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CLINICAL TRIAL ANNOUNCEMENT

Study of Tumor Treating Fields (Optune®, 200kHz) concomitant with radiation therapy and temozolomide for the treatment of Newly Diagnosed Glioblastoma

Official Title: EF-32: Pivotal, Randomized, open-label study of Tumor Treating Fields (Optune®, 200kHz) concomitant with radiation therapy and temozolomide for the treatment of newly diagnosed glioblastoma

Glioblastoma (GBM) is the most common primary intracranial neoplasm in adults. The currently accepted standard treatment of newly diagnosed GBM is based on: Surgical resection to the extent safely feasible followed by RT concomitant with TMZ, followed by adjuvant TMZ chemotherapy concomitant with TTFields. Despite numerous attempts to improve the outcome of patients with GBM, until recently the 3-year survival of patients treated with maximal surgical resection when feasible, 60 Gy radiotherapy (RT) together with concomitant temozolomide (TMZ) (RT/TMZ), followed by maintenance (adjuvant) TMZ for 6 months was only 6% with median survival of 14.6 months. In a prospective pivotal study⁶, the addition of TTFields (200 kHz) to maintenance temozolomide increased the median overall survival of patients enrolled in the study following RT/TMZ to 20.9 months.

The purpose of this study is to test the effectiveness and safety of TTFields given to newly diagnosed GBM patients, concomitantly with radiation therapy and temozolomide compared to treatment with radiation therapy and temozolomide, where in both arms TTFields and maintenance temozolomide are continued following radiation therapy.

The Optune® System - is a portable, battery operated device which produces TTFields within the human body by means of surface transducer arrays. TTFields are applied to the patient by means of surface INE Transducer Arrays that are electrically insulated.

Key Inclusion Criteria:

- Patients with histologically confirmed diagnosis of GBM
- Age $\geq$ 22 years

Key Exclusion Criteria:

- Infratentorial or leptomeningeal disease
- Implanted pacemaker, defibrillator, deep brain stimulator, or other device
- Evidence of increased intracranial pressure