FDA Advisory Panel Recommends Approval of the NeuroPace RNS® System for Medically Refractory Epilepsy

Novel Device Uses Responsive Brain Stimulation to Treat Patients Who Do Not Respond to Medication

MOUNTAIN VIEW, CA - February 25, 2013 - NeuroPace, Inc. today announced that on February 22, 2013 the U.S. Food and Drug Administration (FDA) Neurological Devices Panel voted unanimously (11 to 0 with two abstentions) that the clinical benefits of the NeuroPace RNS System outweigh the risks of its use. NeuroPace is seeking approval for the RNS System for treating adults with partial onset seizures that have not been controlled with two or more antiepileptic medications. The final decision regarding approval of the device is made by the FDA.

"We have worked for over 15 years to develop and clinically evaluate the RNS System. We are very excited that patients and physicians who need new treatment options so desperately are now likely to have the RNS System commercially available in the near future," said Frank Fischer, NeuroPace CEO.

The RNS System has been evaluated in three clinical trials, including the prospective, randomized, double blinded, sham-stimulation controlled pivotal study. The pivotal study primary effectiveness endpoint was met by demonstrating a 37.9% reduction in seizure frequency in the treatment group compared to a 17.3% reduction in the sham-stimulation control group during a three month blinded evaluation period. This difference was statistically significant ($p=0.012$). Long-term results demonstrated sustained improvements in seizure frequency with median seizure frequency reductions of 44% and 53% at one and two years post-implant, respectively.

"There is strong clinical evidence that this new therapy offers substantial benefits to a significant population of people with medically refractory partial onset seizures," said Martha Morrell, MD, NeuroPace Chief Medical Officer and Clinical Professor of Neurology at Stanford University. "We look forward to working closely with the FDA to finalize both the labeling and the post-approval study commitments so that this technology can become available to patients as quickly as possible."

FDA accepted the company's Premarket Approval (PMA) application in November 2010 based on data from the pivotal study. A total of 256 patients have been implanted with the RNS System, and more than 1,200 patient years of experience with responsive stimulation have been accumulated to date.

About the RNS System
The RNS System is the first closed-loop responsive brain stimulation system designed to treat partial onset seizures. The system detects abnormal electrical activity in the brain through leads containing electrodes that are placed at the patient's seizure focus. When detection thresholds are met, the device delivers small bursts of electrical stimulation to suppress the abnormal activity before any seizure symptoms occur. Physicians can program the detection and stimulation parameters of the implanted RNS Neurostimulator non-invasively to customize therapy for individual patients.

About NeuroPace
NeuroPace designs, develops, manufactures and intends to 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% of the 50 million people worldwide (including 3 million Americans) with epilepsy experience uncontrolled seizures. In addition to treating epilepsy, responsive neurostimulation holds the promise of treating several other disabling medical disorders that negatively impact quality of life for millions of patients around the world.

Located in Mountain View, California, NeuroPace is a privately-held company.

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