# Clinical Trials Data KIT - Document 72

# Ipilimumab and Imatinib Mesylate in Advanced Cancer

## Clinical Trial: https://clinicaltrials.gov/study/NCT01738139

"eligibilityCriteria": "Inclusion Criteria:\n\n\* For dose escalation study, patients must have histological confirmation of solid tumors that is metastatic or unresectable. For expansion cohorts, patients must have metastatic or unresectable gastrointestinal stromal tumor (GIST), melanoma, or uncategorized tumors with tumor biopsies that are positive for c-KIT mutations by polymerase chain reaction (PCR) or immunohistochemistry (IHC). For patients enrolled in the melanoma expansion cohort, only select KIT mutations will be eligible. Patients with mutations in exon 13 V654X, 14 T6701, 17 D816X and all exon 18 mutations will not be eligible for enrollment.\n\* Patients who have completed previous therapies 4-weeks prior to (or within 5 drug half lives) enrollment on study. Radiation therapy wash out period will be 2 weeks. This includes an exception of patients with metastatic GIST tumors who are taking maintenance imatinib mesylate therapy. These patients are allowed to remain on imatinib mesylate therapy up to enrollment in this study.\n\* Eastern Cooperative Oncology Group (ECOG) performance status \\< 2 (Karnofsky \\> 60%).\n\* Leukocytes \\> 3,000/mcL\n\* Absolute neutrophil count \\> 1,500/mcL\n\* Platelets \\> 100,000/mcL\n\* Total bilirubin \\< or = 2.0 mg/dL. (Does NOT apply to patients with Gilbert's syndrome)\n\* Aspartate aminotransferase (AST) (serum glutamic-oxaloacetic transaminase \\[SGOT\\])/alanine aminotransferase (ALT) (serum glutamate pyruvate transaminase \\[SGPT\\]) \\< 2.5 X institutional upper limit of normal (patients with liver involvement will be allowed \\< or = 5.0 X institutional upper normal limit)\n\* Serum creatinine \\< 2.0 mg/dL\n\* Patients MUST have recovered from all treatment related toxicities to grade 1 National Center Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) (version \\[v\\] 4.0) in severity.\n\* Patients must be willing and able to review, understand, and provide written consent before starting therapy.\n\* Patients with histologically proven intracranial glioblastoma, gliosarcoma or anaplastic astrocytoma will be eligible. Patients must have shown unequivocal radiographic evidence for tumor progression by magnetic resonance imaging (MRI) scan. A scan should be performed within 14 days prior to registration and on a steroid dose that has been stable for at least 5 days. If the steroid dose is increased between the date of imaging and registration, a new baseline MRI is required.\n\* Patients in the expansion cohort must also agree to participate in the biomarker study. However, patients in the melanoma KIT positive mutant subgroup, patients must agree to participate in the biomarker study and biopsies.\n\* Patients must be willing to stay within 2 hours drive of MD Anderson Cancer Center whilst receiving Ipilimumab therapy. Patient must also agree to present to MD Anderson emergency center while on Ipilimumab therapy.\n\nExclusion Criteria:\n\n\* Autoimmune disease: Patients with a history of inflammatory bowel disease (including Crohn's disease and ulcerative colitis) and autoimmune disorders such as rheumatoid arthritis, systemic progressive sclerosis \\[scleroderma\\], systemic lupus erythematosus or autoimmune vasculitis \\[e.g., Wegener's granulomatosis\\] are excluded from this study.\n\* History of acute diverticulitis, intra-abdominal abscess, gastrointestinal (GI) obstruction, abdominal carcinomatosis or other known risk factors for bowel perforation.\n\* Any underlying medical or psychiatric condition, which in the opinion of the Investigator, will make the administration of study drug hazardous or obscure the interpretation of adverse events (AEs): e.g. a condition associated with frequent diarrhea or chronic skin conditions, recent surgery or colonic biopsy from which the patient has not recovered, or partial endocrine organ deficiencies.\n\* Uncontrolled intercurrent illness including, but not limited to, ongoing or active infection, history of congestive heart failure, unstable angina pectoris, cardiac arrhythmia, or psychiatric illness/social situations that would limit compliance with study requirements.\n\* Known human immunodeficiency virus (HIV), hepatitis B, or hepatitis C.\n\* Any non-oncology live vaccine therapy used for prevention of infectious diseases (for up to one month prior to or after any dose of ipilimumab).\n\* Concomitant therapy with any of the following: IL-2, interferon or other non-study immunotherapy regimens; cytotoxic chemotherapy; immunosuppressive agents; other investigational therapies; or chronic use of systemic corticosteroids (when used in the management of cancers other than intracranial glioblastoma, gliosarcoma or anaplastic astrocytoma, or when used to treat non-cancer-related illnesses).\n\* Patients who do not agree to practice appropriate birth control methods while on therapy.\n\* Pregnant women are excluded from this study. Women of child-bearing potential and men must agree to use contraception 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.",  
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"CHILD",  
"ADULT",  
"OLDER\_ADULT"  
]

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

Answer:  
A patient with a KIT gene mutation \*might\* be eligible for this trial, depending on several factors:  
  
\* \*\*Tumor Type:\*\* If the patient has a GIST, melanoma, or an uncategorized tumor with a KIT mutation, they \*could\* be eligible for an expansion cohort. However, for melanoma, certain KIT mutations in exons 13, 14, 17, and 18 are excluded. The specific mutation the patient has needs to be checked against the exclusion criteria. If the patient has a different type of solid tumor, they \*might\* be eligible for the dose escalation portion of the study.  
  
\* \*\*Other Eligibility Criteria:\*\* The patient must also meet \*all other\* inclusion criteria (performance status, blood counts, organ function, etc.) and \*not\* meet any of the exclusion criteria (autoimmune diseases, active infections, other medications, etc.).  
  
In summary, having a KIT mutation is not a guarantee of eligibility. More information about the patient's specific mutation, tumor type, and overall health status is needed to determine definitive eligibility.