NeuroPace RNS System Receives FDA Approval for MRI Labeling, Allowing Thousands More Patients to Benefit from Personalized, Data-Driven Epilepsy Treatment

March 9, 2020

Full-body MRI opens up valuable medical imaging possibilities for RNS System patients

MOUNTAIN VIEW, Calif. – March. 9, 2020 – NeuroPace, Inc., a Silicon Valley-based medical technology company, today announced that its RNS® System has received U.S. Food and Drug Administration (FDA) approval of MRI labeling for the RNS System, expanding treatment options for the approximately one million patients in the United States living with seizures that do not respond to medication.

Individuals with focal onset seizures that also have brain anomalies that require monitoring, such as tuberous sclerosis, brain tumors or multiple sclerosis, as well as those with non-brain MRI requirements, can now be offered the RNS System as a treatment option. This will also allow people to receive the RNS System before committing to an irreversible surgery such as laser ablation, while keeping their future treatment options open.

"MRI conditional labeling opens up valuable medical imaging possibilities for our patients treated with the model RNS-320 neurostimulator, who can now receive full-body 1.5T magnetic resonance imaging (MRI) scans under appropriate conditions," said Michael Favet, President and CEO of NeuroPace. "I'm pleased that we have removed a potential barrier to treatment and increased the number of patients who can benefit from this life-changing therapy."

"The approval decision is wonderful news for the many people living with refractory epilepsy. This therapy not only reduces seizures, it also empowers clinicians with data-driven insights into their patients' epilepsy," said Dr. David Burdette of Spectrum Health.

Treatment with the RNS System has been shown in a real-world, multi-center retrospective study to deliver outcomes never before seen with any neuromodulation device for epilepsy. Patients saw median seizure frequency reduction of 82% at 3 years, and 1 in 3 patients achieved 90% or greater seizure reduction[1]. In addition to therapeutic benefits, the RNS System is the only epilepsy treatment that captures direct, real-world EEG data, enabling clinicians to personalize and optimize therapy over time.

About the RNS® System

The RNS System is the world's only closed-loop brain-responsive neurostimulation system designed to prevent seizures at their source. The RNS System is composed of a neurostimulator, leads that are placed at the seizure foci, a remote monitor used by patients to upload their data, and an RNS Tablet and Patient Data Management System (PDMS) used by physicians. Physicians can view their patient's EEG data on a secure website and program the device to personalize therapy for each individual. Unlike anti-epileptic drugs or resective surgery, brain-responsive neuromodulation outcomes typically improve with time and do not cause the cognitive side effects that can be associated with those alternatives. The RNS System is now available at nearly all comprehensive epilepsy centers in the United States and is widely covered by private and government insurance.

The RNS System is an adjunctive therapy for adults with refractory, focal onset seizures with no more than 2 epileptogenic foci. See important safety information at https://www.neuropace.com/safety/.

About NeuroPace

NeuroPace is the global leader in the emerging field of brain-computer interface technologies, which is projected to become a $1.2 billion market by 2024. We are 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.

[1]Lin, et. al. Real-world experience with brain-responsive neurostimulation for focal onset seizures. Poster, AES 2019 (Abst. 1.216)

# # #

Media Contact:
Lara Lingenbrink
Health+Commerce
858.525.1414
Lara@healthandcommerce.com