NeuroPace Receives IDE Approval to Initiate NAUTILUS Pivotal Study of its RNS System for Idiopathic Generalized Epilepsy

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IDE study will be first to evaluate the effectiveness of brain-responsive neuromodulation to treat primary generalized epilepsy in patients aged 12 and older

MOUNTAIN VIEW, Calif., Nov. 10, 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 an Investigational Device Exemption (IDE) from the U.S. Food and Drug Administration (FDA) to study the company's RNS ® System in patients with drug-resistant idiopathic generalized epilepsy.

Idiopathic generalized epilepsy (IGE) is the second most common type of epilepsy, after focal epilepsy.[1] In the approximately one-third of IGE patients who are not effectively treated with medications, this disorder is debilitating, has substantial impact on day-to-day life, and carries risk for social and psychiatric disability, injury and premature death.

The NAUTILUS pivotal study will be the first in the United States to evaluate use of brain-responsive neuromodulation for the treatment of IGE. It is a prospective single blind, multi-center, randomized study that is projected to start enrolling patients in 2022.

"We are pleased with FDA's decision to grant IDE approval for the pivotal study, allowing us to evaluate the safety and effectiveness of the RNS System in patients who are living with drug-resistant, idiopathic generalized epilepsy," said Martha Morrell, MD, Chief Medical Officer of NeuroPace. "We look forward to working closely with the study investigators to evaluate a new treatment option that could potentially improve quality of life for these individuals in a meaningful way."

The RNS System is the only FDA-approved brain-responsive neuromodulation system that delivers personalized, targeted treatment at the seizure source in patients with drug-resistant focal epilepsy. Unlike other neuromodulation devices, the RNS System is a closed-loop technology that monitors and responds to a patient's unique brain patterns to deliver therapy in real time – when and where it is needed – typically before clinical symptoms occur.

In March 2021, the company received Breakthrough Device Designation status from the FDA for the potential use of its RNS System to treat idiopathic generalized epilepsy. The Breakthrough Devices Program aims to speed development and assessment of devices that have the potential to provide more effective treatment or diagnosis for life-threatening or irreversibly debilitating conditions.

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. [2]

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 as an adjunctive therapy for patients 18 years of age and older with drug-resistant focal epilepsy with no more than 2 epileptogenic foci. See important safety information at www.neuropace.com/safety/.

About NeuroPace, Inc.

Based in Mountain View, Calif., NeuroPace is a commercial-stage medical device company focused on transforming the lives of people suffering from epilepsy by reducing or eliminating the occurrence of debilitating seizures. Its novel and differentiated RNS System is the first and only commercially available, brain-responsive platform that delivers personalized, real-time treatment at the seizure source. This platform can drive a better standard of care for patients suffering from drug-resistant epilepsy and has the potential to offer a more personalized solution and improved outcomes to the large population of patients suffering from other brain disorders.

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[1] Marini, et al., J Neurol Neurosurg Psychiatry, 2003. Gastaut, et al., Epilepsia, 1975.

[2] Nair, et al, Neurology, 2020