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**BRADMER NEURADIAB (131 I-LABELLED ANTI-TENASCIN MONOCLONAL ANTIBODY) TRIAL FOR GLIOBLASTOMA MULTIFORME (IRB #14462)**

Glioblastoma (glioblastoma multiforme, or GBM) is a malignant primary brain tumor which cannot be cured today. It progresses rapidly with a median survival of 12-14 months even with surgery, radiation therapy, and chemotherapy.

This is a randomized, multi-center, industry-sponsored trial of the investigational compound Neuradiab in newly diagnosed patients with a GBM which can be at least mostly removed.

Even with the operating microscope at surgery, there are always malignant tumor cells which cannot be seen and cannot be removed.

Neuradiab is a compound which contains an antibody to an external cellular protein, tenascin, linked to radioactive iodine. The protein tenascin is found on virtually all GBM cells and on none of the brain's normal cells. The radioactive iodine basically gives a tumor-specific targeted dose of radiation to tumor cells remaining in the surgical cavity.

The proposed study population is comprised of individuals who have been newly diagnosed with GBM. Subjects will be given time to accept and understand their diagnosis before being approached regarding participation in this study to avoid the appearance of coercion. Potential subjects will be identified by one of the study investigators in the clinic or will be referred to the research team by an outside physician. Interested individuals will be provided with a copy of the informed consent to take home for review with family, friends and/or other physicians. The potential subject will contact the research team to schedule a visit to further discuss the study with one of the study investigators. Once all questions have been addressed and the potential participant is willing to enroll in the study, one of the study investigators will officially obtain informed consent.

Subjects will undergo surgery for their tumor in standard fashion. Instead of undergoing standard radiation postoperatively, this radiation will be delayed for a short time. A catheter will then be placed into the tumor resection cavity. The catheter will be tested, and a dosing study will be completed so that a specific dose of Neuradiab can be calculated that is individual to the patient. Patients then will undergo standard radiation and chemotherapy.

Participants' study duration is expected to last up to 4 years. After surgery, subjects will be followed according to the following schedule.

- every 2 months for the first year after treatment and then
- every 3 months during the second year, then
- every 4 months during the third year, and
- every 6 months thereafter

Subjects will be asked to complete questionnaires and maintain a diary to keep track of the number of capsules taken each day.

Neuradiab has been tested in both animal models and at other institutions with good efficacy and few side effects. A Phase II study in 33 patients receiving standard therapies in addition to Neuradiab, median survival was 79 weeks (19.8 months), compared to typically 52-60 weeks with standard treatment. Another protocol using patient-specific dosing of the drug had median survival of 91 weeks (22.8 months).

All subjects enrolled in this study will be screened for evidence of AIDS and major psychiatric impairments by reviewing their medical records and obtaining medical history.

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