Cancer Research Consortium of West Michigan
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FAST FACTS

ALLIANCE A071702 - A PHASE II STUDY OF CHECKPOINT BLOCKADE IMMUNOTHERAPY IN PATIENTS WITH SOMATICALLY HYPERMUTATED RECURRENT GLIOBLASTOMA

Pre-Registration Eligibility Criteria

1. Histologically confirmed glioblastoma (WHO grade IV) presenting at first or second recurrence including secondary glioblastoma.
2. Presence of measurable disease, as defined by a bidimensionally measurable lesion on MRI with a minimum diameter of 10 mm in both dimensions, prior to resection or biopsy of recurrent tumor.
3. Tissue available from surgical resection or biopsy of recurrent tumor ≤28 days prior to pre-registration, or planned surgery or biopsy of recurrent tumor ≤28 days after pre-registration.
4. Does not require > 4 mg dexamethasone beyond the perioperative period defined as the time ≤ 2 weeks after surgical procedure.
5. No active autoimmune disease or history of autoimmune disease.
    a. These include but are not limited to patients with a history of immune related neurologic disease, multiple sclerosis, autoimmune (demyelinating) neuropathy, Guillain-Barre syndrome, myasthenia gravis; systemic autoimmune disease such as SLE, connective tissue diseases, scleroderma, inflammatory bowel disease (IBD), Crohn's, ulcerative colitis, hepatitis; and patients with a history of toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome, or phospholipid syndrome should be excluded because of the risk of recurrence or exacerbation of disease.

    b. Patients with vitiligo, endocrine deficiencies including thyroiditis managed with replacement hormones including physiologic corticosteroids are eligible. Patients with rheumatoid arthritis and other arthropathies, Sjögren's syndrome and psoriasis controlled with topical medication and patients with positive serology, such as antinuclear antibodies (ANA), anti-thyroid antibodies should be evaluated for the presence of target organ involvement and potential need for systemic treatment but should otherwise be eligible.
6. No prior treatment with checkpoint blockade therapies (anti-CTLA4, anti-PD1/PD-L1) or bevacizumab.
7. No prior treatment with laser ablation at the time of recurrent tumor tissue sampling. Patients who have previously undergone laser ablation ≥ 4 months prior to recurrent tumor tissue sampling can be included.
8. Age ≥ 18 years
9. ECOG Performance Status ≤ 2
10. Able to undergo brain MRI with contrast
11. Adequate marrow and organ function as defined by the following:
    - Absolute Neutrophil Count ≥ 1500/mm3

    - Platelet count ≥ 100,000/mm3

    - Total bilirubin ≤ 1.5 x Upper Limit of Normal (ULN)*

    - Alanine aminotransferase (ALT) and aspartate aminotransferase (AST) ≤ 2.0 x ULN

    - Creatinine ≤ 1.5 x ULN **OR** creatinine clearance (CrCl) ≥ 50 mL/min
    (if using the Cockcroft-Gault formula below):
    Female CrCl = (140 - age in years) x weight in kg x 0.85
    72 x serum creatinine in mg/dL
    Male CrCl = (140 - age in years) x weight in kg x 1.00
    72 x serum creatinine in mg/dL
    * If Gilbert syndrome, then total bilirubin ≤ 3 x ULN

12. History of active malignancy (outside of the patient's glioblastoma) that has required treatment within the previous 2 years. Participant with prior history of in situ cancer or basal or squamous cell skin cancer are eligible.

Registration Eligibility Criteria

1. Tissue obtained from biopsy or resection at first or second recurrence exhibits TMB ≥ 10 on FoundationOne CDx testing

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