Responsive Brain Stimulation Device Demonstrates Safety and Seizure Reduction

Study highlights long-term safety and efficacy of RNS System in Adults with Intractable Seizures

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Washington, D.C., December 7, 2013 – Researchers present the findings from a 2-year multicenter randomized double blinded controlled clinical study and a 7 year long-term treatment study of the NeuroPace RNS System at the American Epilepsy Society’s 67th Annual Meeting. The RNS System is a novel, implantable therapeutic device that delivers responsive neurostimulation, an advanced technology designed to detect abnormal electrical activity in the brain and respond by delivering imperceptible levels of electrical stimulation to normalize brain activity before an individual experiences seizures. NeuroPace received pre-market approval from the U.S. Food and Drug Administration in November.

The RNS System has been evaluated in three clinical trials, including a prospective, randomized, double-blinded, sham stimulation controlled pivotal study (Platform B.05/ Abstract 1749149). 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. The pivotal study primary effectiveness endpoint was met by demonstrating a 37.9 percent reduction in seizure frequency in patients treated with responsive stimulation compared to a 17.3 percent reduction in patients who were implanted with the device but were not receiving responsive stimulation during a three month blinded period. The difference is statistically significant (p=0.012). For those subjects who reached two years post-implant, 55% of the subjects experienced a 50% or greater reduction in seizures.

An evaluation of the 191 implanted patients from the pivotal study found that there was no difference between the active and sham stimulation groups in the rate of adverse events, including depression, memory impairment and anxiety. There were no serious unanticipated device related adverse events reported in any of the clinical trials. Although there can be no assurances that additional long-term data will not reveal new adverse information presently unknown to NeuroPace, two year data shows no increase or worsening of adverse events.

“The results of the pivotal study clearly demonstrate that the safety and efficacy of the RNS System is sustained over two years. Additional data about safety and efficacy beyond two years is being collected in a long-term follow-up study,” said Martha Morrell, MD, NeuroPace Chief Medical Officer and Clinical Professor of Neurology at Stanford University.
Editors Note: Authors of the above studies will be available at a press briefing at 9:00am (EST) in the press room at the American Epilepsy Society meeting, Room 209A, upper level of the Walter E. Washington Convention Center. To join the briefing by phone: 605-475-4000 code 521653#

About Epilepsy
The epilepsies affect 50 million people worldwide, including three million in the United States. The disorder can have a single specific, well-defined cause, such as a head injury, or manifest as a syndrome with a complex of symptoms. It is the third most common neurological disorder after Alzheimer’s disease and stroke.

About the American Epilepsy Society (AES)
The American Epilepsy Society, based in West Hartford, Conn., seeks to advance and improve the treatment of epilepsy through the promotion of research and education for healthcare professionals. Society membership includes epileptologists and other medical professionals, allied healthcare professionals, and scientists concerned with the care of people who have seizure disorders.

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Information Contacts: Peter Van Haverbeke, cell 703-927-9639, pvanhaverbeke@gmail.com
Natalie Judd, cell 203-605-9515, office 203-389-5223, natalie@bigvoicecomm.com