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### **PIVOTAL TRIAL DATA DEMONSTRATE NEUROPACE RNS<sup>®</sup> SYSTEM REDUCED SEIZURES IN PEOPLE WITH EPILEPSY**

*NeuroPace to Submit PMA Application to FDA Based on Positive Trial Results*

**BOSTON – December 7, 2009** – NeuroPace, Inc. today announced that results from its pivotal trial demonstrated the RNS<sup>®</sup> System, a novel investigational device that utilizes responsive brain neurostimulation, significantly reduced the frequency of seizures among people who have a common form of epilepsy that is difficult to treat with medication. The pivotal trial data, which were presented at the American Epilepsy Society's (AES) 63<sup>rd</sup> Annual Meeting today, included 191 people with medically intractable partial onset epilepsy enrolled at 31 sites located in the United States.

The RNS System is designed to continuously monitor brain electrical activity and, after identifying a patient's unique "signature" indicating a seizure is starting, deliver brief and mild electrical stimulations with the intention of suppressing the seizure. NeuroPace plans to submit a premarket approval (PMA) application to the U.S. Food & Drug Administration (FDA) in early 2010 seeking approval of the RNS System for the treatment of epilepsy.

"For people who cannot control their seizures effectively with medication, the data show the RNS System may be a safe and effective treatment option," said Martha Morrell, MD, Chief Medical Officer of NeuroPace, Inc. and Clinical Professor of Neurology at Stanford University. "The results also indicate the device became even more effective over time. These findings, drawn from a data set that includes people living with the

most difficult type of epilepsy to manage, truly speak to the potential of responsive neurostimulation in controlling seizures.”

The trial demonstrated a statistically significant reduction in seizure frequency in the treatment group (responsive stimulation active) as compared to the sham stimulation group (responsive stimulation inactive). During the last two months of the three month blinded evaluation period of the study, people in the treatment group experienced a mean percentage reduction of 29 percent in their disabling seizures compared to 14 percent reduction for those in the sham stimulation group. In the long term, open label period of the trial, at least 12 weeks of data were available for 171 study participants; 47 percent of these subjects experienced a 50 percent or greater reduction in their seizure frequency based on their most recent 12 weeks of data, as compared to their baseline.

The trial also demonstrated a serious adverse event rate less than comparative surgical procedures. There were no serious unanticipated device related adverse events reported in the trial. There was no difference between the treatment and sham stimulation groups when comparing the rate of adverse events, including depression, memory impairment and anxiety.

### **About the RNS System**

The RNS System is designed with novel technology to detect abnormal electrical activity in the brain and then deliver small amounts of electrical stimulation to suppress the abnormal activity before any seizure symptoms occur. This type of treatment is called responsive stimulation and differs from deep brain stimulation, which delivers stimulation continuously or on a pre-set schedule. With the RNS System, physicians have the ability to non-invasively program the detection and stimulation parameters of an implanted RNS Neurostimulator specifically for individual patients.

### **About the RNS System Pivotal Clinical Trial**

#### *Trial Patient Population*

The RNS System Pivotal Clinical Investigation is a randomized, double-blind, sham stimulation controlled investigation that included 191 people implanted with the RNS System across 31 sites. All subjects in the study were required to be 18 or older and have partial onset epilepsy, with seizures that start from one or two areas of the brain, that has not been effectively treated with two or more antiepileptic medications alone or in combination.

### *Trial Design*

Patients in the study were implanted with the RNS System once eligibility criteria were met. The blinded evaluation period of the trial began eight weeks after the RNS System was implanted and lasted an additional 12 weeks. Half the participants were randomly assigned to have responsive stimulation activated and half had responsive stimulation remain inactive. Participants and one doctor at each site in the trial did not know whether the stimulation was active or not. A separate doctor at each site programmed the device for people in the treatment group in order to keep the data blinded. Five months after the RNS System was implanted, which is when the double-blinded portion of the trial was completed, stimulation was activated for all participants in the trial. This portion of the trial, which produced long term data, is called the open label period. Each participant will be evaluated in the pivotal trial for two years after being implanted with the RNS System. After completing the pivotal trial, participants have the option to enroll in a subsequent trial designed to gather an additional five years of safety and efficacy data.

## **About NeuroPace**

NeuroPace was founded to design, develop, manufacture and market implantable devices for the treatment of neurological disorders by responsive brain stimulation. 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 50 million people worldwide, including more than 3 million Americans, experience uncontrolled seizures. In addition to treating epilepsy, responsive neurostimulation holds the promise of treating several other disabling medical disorders that impact the quality of life for millions of patients around the world.

Located in Mountain View, California, NeuroPace is a privately-held company with approximately 90 employees.

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