CLINICAL TRIAL ANNOUNCEMENT

A Phase II Study of NovoTTF-200A Alone and With Temozolomide in Patients With Low-Grade Gliomas

Official Title: A Single-Center, Open-Lable, Randomized Phase II Study of NovoTTF-200A Alone and Combined With Temozolomide in Patients With Low-Grade Gliomas

The purpose of this study is to test the effectiveness and safety of the NovoTTF-200A device in patients with low-grade glioma when it’s used by itself or used together with temozolomide.

NovoTTF-200A is a device that produces alternating electrical fields within the human body that disrupt cell division. These very low intensity intermediate frequency electric fields (TTFields) impair the growth of tumor cells through the arrest of cell division and inducing apoptosis.

Key Inclusion Criteria:
- Histologically confirmed low-grade glioma including astrocytoma grade 2, oligodendroglioma grade 2, or oligoastrocytoma grade 2.
- Tumor is supratentorially located and measurable.
- Disease that has not received prior radiation, radiosurgery, chemotherapy, or other investigational treatment directed at the brain tumor at any time. Previous surgical procedures is allowed.
- Age ≥ 18 years.
- Life expectancy > 12 weeks.
- Either not receiving steroids for disease symptoms or are on stable dose of steroids for at least 5 days.
- Karnofsky Performance Status (KPS) ≥ 60%

Key Exclusion Criteria:
- Pilocytic astrocytoma, gangliogioma, pleomorphic xanthoastrocytoma, or dysembryoplastic neuroepithelial tumors are not eligible.
- Current or anticipated use of other investigational agents.
- Implanted electronic medical device in the brain (e.g., deep brain stimulator, vagus nerve stimulator, programmable shunt).
- Patients who are less than 4 weeks from surgery or have insufficient recovery from surgical-related trauma or wound healing.
- Severe or uncontrolled medical disorder that would, in the investigator’s opinion, impair ability to receive study treatment.

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
PNI/JWCI & Novocure, Inc.

Saint John’s Health Center
PROVIDENCE Health & Services