Anti-Lag-3 (Relatlimab) and Anti-PD-1 Blockade (Nivolumab) Versus Standard of Care (Lomustine) for the Treatment of Patients With Recurrent Glioblastoma

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Histologically-proven glioblastoma (World Health Organization \[WHO\] 2021 criteria) * Progressive or recurrent disease per Response Assessment in Neuro-Oncology (RANO) criteria * No IDH mutation (IDH1 R132H negative by immunohistochemistry \[IHC\] or sequencing) * Patients must be in first recurrence of glioblastoma following radiation therapy and temozolomide * No prior therapies except radiation, surgery, temozolomide, Tumor Treating Fields (TTFields), and/or Gliadel wafers (placed during the first surgery at diagnosis of glioblastoma multiforme \[GBM\]). Prior radiation therapy, TTFields, or placement of Gliadel wafers must be completed at least 2 weeks prior to registration. Prior temozolomide must be completed at least 3 weeks prior to registration * No prior use of nivolumab or other anti-PD1 agents * Patients must be neurologically stable off corticosteroids for at least 5 days prior to registration * Age: ≥ 18 years * Karnofsky Performance Status: ≥ 60% (i.e. patient must be able to care for themselves with occasional help from others) * Absolute lymphocyte count (ALC): ≥ 1000/mm\^3 * Absolute neutrophil count (ANC): ≥ 1500/mm\^3 * Platelet count: ≥ 100,000/mm\^3 * Hemoglobin: ≥ 9.0 g/dL * Activated partial thromboplastin time (APTT) or partial thromboplastin time (PTT): ≤ 1.5 x upper limit of normal (ULN) * Total bilirubin: \< 2.0 x ULN (Except for patients with Gilbert's syndrome, who must have direct bilirubin \< 2.0 x ULN) * Aspartate aminotransferase (AST) / alanine aminotransferase (ALT): \< 3.0 x ULN * Calculated (calc.) creatinine clearance (CrCl): ≥ 50 mL/min * Calculated by Cockcroft-Gault equation * Not pregnant and not nursing, because this study involves an investigational agent whose genotoxic, mutagenic and teratogenic effects on the developing fetus and newborn are unknown and an agent that has known genotoxic, mutagenic and teratogenic effects. Therefore, for women of childbearing potential only, a negative pregnancy test done within 14 days prior to registration is required * Patients with a prior or concurrent malignancy whose natural history or treatment does not have the potential to interfere with the safety or efficacy assessment of the investigational regimen are eligible for this trial * No active brain metastases or leptomeningeal disease * HIV: HIV-infected patients on effective anti-retroviral therapy with undetectable viral load within 6 months prior to registration are eligible for this trial * Hepatitis B: For patients with evidence of chronic hepatitis B virus (HBV) infection, the HBV viral load must be undetectable on suppressive therapy, if indicated * Hepatitis C: Patients with a history of hepatitis C virus (HCV) infection must have been treated and cured. For patients with HCV infection who are currently on treatment, they are eligible if they have an undetectable HCV viral load * No known medical condition causing an inability to swallow oral formulations of agents * No current symptomatic pulmonary disease * No autoimmune disorders that require systemic treatment (except hyperthyroidism or diabetes mellitus)

Conditions & Interventions

Interventions:
PROCEDURE: Biopsy Procedure, PROCEDURE: Biospecimen Collection, DRUG: Lomustine, PROCEDURE: Magnetic Resonance Imaging, BIOLOGICAL: Nivolumab, BIOLOGICAL: Relatlimab, PROCEDURE: Surgical Procedure

Conditions:
Progressive Glioblastoma, Recurrent Glioblastoma

More Information

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