NeuroPace Announces Early Completion of Patient Enrollment in NAUTILUS Pivotal Study

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NAUTILUS is the first and only pivotal clinical study to evaluate neuromodulation therapy for treating drug refractory idiopathic generalized epilepsy

Neuromodulation therapy is not currently indicated for patients with drug refractory generalized epilepsy

If successful, NeuroPace's RNS System would represent the first neuromodulation indication in idiopathic generalized epilepsy

MOUNTAIN VIEW, Calif., Dec. 21, 2023 (GLOBE NEWSWIRE) -- NeuroPace, Inc. (Nasdaq: NPCE), a commercial, growth-stage, medical technology company focused on transforming the lives of people living with epilepsy, today announced the completion of the patient enrollment goal in its NAUTILUS pivotal study for the treatment of idiopathic generalized epilepsy (IGE) more than one quarter ahead of schedule.

"We are extremely proud to have completed patient enrollment in our NAUTILUS pivotal study significantly ahead of schedule," said Martha Morrell, M.D., NeuroPace's Chief Medical Officer. "We would like to recognize and thank the clinical investigators and patients that have enrolled in this important and groundbreaking trial. We believe that the pace of enrollment in the trial highlights the significant unmet need that exists for patients with drug refractory idiopathic generalized epilepsy."

NAUTILUS is the first and only pivotal clinical study to evaluate neuromodulation therapy in idiopathic generalized epilepsy, or IGE, and, if successful, RNS could secure the first device-based indication for generalized epilepsy. Forty percent of drug-refractory epilepsy patients are diagnosed with generalized epilepsy, and NeuroPace believes that this early patient enrollment milestone is reflective of the excitement amongst patients and clinicians in potentially addressing this significant unmet need with the RNS System. Patients with generalized epilepsy do not need Phase II invasive monitoring and would be able to proceed to RNS System therapy faster, through a noninvasive diagnostic process that could be performed both within and outside of the Comprehensive Epilepsy Center setting. These efforts are part of NeuroPace's broader focus of expanding access to RNS System therapy to aid in addressing the treatment gap for the 1.2 million drug refractory epilepsy patients in the United States.

IGE is the second most common type of epilepsy, after focal onset epilepsy, where seizures originate from various parts of the brain at once. It is typically diagnosed in childhood or adolescence and often results in life-long seizures. Patients with IGE often have seizures that may 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).

The NAUTILUS Study received an Investigational Device Exemption (IDE) approval from the U.S. Food and Drug Administration (FDA) and is a prospective, multicenter, single-blind randomized, sham stimulation controlled pivotal study designed to demonstrate that the RNS System is safe and effective as an adjunctive therapy for patients aged 12 and older with drug-resistant IGE. NeuroPace received FDA Breakthrough Device Designation status in 2021 for the potential use of its RNS System to treat IGE. The trial requires evaluation of a primary safety endpoint and an effectiveness evaluation 12-months post-implant. If the study achieves its primary endpoints, NeuroPace plans to submit a PMA Supplement and also intends to publish findings in a peer-reviewed medical journal.

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. The RNS System is the only system that not only provides therapy, but monitors, detects, and records brain activity, helping patients reduce their seizure burden, while helping clinicians provide comprehensive patient care.

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 among other things, the statements related to clinical trial milestones and expectations, clinical trial execution, financial guidance, commercial strategy, commercial and operational execution, expansion, operational performance, and growth, above. These forward-looking statements are subject to inherent uncertainties, risks, and assumptions that are difficult to predict. Actual outcomes and results could differ materially due to a number of factors, including the risks and uncertainties 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 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, 2022 filed with the SEC on March 2, 2023 and its Quarterly Report on Form 10-Q for the period ended September 30, 2023 to filed with the SEC on November 8, 2023, as well as any other 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.

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