# Clinical Trials Data BRAF - Document 27

# Study of MK-3475 in Patients With Microsatellite Unstable (MSI) Tumors (Cohorts A, B and C)

## Clinical Trial: https://clinicaltrials.gov/study/NCT01876511

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Cohort A only: Patients with microsatellite instability (MSI) positive colorectal cancer\n\* Cohort B only: Patients with MSI negative colorectal cancer\n\* Cohort C only: Patients with MSI positive non-colorectal cancer -\n\* Have measurable disease\n\* Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 to 1\n\* Adequate organ function as defined by study-specified laboratory tests\n\* Must use acceptable form of birth control through the study and for 28 days after final dose of study drug\n\* Signed informed consent form\n\* Willing and able to comply with study procedures\n\* Agree to have a biopsy of participants' cancer\n\* Patients with colon cancer must have received at least two prior cancer therapy regimens.\n\* Patients with other cancer types must have received at least one prior cancer therapy\n\* Progressive disease\n\nExclusion Criteria:\n\n\* Patients with uncontrolled intercurrent illness, including but not limited to ongoing or active infection, systematic congestive heart failure, unstable angina pectoris, cardiac arrhythmia or psychiatric condition that would limit compliance with study requirements.\n\* Patients who have had chemotherapy or biological cancer therapy within 2 weeks prior to the first dose of study drug\n\* Patients who have had radiation within 2 weeks prior to the first dose of study drug\n\* Patients who have undergone major surgery within 4 weeks of dosing of investigational agent\n\* Patients who have received another investigational product or investigational device within 4 weeks prior to receiving study drug\n\* Patients who have received any of the following concomitant therapy: Interleukin-2 (IL-2), interferon, or other non-study immunotherapy regimens, immunosuppressive agents, other investigational therapies or chronic use of systemic corticosteroids within one week prior to first dose of study drug\n\* Patients who have received a live vaccine within 4 weeks prior to or after any dose of MK-3475 (exception: inactivated flu vaccines)\n\* Patients who have received growth factors, including but not limited to granulocyte-colony stimulating factor (G-CSF), granulocyte macrophage-colony stimulating factor (GM-CSF), erythropoietin, etc. within 2 weeks of study drug administration\n\* Patient who have had prior treatment with anti-PD-1 (anti-programmed cell death protein 1), anti-PD-L1, anti-PD-L2, anti-CD137, anti-OX-40, anti-CD40, or anti-CTLA-4 antibodies\n\* Patients with history of any autoimmune disease:inflammatory bowel disease, (including ulcerative colitis and Crohn's Disease), rheumatoid arthritis, systemic progressive sclerosis (scleroderma), systemic lupus erythematosus (SLE) autoimmune vasculitis, central nervous system (CNS) or motor neuropathy considered to be of autoimmune origin.\n\* Patients who have known history of infection with HIV, hepatitis B, or hepatitis C\n\* Patients with evidence of interstitial lung disease\n\* Systemically active steroid use\n\* Patients on home oxygen\n\* Patients with oxygen saturation of \\<92% on room air by pulse oximetry\n\* Pregnant or lactating\n\* Conditions, including alcohol or drug dependence, or intercurrent illness that would affect the patient's ability to comply with study visits and procedures\n\* Patient with known active central nervous system metastases and/or carcinomatous meningitis.\n\* Patients with primary brain tumors.\n\* Requires any other form of systemic or localized antineoplastic therapy while on study\n\* Has any tissue or organ allograft\n\* Patients with history of allogeneic hematopoeitic stem cell transplant",  
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"ADULT",  
"OLDER\_ADULT"  
]

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

Answer:  
This trial information \*\*does not\*\* mention BRAF mutations as either an inclusion or exclusion criterion. Therefore, we \*\*cannot determine\*\* eligibility based on BRAF status alone. A patient with a BRAF mutation \*might\* be eligible if they meet \*all\* other inclusion criteria and \*none\* of the exclusion criteria for one of the cohorts (A, B, or C). They would need to have the specified type of cancer (MSI-positive colorectal, MSI-negative colorectal, or MSI-positive non-colorectal), have received the required prior therapies, and meet all other criteria regarding performance status, organ function, etc.