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CLINICAL TRIAL ANNOUNCEMENT

Phase II Trial to Evaluate AV-GBM-1 in Patients with Newly Diagnosed Glioblastoma

Official Title: Phase II trial of AV-GBM-1 (autologous dendritic cells loaded with autologous tumor associated antigens) as an adjunctive therapy following primary surgery plus concurrent chemoradiation in patients with newly diagnosed GBM

The purpose of this research study is to determine the overall survival (OS) from the date of enrollment for patients intended-to-treat with AV-GBM-1 (dendritic cell vaccine).

AV-GBM-1 is autologous dendritic cells (DCs) loaded with tumor associated antigens (TAA) from a short-term cell culture of autologous tumor cells. It is admixed with granulocytemacrophage colony stimulating factor (GM-CSF) as an adjuvant, prior to injection. An autologous tumor cell line must be established from tissue collected during surgery and a successful leukapheresis product after surgery.

GBM accounts for about 15% of primary brain tumors and 50% of gliomas in adults, but is by far the most lethal. For the past decade, optimal aggressive multi-modality therapy has included debulking surgery and concurrent chemotherapy (with temozolomide, TMZ) and radiation therapy, followed by adjuvant chemotherapy (with TMZ) for at least six months or until the time of disease progression. This trial is relatively unique in the use of DC loaded with TAA from a short-term culture of autologous self-renewing cancer cells that have features of cancer stem cells (CSCs) and early progenitor cells. GBM is especially attractive for this approach because surgical debulking is part of standard therapy for newly diagnosed disease. Patient-specific DC vaccines (DCVs) have been associated with minimal toxicity and encouraging long-term survival in patients with metastatic melanoma.

Depending on the managing physician's treatment plan, the product may be administered alone, in combination with standard TMZ, or in combination with other standard therapy. The intent is to give the first 3 weekly injections of AV-GBM-1 prior to beginning adjuvant or salvage chemotherapy.

Key Inclusion Criteria:

- Histology confirmed to be GBM (Grade IV WHO, glioblastoma, gliosarcoma)
- Successful establishment of an autologous cancer cell line
- Collection of a satisfactory leukapheresis product
- About to begin concurrent CT/RT