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CLINICAL TRIAL ANNOUNCEMENT

A Longitudinal Assessment of Tumor Evolution in Patients with Brain Cancer

Protocol: JWCI-17-0801

This is a randomized, investigational, longitudinal assessment of tumor evolution in patients with newly diagnosed glioblastoma. Study is designed to assess the safety and tolerability of administering nivolumab and nivolumab in combination with ipilimumab prior to radiation therapy and to collect biological specimens before, during, and after treatments to identify determinants of response and safety. Parallel assessment of the effect of standard radiation an temozolomide on tumor microenvironment will provide a comparison leading to a deeper understanding of tumor stratification for personalized medicine.

Three treatment arms in the study will include (1) Standard of Care: Radiation + Temozolomide, (2) Nivolumab prior to radiation, (3) Nivolumab + Ipilimumab prior to radiation, (4) Nivolumab + Ipilimumab + Bevacizumab prior to radiation, (5) Nivolumab + Ipilimumab + Temozolomide prior to radiation, and (6) Nivolumab + Ipilimumab + Bevacizumab + Temozolomide prior to radiation.

Nivolumab is a programmed death receptor-1 (PD-1) blocking human monoclonal antibody. Ipilimumab is a monoclonal antibody that binds to the cytotoxic T-lymphocyte-associated antigen 4 (CTLA-4) and blocks its interaction with various ligands. Bevacizumab is a monoclonal antibody that targets VEGF as gliomas are highly vascular and have a high expression of VEGF. Temozolomide is an alkylating agent which can slow the growth of cancer cells.

Glioblastoma (GBM) being one of the most common malignant central nervous system tumors, remains a disease with a significant unmet medical need. Cancer immunotherapy has recently proven its value in the treatment of many solid and hematological cancers. GBM are known to induce local and systemic immunosuppression and immunotherapy holds promise of specifically targeting and eliminating tumor cells while sparing normal brain.

Key Inclusion Criteria:

- Participant is being evaluated for a potential diagnosis of high grade glioma
- Age ≥18.
- KPS score of ≥60.

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