NeuroPace Awarded Five-Year NIH Grant Funding of More than $9M to Study RNS System in Patients with Lennox-Gastaut Syndrome

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Feasibility IDE study will be the first to evaluate responsive neuromodulation for a severe and disabling childhood-onset epilepsy

MOUNTAIN VIEW, Calif., June 30, 2021 (GLOBE NEWSWIRE) -- NeuroPace, Inc., a medical technology company dedicated to transforming the lives of people suffering from epilepsy, today announced that it has received a National Institutes of Health (NIH) grant through the Brain Research through Advancing Innovative Neurotechnologies® (BRAIN) Initiative that will provide up to $9.3 million over five years to evaluate the use of NeuroPace's RNS® System to treat Lennox-Gastaut Syndrome (LGS). LGS is a devastating form of childhood-onset epilepsy that causes cognitive dysfunction and frequent generalized onset seizures that often lead to injury. The Investigational Device Exemption (IDE) study, which will be the first to evaluate a neuromodulation device in patients with Lennox-Gastaut Syndrome, is projected to start enrolling patients in the second half of next year.

"LGS is a horrific epilepsy syndrome that develops in very young children and results in daily seizures, frequent seizure emergencies and hospitalizations, and significant developmental delays," said Tracy Dixon-Salazar, Ph.D., Executive Director of the LGS Foundation and mother of an adult living with LGS. "Most people living with LGS have tried more than a dozen treatments and yet seizures persist and families live life waiting for the next seizure crisis. I am so encouraged by the research being done with the RNS System and am hopeful that this treatment can help LGS families who are in desperate need of better therapies."

The study funded by the grant will explore the potential of NeuroPace's brain-responsive neuromodulation technology as a new therapy for persons living with LGS. In addition to the potential therapeutic benefits, the ability of the RNS System to provide continuous monitoring and recording of brain activity could help to optimize therapy for each individual, and may offer new insights into this condition.

The NIH-funded research will be a collaborative effort involving eight U.S. academic centers. Six clinical study sites will enroll a total of 20 patients with LGS and drug-resistant generalized onset seizures. Two other academic sites will create patient-specific maps of brain seizure networks, providing unprecedented insight into how to personalize the treatment for each participant. Patients selected to participate in the study will be enrolled in two cohorts of 10, with safety and efficacy milestones in the first cohort governing the enrollment of the second cohort.

The IDE study, once approved by the U.S. Food and Drug Administration (FDA), will primarily aim to evaluate the safety and effectiveness of the RNS System in treating seizures associated with LGS. If the RNS System meets certain criteria, experience from the study will inform the design of a future larger clinical study.

"We are pleased that the NIH recognizes the promise of responsive neuromodulation to potentially address the current gap in therapeutic options for patients with debilitating seizure disorders such as LGS," said Martha Morrell, M.D., Chief Medical Officer of NeuroPace and principal investigator of the study. "These recordings obtained directly from the brain in a natural setting will show us what is happening when an LGS seizure starts and spreads. We believe that this unprecedented window to the brain will provide us with a deeper understanding of generalized onset seizure networks and help identify biomarkers in the brain that signal when a seizure is about to occur. We're hopeful that treatment with the RNS System can ultimately improve the lives of patients with LGS and their families, and that what is learned from the brain data can also be applied to treatment of other types of generalized onset seizures."

Clinical and electrophysiological data collected during the study will be used in efforts to identify a biomarker of clinical response, potentially aiding future epilepsy research and clinical practice.

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About the RNS® System

The RNS® System, a paradigm-shifting treatment for drug-resistant focal epilepsy, is the only brain-responsive neuromodulation system approved by the FDA. The closed-loop technology delivers personalized, data-driven treatment targeted to the seizure source by continuously monitoring brain activity, recognizing a patient's unique seizure pattern, and responding in real-time with imperceptible stimulation to prevent seizures. By recording ongoing EEG data, the RNS System provides physicians with a unique "window to the brain," enabling them to remotely monitor their patients, gain insights based on brain activity, and use that information to optimize patient care.

Long-term clinical studies demonstrate that the RNS System provides significant reduction in seizure frequency and enduring improvements in quality of life and cognition with no stimulation-related side effects.

The RNS System is available at most comprehensive epilepsy centers in the United States and is widely covered by insurance. It is currently approved in the United States for patients 18 years of age and older with drug-resistant focal epilepsy. See important safety information at www.neuropace.com/safety/.

About NeuroPace, Inc.

Based in Mountain View, Calif., NeuroPace was founded to transform the lives of people living with epilepsy, a debilitating neurological disorder affecting approximately 1 in 26 people. In 2013, it introduced the RNS® System, the first and only FDA-approved closed-loop, brain-responsive neuromodulation system that delivers truly personalized, data-driven treatment. In addition to treating drug-resistant focal epilepsy, long-term EEG data recorded by the RNS System is helping to advance scientific understanding of the human brain. The company's brain-responsive

neuromodulation technology holds the promise of treating additional neurological disorders that impact the quality of life for millions of people around the world. For more information, please visit www.neuropace.com.

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