

Neuropace, Inc.

Neuropace, Inc. was founded in 1999 to design, develop, manufacture and market implantable responsive neurostimulation devices for treating neurological disorders by direct brain stimulation.

The NeuroPace RNS™ System provides a novel approach to the treatment of medically intractable partial onset seizures. The RNS™ System includes a cranially implanted programmable neurostimulator that is connected to depth and/or subdural leads, a programmer, a patient remote monitor and an internet based interactive data repository. The neurostimulator is programmed by the physician to detect epileptiform activity preceding a seizure and to deliver stimulation to the seizure focus. Detection settings are tailored to the appearance of the epileptiform activity. Stimulation settings such as frequency, duration, pulse width, and current are individualized for the patient.

Clinical trials included a Feasibility trial designed to assess safety of the RNS™ System and to show preliminary evidence for efficacy as an adjunctive therapy in reducing the frequency of seizures in adults with medically intractable partial onset seizures. 65 subjects were implanted with the RNS System at 11 centers. There were no unanticipated device related or surgery related serious adverse events and there was preliminary evidence for efficacy. These data supported commencement of the RNS™ System Pivotal Investigation

The RNS™ System Pivotal Investigation is a double blinded randomized sham controlled trial designed to demonstrate that responsive neurostimulation is safe and effective as an adjunctive treatment in adults with medically intractable partial onset seizures. 191 subjects were implanted with the RNS™ System at 31 sites. Subjects had an average of 3 or more partial onset seizures a month, had failed 2 or more antiepileptic medication trials and had seizures originating from one or two seizure foci.

After a Pre-Implant baseline, the RNS System was implanted and programmed to detect epileptiform activity. Four weeks post-operatively, subjects were randomized 1:1 to Sham (no stimulation) or Treatment (responsive stimulation) groups. The 12 week Blinded Evaluation Period began 4 weeks later and was followed by an 84 week Open Label Period during which all subjects received stimulation.

Responsive stimulation significantly reduced the frequency of seizures in the Treatment group [N=96] compared to the Sham stimulation group [N=93] over the Blinded Evaluation Period ($p < 0.012$, GEE) and effectiveness improved over time. Over 50% of the subjects that completed the Open Label had a 50% or greater reduction in seizures. Stimulation was well tolerated and safety was favorable compared to comparable procedures.

NeuroPace will submit a PMA to FDA in 2010.