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Pivotal Trial Data Demonstrate Neuropace RNS System Reduced Seizures in People with Epilepsy

Boston, December 2009--NeuroPace, Inc. recently announced that results from its pivotal trial demonstrated the RNS® 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) 63rd Annual Meeting, 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, M.D., 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.