Cancer Research Consortium of West Michigan
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FAST FACTS

MATCH Treatment Subprotocol Z1D: Nivolumab in Patients with Tumors with Mismatch Repair Deficiency (Excluding Colorectal Cancer)

Nivolumab 240mg IV days 1 and 15 of each cycle. After 4 cycles of therapy, 480mg IV day 1 of each cycle until progression / Cycle = 28 days

1. Patients must fulfill all eligibility criteria outlined in Section 3.1 of MATCH Master Protocol (excluding Section 3.1. 4 and 3.1.6) at the time of registration to treatment step (Step 1, 3, 5, 7)
2. Patients must have mismatch repair deficiency as determined by the MATCH screening assessment. See Appendix I for a list of the mismatch repair genes whose absence results in mismatch repair deficiency and corresponding Levels of Evidence.
3. Patients must not have known hypersensitivity to nivolumab or compounds of similar chemical or biologic composition.
4. No prior therapy with anti-PD-1, anti-PD-L1, anti-PD-L2, anti-CD137, anti-OX-40, anti-CD40 or anti-CTLA-4 antibodies (or any other antibody targeting T cell co-regulatory pathways).
5. Patients with colorectal cancer are excluded.
6. Must not have received any of the following therapies within four weeks prior to the first dose of the study drug: IL-2, interferon, or other non-study immunotherapy regimens or immunosuppressive agents.The master protocol eligibility criterion regarding wash-out period from prior therapy is also applicable (See Section 3.1.13 of the Master Protocol).
7. Must not have a history of toxic epidermal necrolysis (Stevens-Johnson syndrome).
8. Must not 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. Use of such agents while on study is also prohibited. Prior use of growth factors should be documented in the patient's medical history.
9. Must not have a 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 (e.g., Wegener's Granulomatosis), CNS or motor neuropathy considered to be of autoimmune origin (e.g., Guillian-Barre Syndrome, Myasthenia Gravis, Multiple Sclerosis). Patients are permitted to enroll if they have vitiligo, type I diabetes mellitus, residual hypothyroidism due to autoimmune condition only requiring hormone replacement, psoriasis not requiring systemic treatment, or conditions not expected to recur in the absence of an external trigger (precipitating event). Entry of patients with autoimmune diagnoses not listed here must be approved by the protocol chair.
10. Must not be on supplemental home oxygen.
11. Must not have evidence of interstitial lung disease
12. Patients with a requirement for steroid treatment or other immunosuppressive treatment: Patients should be excluded if they have a condition requiring systemic treatment with either corticosteroids (>10 mg daily prednisone equivalents) within 14 days of study drug administration. Inhaled or topical steroids and adrenal replacement doses >10 mg daily prednisone equivalents are permitted in the absence of active autoimmune disease.
13. No history of severe hypersensitivity reaction to any monoclonal antibody.

14. Women of childbearing potential and men must agree to use adequate contraception (hormonal or double barrier method of birth control; abstinence) prior to study entry, for the duration of study participation, and for 31 weeks after completion of study (for male patients) and 23 weeks after completion of study (for female patients).
15. Patients with Hepatitis B Virus (HBV) or Hepatitis C Virus (HCV) infection may be eligible provided they have the following:
    - There must be no evidence of clinically significant hepatic injury from hepatitis virus infection.
    - For HBV, patients must be on suppressive therapy and have undetectable HBV viral load.
    - For HCV, patients must either be on suppressive therapy for HCV or have already completed therapy thought to have eradicated HCV.