



NeuroPace RNS® System Reduces Seizures and Improves Quality of Life for People with Epilepsy

Long-term Treatment Study Data Show Sustained Effectiveness in Adults Historically Resistant to Other Treatments

MOUNTAIN VIEW, CA – February 3, 2015 – [NeuroPace, Inc.](http://www.neuropace.com) today announced that interim results from its ongoing long-term treatment (LTT) study demonstrate the RNS® System significantly reduces seizure frequency among adults who have a common form of epilepsy that is difficult to treat with medication. Results of the ongoing LTT study, which were recently published in *Neurology*, include data on 230 people with medically intractable partial onset epilepsy enrolled at 33 Comprehensive Epilepsy Centers in the United States. The median reduction in seizure frequency compared to patients' pre-implant seizure frequency was 60 percent at the beginning of the third year post-implant and 66 percent at the beginning of the sixth year.

NeuroPace received premarket approval (PMA) from the U.S. Food and Drug Administration (FDA) for the RNS System in November 2013. It is approved as a treatment for adults with partial onset seizures with one or two seizure onset zones whose seizures have not been controlled with two or more antiepileptic drugs.

“The interim study results, which covered 1,293 patient stimulation years, confirm our belief that the therapeutic benefits of the RNS System are not only sustained, but actually increase over time for many people,” said Martha Morrell, MD, Chief Medical Officer of NeuroPace, Inc. and Clinical Professor of Neurology at Stanford University. “Beyond the sustained seizure frequency reduction, patients in this study gained significant improvements in quality of life in areas such as memory, language, attention and overall health. This patient population has been unable to find relief with other treatments, and we are extremely hopeful that the RNS System can help hundreds of thousands of adults in the U.S. with refractory partial seizures in the future.”

The LTT study is an ongoing seven-year, multi-center prospective open-label study for participants who previously completed a feasibility or randomized controlled trial of the RNS System. Ninety-seven percent of these patients elected to continue treatment and participate in the LTT study. The median reduction in seizure frequency in the pivotal study was 44 percent at one year and 53 percent at two years, and ranged up to 66 percent over post-implant years three through six in the LTT study. Furthermore, 23 percent of patients experienced at least one six month period free of seizures. For comparison, these patients had to average at least three seizures per month in order to enroll

in the original trial. The study also demonstrated significant improvements in overall quality of life and indicates a more positive perception of cognitive function, relationships and social function, overall health, and vulnerability to seizures. There were no serious unanticipated device related adverse events in the trial and responsive neurostimulation was well-tolerated and safe over time.

As a closed-loop system, the RNS System monitors the brain's own signals, interprets those signals, provides stimulation when needed, and then assesses the brain's response. The breakthrough aspect of the RNS System is its advanced detection and stimulation capabilities. This is unlike all other existing neurostimulation therapies, which continuously or intermittently stimulate the brain without determining the need for treatment or monitoring the response.

The RNS System has been evaluated in three clinical trials, including a prospective, randomized, double-blinded, sham stimulation controlled pivotal study and the LTT study. Results of the clinical trials demonstrate that the substantial clinical improvements experienced by patients over the short- and long-term are meaningful and durable over many years of therapy. At this time, some patients have been treated with the RNS System for more than 11 years, and more than 1,500 patient years of experience with responsive neurostimulation have been accumulated to date.

About the RNS® System

The RNS System is the first closed-loop responsive brain stimulation system. The system is designed to treat partial onset seizures by detecting specific types of electrical activity in the brain through leads containing electrodes that are placed near the patient's seizure focus or foci. When detection thresholds are met, the device delivers small bursts of electrical stimulation intended to reduce the frequency of seizures. Physicians can program the detection and stimulation parameters of the implanted RNS Neurostimulator non-invasively to customize therapy for each individual.

Indication for Use: The RNS® System is an adjunctive therapy in reducing the frequency of seizures in individuals 18 years of age or older with partial onset seizures who have undergone diagnostic testing that localized no more than two epileptogenic foci, are refractory to two or more antiepileptic medications, and currently have frequent and disabling seizures (motor partial seizures, complex partial seizures and / or secondarily generalized seizures). The RNS® System has demonstrated safety and effectiveness in patients who average three or more disabling seizures per month over the three most recent months (with no month with fewer than two seizures), and has not been evaluated in patients with less frequent seizures.

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About NeuroPace

[NeuroPace](#) designs, develops, manufactures and markets implantable devices for the treatment of neurological disorders. The company's initial focus is the treatment of epilepsy, a debilitating neurological disorder affecting approximately one percent of the population worldwide. An estimated 30-40 percent of the 65 million people worldwide (including nearly three million Americans) with epilepsy experience uncontrolled seizures. In addition to treating epilepsy, responsive neurostimulation holds the promise of treating several other disabling neurological disorders that negatively impact quality of life for millions of patients throughout the world.

Located in Mountain View, California, NeuroPace is a privately held company.

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