum daily dose of 2mg, for line patency permitted\\]\n\* Known sensitivity to cetuximab\n\* Unresolved \u2265 grade 1 diarrhea\n\* Malignant ascites that require invasive treatment\n\* Concurrent medications that are substrates, inhibitors or inducers of CYP3A4, CYP2C8, CYP2C9 and CYP2C19 and cannot be switched or discontinued or switched to an alternative drug prior to commencing AUY922 dosing need special consideration on a case by case basis\n\* Major surgery \u2264 2 weeks prior to randomization or who have not recovered from such therapy\n\* Impaired cardiac function",  
 "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:  
No. The inclusion criteria specifically state "KRAS wild type metastatic colorectal cancer." The exclusion criteria also explicitly state "Colorectal cancer with a KRAS mutation or in which the KRAS genotype status is unknown." Therefore, a patient with a KRAS mutation is \*not\* eligible for this trial.