NT-37. A PHASE II RANDOMIZED STUDY OF NovoTTF THERAPY VERSUS SUPPORTIVE CARE IN NON-SMALL CELL LUNG CANCER PATIENTS WITH 1-5 BRAIN METASTASES FOLLOWING OPTIMAL STANDARD LOCAL TREATMENT

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BACKGROUND: NovoTTF Therapy is a non-invasive, anti-mitotic treatment modality, based on low intensity alternating electric fields. During mitosis Tumor Treating Fields (TTFields) interfere with the formation of the mitotic spindle and physically translocate charged organelles. TTFields inhibit proliferation of non-small cell lung cancer (NSCLC) in vitro and in vivo. THE EF-21 CLINICAL TRIAL DESIGN: Patients with 1-5 NSCLC brain metastases (BM) who initially received optimal local treatment to all metastases are randomized in a ratio of 1:1 to either NovoTTF Therapy or supportive care arms. Patients are followed-up monthly (brain MRI every 3 months). Patient in the control arm may cross over at time of recurrence in the brain. OBJECTIVES: The current trial is designed to study the safety, tolerability and efficacy of NovoTTF therapy in this patient population. ENDPOINTS: Median time to local and distant progression in the brain (primary), neurocognitive function, quality of life, toxicity, overall survival and overall progression free survival (secondary). MAJOR ELIGIBILITY CRITERIA: Diagnosis of BM from NSCLC with stable systemic cancer, 1-5 BM following optimal local therapy, optimal systemic therapy for NSCLC. TREATMENT: Continuous NovoTTF Therapy at 150 kHz, applied to the brain using the NovoTTF-100A(M) System. The System is a portable medical device delivering alternating electric fields to the brain using 4 Transducer Arrays, which may be covered by a wig or a hat for cosmetic reasons. STATISTICAL CONSIDERATIONS: This is a prospective, randomized (1:1), multicenter study for 60 patients, comparing the hazard of progression in the brain over time between both arms using the Kaplan-Meier method. This trial has 80% power at a two sided alpha of 0.05 to detect a hazard ratio of 0.35 in time to progression in the brain. Randomization is stratified by number of BM (single vs. 2-5) and WHO performance score (0-1 vs. 2).