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**Randomized Double-Blind Study of External Trigeminal Nerve Stimulation for Intractable Epilepsy (Drug Resistant Epilepsy)**

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**Rationale:** There is growing interest in neuromodulation for epilepsy as an alternative to failed drug therapy. Trigeminal Nerve Stimulation (TNS) is an emerging therapy, which has unique advantages: it can be delivered externally, bilaterally, and at low cost. The Epilepsy Therapy project, in partnership with the Epilepsy Foundation of America, the Michael Milken Family Foundation and Boston Scientific, funded a phase II, Randomized Double-Blind Study of External Trigeminal Nerve Stimulation for Intractable Epilepsy. The purpose of this study is to evaluate the safety and effectiveness of this new treatment for drug resistant epilepsy.

**Methods:** 50 subjects with drug resistant epilepsy (complex partial or secondary generalized tonic-clonic seizures) were enrolled in a prospective randomized double-blind active-control clinical trial. Subjects were randomized to either High or Low (active control) TNS settings for at least 12-hours per day. Subjects first entered a 6-week pre-treatment baseline period, followed by an 18-week acute treatment period. After completion of the 18-week double-blind study, all subjects who completed the acute study were offered treatment with TNS at High settings. Outcomes include the percent reduction in seizures between and within groups compared to baseline. Safety monitoring, including systolic and diastolic blood pressure, heart rate, and Beck Depression Inventory were performed throughout the study.

**Results and Conclusions:** The initial results of this recently completed Phase II study will be presented. TNS is emerging as the first non-invasive/minimally invasive neuromodulation treatment for Drug Resistant Epilepsy.