NeuroPace Announces First Patient Implanted in NAUTILUS Pivotal Study for the Treatment of Idiopathic Generalized Epilepsy (IGE)

October 11, 2022

NeuroPace Announces First Patient Implanted in NAUTILUS Pivotal Study for the Treatment of Idiopathic Generalized Epilepsy (IGE)

Groundbreaking NAUTILUS study will evaluate the safety and effectiveness of the RNS System to treat generalized epilepsy in patients aged 12 and older

MOUNTAIN VIEW, Calif., October 11, 2022 (GLOBE NEWSWIRE) -- NeuroPace, Inc. (Nasdaq: NPCE), a commercial stage medical device company focused on transforming the lives of people living with epilepsy, today announced the first patient implanted in the NAUTILUS clinical study. The pivotal study will evaluate the safety and effectiveness of the RNS® System in individuals aged 12 and older with drug-resistant idiopathic generalized epilepsy (IGE), also known as primary generalized epilepsy.

The first procedure took place at Vanderbilt Health in Nashville, Tenn. with co-investigators Angela Crudele, MD, and Dario Englot, MD, PhD. “Today, we have limited treatment options for patients who have drug-resistant, idiopathic generalized epilepsy,” said Dr. Crudele. “This condition can be very difficult to treat and has a significant impact on a patient’s and family’s quality of life. I am excited about the possibility of having an FDA-approved treatment for this population, such as a brain-responsive neuromodulation, and giving these patients a better future.”

Idiopathic Generalized Epilepsy (IGE) is the second most common type of epilepsy, after focal onset epilepsy . IGE accounts for between 15 to 30% of epilepsies , is usually diagnosed in childhood or adolescence, and often results in life-long seizures. Patients with IGE frequently have seizures that cause loss of consciousness and commonly experience injuries from seizure-related falls. Further consequences from uncontrolled seizures include poor cognitive outcomes, depression, decreased social interaction with peers, increased seizure frequency, and sudden unexplained death in epilepsy (SUDEP).

Bonnie, who has had drug-resistant epilepsy since infancy, was the first patient treated in the NAUTILUS study. She said, “I missed a lot of school when I was younger from my epilepsy. I was held back and unable to drive. My family is always worried about me and concerned I might have a seizure. My greatest hope for the trial is to be stable enough to have a job."

“This is a groundbreaking study that could allow individuals who have drug-resistant generalized epilepsy to be treated with the RNS System. Brain-responsive neuromodulation is a proven therapy for drug-resistant focal epilepsy, with long-term studies demonstrating significant seizure reduction and quality of life improvements for patients,” said Martha Morrell, MD, Chief Medical Officer of NeuroPace. “I look forward to investigating whether this therapy could provide similar benefits to patients suffering from primary generalized epilepsy, helping to fill a large unmet need in this population.”

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 NAUTILUS Study is a prospective, multicenter, randomized, controlled pivotal study designed to demonstrate that the RNS System is safe and effective as an adjunctive therapy for primary generalized seizures in individuals aged 12 and older who have drug-resistant IGE.

In 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 Epilepsy

One in 26 Americans will develop epilepsy in their lifetime, with approximately 150,000 new cases of epilepsy diagnosed annually. An estimated 3.4 million Americans currently live with epilepsy. Epilepsy is a chronic disorder, the hallmark of which is recurrent, unprovoked seizures. More people live with epilepsy than autism spectrum disorder, Parkinson’s disease, multiple sclerosis and cerebral palsy – combined.

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 effects4. 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. 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 living with 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.

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 future growth, commercialization efforts, expected returns, growth plans and revenue expectations, as well as our assumptions underlying these expectations. These forward-looking statements are subject to inherent uncertainties, risks, and assumptions that are difficult to predict, including the possibility of delays or failures associated with implementation, regulatory actions, failure to maintain or renew key customer and other business relationships, failure to maintain competitive offerings, the possibility of unfavorable results, and other risks associated with our commercialization efforts or business. You should not put undue reliance on these statements or the information presented. These and other risks and uncertainties include those described more fully in the section titled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operation” and elsewhere in its 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 and its quarterly report on Form 10-Q filed with the SEC on August 11, 2022, as well as any reports that it may file with the SEC in the future. Forward-looking statements contained in this announcement are based on information available to NeuroPace as of the date hereof. NeuroPace undertakes no obligation to update such information except as required under applicable law. These forward-looking statements should not be relied upon as representing NeuroPace’s views as of any date subsequent to the date of this press release and should not be relied upon as a prediction of future events. In light of the foregoing, investors are urged not to rely on any forward-looking statement in reaching any conclusion or making any investment decision about any securities of NeuroPace.

Media Contacts:

Health+Commerce for NeuroPace

Shay Smith

shay@healthandcommerce.com

Investor Contact:

Gilmartin Group

Matt Bacso, CFA

investors@neuropace.com