PACIFIC NEUROSCIENCE INSTITUTE℠

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

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CLINICAL TRIAL ANNOUNCEMENT

Phase II Trial to Evaluate **Optune** with concurrent **Bevacizumab** in Patients with Recurrent **Meningioma**

Official Title:
A Phase 2, single arm, multicenter, open label trial Combining Optune with concurrent Bevacizumab in the setting of Recurrent or Progressive Meningioma

The purpose of this study is to determine the efficacy of Optune (TTF) therapy with Bevacizumab as assessed by Progression Free Survival at 6 months (PFS-6) in patients with recurrent or progressive meningioma

Meningioma is the most common primary brain tumor with a prevalence of about 170,000 in the United States. Of these tumors, approximately one third are high-grade meningioma with about 25-30% being grade 2 or atypical meningioma and approximately 3% being grade 3 or anaplastic meningioma. Surgery and radiation are the mainstay treatment for meningioma. Despite these treatment measurements, the recurrence rate remains high and in the case of grade 3 meningioma overall survival is as low as 3 years after diagnosis. Currently, there is no single standard of care for recurrent meningioma treatment. Beyond surgery and radiation, chemotherapy has also been evaluated in meningioma both formally in clinical trials and retrospectively. Unfortunately, many of these tested chemotherapeutic agents have had little or no activity in meningioma. One medical therapy that has shown activity in recurrent and high-grade meningioma is Bevacizumab

Bevacizumab – is a monoclonal antibody that prevents the interaction of vascular endothelial growth factor (VEGF) with VEGFR-1 and VEGFR-2 (KDR).

Optune – utilizes alternating electric fields and has shown that when properly tuned, very low intensity, intermediate frequency electric fields inhibit the proliferation of tumor cells.

Key Inclusion Criteria:
- Histologic diagnosis of meningioma, WHO grade 2 or 3 (atypical or anaplastic)
- Patient's tumor must have a supratentorial component
- Must have developed recurrent disease/progression
- Patients with prior treatment with bevacizumab are eligible

Key Exclusion Criteria:
- Patients with active implanted medical device, a skull defect, programmable VP shunts, and patients with vagal nerve stimulators