PACIFIC NEUROSCIENCE INSTITUTE℠

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

CLINICAL TRIAL ANNOUNCEMENT

Study to Evaluate Trans Sodium Crocetinate (TSC) in patients with Newly Diagnosed Glioblastoma

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Sponsor

Diffusion Pharmaceuticals

Saint John's Health Center
PROVIDENCE Health & Services

Official Title: Open-label, Randomized, Controlled, Phase 3 Safety and Efficacy Study of Trans Sodium Crocetinate (TSC) with Radiation Therapy and Temozolomide in Newly Diagnosed Glioblastoma (GBM) Biopsy-Only Subjects

Trans Sodium Crocetinate (TSC) - is a bipolar synthetic carotenoid used to treat diffusion-limited hypoxia by selectively enhancing the reoxygenation of hypoxic tissues. Glioblastoma tumors exhibit areas of hypoxia in their microtumor environment that are well known to be highly resistant to radiation therapy and chemotherapy (RT), limiting effective drug delivery and activity. Off-setting the effects of hypoxia in GBM is an essential element for the effectiveness of RT and/or chemotherapy to provide for enhanced tumor sensitivity and allow for a better clinical outcome. In patients with newly diagnosed GBM, this novel treatment approach will combine TSC with standard of care Temozolomide and Radiation Therapy.

Two cohorts , Group 1 (Standard of Care for first-line treatment of GBM plus Trans Sodium Crocetinate) and Group 2 (Standard of Care for first-line treatment of GBM) will be included in this study.

Key Inclusion Criteria:

- Age 18-70
- Only surgical consideration is biopsy. Subjects who had gross total resection, partial resection and/or debulking are excluded
- Measurable (>10mm x 10mm) contrast enhancing disease
- Tumor Treatment Field (TT Fields) therapy allowed

Key Exclusion Criteria:

- Subjects must not have had prior RT, chemotherapy (including Gliadel wafer), immunotherapy or therapy with a biologic agent, or hormonal therapy
- Subject who cannot undergo MRI
- Subject receiving concurrent chemotherapeutics or investigational agents within 30 days of study entry, including gliadel wafers or gliasite application
- Subjects diagnosed with another malignancy within 3 years prior to study start with the exception of adequately treated basal cell carcinoma, squamous cell carcinoma, non-melanomatous skin cancer or carcinoma in situ of the uterine