NEUROPACE

Dec. 4, 2016 18:05 UTC

NeuroPace, Inc. Announces Results of 7 Years of Clinical Trial Follow-up Demonstrating 72 Percent Seizure Reduction with the RNS® System

Study Presented at American Epilepsy Society Meeting Demonstrates Sustained Effectiveness in Adults with Drug-Resistant Partial Onset Epilepsy

MOUNTAIN VIEW, Calif. & HOUSTON--(BUSINESS WIRE)-- NeuroPace, Inc. today announced the results from 7 years of clinical trial follow-up, which demonstrated significant seizure reduction with the RNS® System among adults who have a common form of epilepsy that is difficult to treat with medication. Results from the study, presented today at the American Epilepsy Society meeting in Houston, include data on people with medically refractory partial onset epilepsy enrolled at 32 Comprehensive Epilepsy Centers in the United States. The median reduction in seizure frequency was 72 percent at seven years (N=185). During the seventh year post-implant, 25 percent of patients had a seizure reduction of ≥93% for any 3 month period. The response is similar for patients regardless of whether the seizures begin in the mesial temporal lobe or in the neocortex. Furthermore, 29 percent of patients experienced one or more 6 month period of seizure freedom[1].

Participants in the RNS System clinical trials are continuing to be treated in an ongoing Long-Term Treatment (LTT) study. The LTT study is an ongoing, multi-center prospective open-label study for participants who previously completed either a feasibility or a randomized controlled trial of the RNS® System. In addition to seizure reduction, patients also reported significant improvements in mood, overall quality of life and cognition.[1]

About Epilepsy

1 in 26 Americans will develop epilepsy in their lifetime, with approximately 150,000 new cases of epilepsy diagnosed annually. An estimated 3 million Americans currently live with epilepsy. More people live with epilepsy than autism spectrum disorder, Parkinson's disease, multiple sclerosis and cerebral palsy – combined.[2]

About the RNS® System

The RNS® System is the first closed-loop brain-responsive neurostimulation system designed to prevent epileptic seizures at their source. It is FDA approved as an adjunctive therapy to treat partial onset epilepsy in patients whose seizures do not respond to medication.

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 1,700 patient years of experience with brain-responsive neurostimulation have been accumulated to date.

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.

[1] Abstract accepted, *American Epilepsy Society*, 2016
[2] Epilepsy Foundation. “Facts about Seizures and Epilepsy.” http://www.epilepsy.com/learn/epilepsy-101/facts-about-seizures-and-epilepsy

Contacts

MSLGROUP
Hillary Marder, 202-683-3130

Source: NeuroPace, Inc.

View this news release online at:
http://www.businesswire.com/news/home/20161205000000/en