NeuroPace Announces First Patient Treated in Pivotal Study Evaluating the RNS System in Adolescents

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RESPONSE Study first to evaluate the effectiveness of brain-responsive neuromodulation to treat focal epilepsy in patients 12 through 17

MOUNTAIN VIEW, Calif.--(BUSINESS WIRE)--May 4, 2022-- NeuroPace, Inc. a medical technology company dedicated to transforming the lives of people suffering from epilepsy, today announced that the first patient was treated in the RESPONSE clinical trial, which will evaluate the safety and effectiveness of the RNS® System in adolescent patients with drug-resistant focal epilepsy. The procedure took place at Westchester Medical Center in New York and follow-up appointments will be conducted at Boston Children's Hospital in New York/Connecticut.

Epilepsy affects 3.4 million people in the U.S., with onset often occurring during the teenage years.[1] While antiepileptic drugs are considered first line treatment and are effective at controlling seizures in a large portion of the epilepsy population, approximately one third of epilepsy patients are considered drug resistant because they do not achieve complete seizure control or cannot tolerate the side effects of these drugs.[2]

"More than 1 million people are living with drug-resistant epilepsy," said Steven Wolf, M.D., and Patricia McGoldrick, N.P., Pediatric Epilepsy at Boston Children's Health Physicians. "The RNS System has demonstrated unprecedented seizure reduction and improved quality of life in adults with drug-resistant focal epilepsy. Through this clinical study, I am looking forward to evaluating the RNS System in an expanded population of adolescent patients who have uncontrolled focal seizures, despite taking medications."

The RESPONSE Study is a prospective, open label, single arm, pivotal study designed to demonstrate that the RNS System is safe and effective as an adjunctive therapy in individuals aged 12 through 17 years with medically refractory partial onset epilepsy.

The RNS System is the only FDA-approved brain-responsive neuromodulation system that delivers personalized, targeted treatment at the seizure source. 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, typically before clinical symptoms occur.

"The RESPONSE Study is an exciting opportunity to evaluate the safety and effectiveness of the RNS System in a younger population aged 12 through 17, when seizures can profoundly impact school, social development, and self-esteem, as well as expose the teen to all of the risks of seizures themselves," said Martha Morrell, M.D., principal investigator of the study and Chief Medical Officer of NeuroPace. "Our recent announcement of nearly 11 years* of battery life for the RNS System is especially beneficial to younger patients—fewer replacement procedures translates into lower health risk and lower cost for patients."

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.[3]

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 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.

Forward Looking Statements

In addition to background and historical information, this press release contains "forward-looking statements" based on NeuroPace's current expectations, forecasts and beliefs, including NeuroPace's expectations and beliefs about potential benefits of and expectations for clinical trials and regulatory approvals or authorizations. These forward-looking statements are subject to inherent uncertainties, risks, and assumptions that are difficult to predict, including the possibility that NeuroPace may not receive regulatory authorization to treat a younger population, NeuroPace's ability to complete the clinical trial in the currently anticipated timelines or at all, and the possibility of unfavorable results. You should not put undue reliance on these statements or the information presented. These and other risks and uncertainties are described more fully in NeuroPace's public filings with the U.S. Securities and Exchange Commission (SEC), including its Annual Report on Form 10-K for the year ended December 31, 2021 filed with the SEC on March 10, 2022. All forward-looking statements contained in this announcement are based on information currently available to NeuroPace as of

the date hereof and NeuroPace undertakes no obligation to update any such forward-looking statements.

* Median battery longevity is 10.8 years for the RNS Neurostimulator (model RNS-320), on average. Estimates for longevity were derived from medium stimulation and detection utilization (mAh/day).

1. U.S. Centers for Disease Control
2. Chen, et al., *JAMA Neurology, 2018*
3. Nair, et al*, Neurology, 2020*

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