



NeuroPace RNS® System Associated with Positive Effects In Memory and Language for People Living with Partial Onset Epilepsy

Study Published in Epilepsia Demonstrates No Adverse Cognitive Effects in Population that Normally Suffers Decline in Mental Processing, Memory, and Communication

MOUNTAIN VIEW, CA – October 20, 2015 – [NeuroPace, Inc.](#) today announced results published in [Epilepsia](#), a peer-reviewed journal dedicated to epilepsy. The study's findings demonstrated that people treated with the RNS System showed no adverse effects on cognition. These results are clinically meaningful because it is common for people living with epilepsy to have significant challenges in several cognitive areas, including memory function, mental processing and reasoning, verbal communication, and decision making. Results of this study include data analyses on 175 people with medically intractable partial onset epilepsy from the open label period of a randomized, controlled, double-blinded pivotal trial with follow up at one and two years.

The RNS System is FDA 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 results of this study have important implications to people living with epilepsy, their caregivers, and the clinical community," said David W. Loring, PhD, director of the neuropsychology program at Emory University and lead author of the publication. "Preserving memory and command of language, among other cognitive functions, is incredibly difficult in people living with medically intractable epilepsy. Studies have found that many therapies, including antiepileptic drugs, epilepsy surgery, and deep brain stimulation carry risks of cognitive decline. For these reasons, it's extremely promising that people treated with the RNS System showed no adverse cognitive side effects, and in fact, some patients demonstrated small but statistically robust improvements in naming or verbal memory."

The primary outcomes of the study were naming ability, measured using the Boston Naming Test, and verbal memory, using the Rey Auditory Verbal Learning Test (AVLT). Naming ability refers to the ability to find the right word to express ideas and thoughts verbally. Verbal memory refers to the ability to remember words and thoughts expressed verbally. The secondary outcomes of the study were executive function, visual memory, and motor processing speed.

The subjects of the study were split into two groups: those people that had seizure onset in the mesial temporal lobe (MTL) and those with seizure onset in the neocortical portion of the brain. The study found no significant group decline on any primary or secondary neuropsychological outcome measure at one or two years. There were statistically significant improvements in naming, largely driven by people in the neocortical group, and statistically significant improvements in verbal memory driven by people in the MTL group.

"The study results support our belief that there are significant benefits of targeted stimulation delivered specifically to the area of the brain where seizures originate, when it's needed," said Martha Morrell, MD, Chief Medical Officer of NeuroPace, Inc. and Clinical Professor of Neurology at Stanford University. "This patient population had struggled for an average of 20 years to control seizures and limit side effects with other treatments prior to treatment with the RNS System. The study findings are remarkable for a group at such high risk for the type of impairment that can have a huge impact on quality of life."

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 aspects of the RNS System include its advanced detection and stimulation capabilities. This is unlike all other existing neurostimulation therapies, which continuously or intermittently stimulate the brain without the ability to determine the need for treatment and monitor the response.

Long-term benefits of the RNS System were recently published in [Neurology](#), demonstrating that the RNS System significantly reduces seizure frequency among adults who have a common form of epilepsy that is difficult to treat with medication. The published interim study results 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. At this time, some patients have been treated with the RNS System for more than 11 years, and more than 1,700 patient years of experience with responsive neurostimulation have been accumulated to date.

About the RNS® System

The RNS System is the first and only closed-loop brain-responsive neurostimulation 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 source. 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.

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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