NeuroPace Receives FDA Breakthrough Device Designation for RNS System for Idiopathic Generalized Epilepsy

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Company plans to pursue indication expansion to broaden access to include patients with second most common type of epilepsy.

MOUNTAIN VIEW, Calif. – March 31, 2021 – NeuroPace, Inc., today announced that the company has received Breakthrough Device Designation status from the U.S. Food and Drug Administration (FDA) for the potential use of its RNS® System to treat idiopathic generalized epilepsy (IGE), which constitutes as many as one third of all epilepsies and is understood to have a strong underlying genetic basis.[1]

NeuroPace plans to pursue an indication expansion to include drug-resistant idiopathic generalized epilepsy for the RNS System, the only FDA-approved brain-responsive neuromodulation system that delivers personalized, targeted treatment at the seizure source. The RNS System is currently available in the United States as an adjunctive therapy for adults with drug-resistant focal epilepsy. A recent publication reported 82% median reduction in seizure frequency at three or more years in this population.[2]

Unlike other neuromodulation devices, the RNS System is a closed-loop technology that is programmed by physicians to monitor and respond to a patient's unique brain patterns, deliver therapy in real time precisely when and where needed, with no chronic stimulation side effects. [3]

"This Breakthrough Device Designation is an exciting validation of the potential of the RNS System to improve the lives of a broader population of people with epilepsy," said Mike Favet, CEO of NeuroPace. "The RNS System's personalized approach to neuromodulation, which recognizes and responds to a patient's unique brain patterns, may offer a new solution for patients with drug-resistant idiopathic generalized epilepsy, a condition that severely impacts quality of life for the individual and family alike. We look forward to initiating a pivotal clinical trial to demonstrate the safety and effectiveness of the RNS System for this patient population."

The FDA Breakthrough Device Program is intended to help patients receive more timely access to breakthrough technologies that have the potential to provide more effective treatment for life-threatening or irreversibly debilitating diseases or conditions. Under the program, the FDA will provide NeuroPace with priority review for clinical trial protocols and commercialization decisions. The Breakthrough Device Designation may also facilitate Medicare reimbursement following FDA approval of the technology for an expanded indication.

Idiopathic generalized epilepsy typically begins in childhood or adolescence, with occasional adult onset. It is the second most common type of epilepsy, after focal epilepsy.[4] 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. No long-term solution exists other than antiepileptic medications, many of which have significant side effects and can cause birth defects if taken during pregnancy.

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. The RNS System records and reports ongoing iEEG data that physicians can securely access not only in person, but also remotely. These data provide a unique "window to the brain", enabling physicians to gain patient-specific insights to optimize epilepsy care.

Clinical studies have demonstrated that the RNS System provides significant reduction in seizure frequency and enduring improvements in quality of life and cognition, with no chronic 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 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

NeuroPace is dedicated to developing groundbreaking technology and advancing brain science to improve the quality of life for millions of individuals who suffer from neurological disorders. The company's first product, the RNS System, is the only FDA-approved brain-responsive neurostimulator for the treatment of focal onset refractory epilepsy. In addition to treating epilepsy, brain-responsive neuromodulation holds the promise of treating other brain disorders that impact quality of life for millions of patients throughout the world.

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[1] Asadi-Pooya, et al, J Neurol Sci, 2013

[2] Razavi, et al., Epilepsia, 2020

[3] Nair, et al, Neurology, 2020

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