



**JOHN WAYNE
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CLINICAL TRIAL ANNOUNCEMENT

Phase 2b/3 Study of ABT-414 with Concurrent Chemoradiation and Adjuvant Temozolomide in Subjects with Newly Diagnosed Glioblastoma (GBM) with Epidermal Growth Factor Receptor (EGFR) Amplification

This study seeks to determine whether the addition of **ABT-414** to concomitant radiotherapy and temozolomide (TMZ) prolongs progression free survival (PFS) and overall survival (OS) in participants with newly diagnosed glioblastoma (GBM) with epidermal growth factor receptor (EGFR) amplification.

ABT-414 is an antibody drug conjugate (ADC) designed for the treatment of tumors harboring amplified genomic EGFR. Antibody drug conjugates are a rapidly growing class of cancer drugs that combine the targeting properties of monoclonal antibodies (mAbs) with the anti-tumor effects of potent cytotoxic drugs.

Inclusion Criteria:

- Must have a clinical diagnosis of Glioblastoma (GBM).
- Must have a confirmed Epidermal growth factor receptor amplification in tumor tissue.
- Must have a Karnofsky Performance Status (KPS) performance score of 70 - 100 (N/A to the sub-study).
- Must have recovered from effects of surgery, postoperative infection and other complications of surgery.
- Must have adequate bone marrow, renal, and hepatic function (For the sub-study, the subject must have adequate bone marrow and renal function and have mild-to-moderate hepatic impairment).

Exclusion Criteria:

- Multifocal, recurrent or metastatic Glioblastoma (GBM) or gliomatosis cerebri (For the sub-study, the subject can have multifocal GBM and gliomatosis cerebri but can't have recurrent or metastatic GBM).
- Prior chemo therapy or radiosensitizer for head and neck cancer.
- Prior radiotherapy to the head or neck in overlap of radiation fields.
- Prior therapy for glioblastoma or other invasive malignancy.
- Prior, concomitant or planned treatment with Novo-TTF, EGFR-targeted therapy, bevacizumab, Gliadel wafers or other intratumoral or intracavity anti-neoplastic therapy.

Please feel free to contact the clinical trial team to learn more about this study.