PACIFIC NEUROSCIENCE INSTITUTE℠

JOHN WAYNE CANCER INSTITUTE
at Providence Saint John's Health Center

For more information, contact the Neuro-Oncology Clinical Trial Team at:
neuro.oncology@jwci.org
310-829-8265

Clinical Trial Investigators

Achal S. Achrol, MD

Garni Barkhoudarian, MD

Daniel Kelly, MD

Santosh Kesari, MD, PhD,

Steven O'Day, MD

Marlon Garzo Saria, PhD, RN

Clinical Trial Team

Najee Boucher, CRA
najee.boucher@providence.org
310-582-7460

Jaya Gill, RN, BSN
jaya.gill@providence.org
310-582-7437

Annie Heng, RN, BSN
HengA@jwci.org
310-582-7457

Tiffany Juarez, PhD
Tiffany.Juarez@jwci.org
310-449-5225

Anand Moses, CRA
MosesA@jwci.org
310-582-7097

Sponsor

Abbvie, Inc.

Saint John's Health Center

PROVIDENCE Health & Services

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 glimatosis 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 antineoplastic therapy.

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