TITLE: RECLAIM Deep Brain Stimulation Clinical Study for Treatment-Resistant Depression

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PURPOSE/OBJECTIVES: This study is designed to evaluate the safety and efficacy of bilateral DBS of the ventral capsule/ventral striatum (VC/VS) as an adjunctive therapy for patients with a documented history of treatment-resistant depression. The study is a randomized double-blind, sham stimulation-controlled, multicenter, prospective parallel design study with two phases. Phase I, the feasibility phase, has FDA approval for 30 subjects at 5 sites to be enrolled and implanted. Phase II, the pivotal phase, may be approved for additional sites. Total enrollment is expected to be 208 subjects. The primary objective is to demonstrate that the improvement in depression for subjects in the active group (stimulation) is greater than for subjects in the control group (sham stimulation) after 16 weeks of therapy. The Montgomery-Asberg Depression Rating Scale scores of patients in the two groups (stimulation and sham stimulation) will be used to determine improvement.

INCLUSION CRITERIA: Inclusion criteria include a primary diagnosis of major depression, with the current episode lasting at least two years. Patients must have multiple failed trials on medications to treat their depression, with drug trials including combination trials and augmentation trials. Patients must be 18 years old or older.

EXCLUSION CRITERIA: Patients are excluded from the study if they have: a) a history of seizure disorder; b) a condition that will require diathermy treatments; c) a medical condition for which MRI is required or anticipated; d) met criteria for bipolar disorder, schizophrenia, schizoaffective disease, obsessive-compulsive disorder or psychosis; e) met criteria for recent substance abuse; f) a history of 2 or more suicide attempts in the last 12 months; g) been determined to be an imminent suicide risk; h) a diagnosis of myocardial infarction or cardiac arrest within 6 months of study enrollment; a history of a neurosurgical ablation procedure; history of hemorrhagic stroke and a life expectancy of less than 3 years.