NeuroPace Announces FDA Submission of Three-Year Data from Post-Approval Study of the RNS System in Focal Epilepsy

November 4, 2024 at 4:05 PM EST

The RNS System Post-Approval Study (PAS) is the largest prospective post-approval study in neuromodulation for patients with drug-resistant focal epilepsy

The RNS System PAS evaluates safety and effectiveness of the RNS System in the adult focal population – the largest patient segment of drug-resistant epilepsy

MOUNTAIN VIEW, Calif., Nov. 04, 2024 (GLOBE NEWSWIRE) -- NeuroPace, Inc. (Nasdaq: NPCE), a medical device company focused on transforming the lives of people living with epilepsy, today announced Food and Drug Administration (FDA) submission of three-year safety and effectiveness data from its prospective Post-Approval Study (PAS) of the RNS System in adults with drug-resistant focal epilepsy. The study enrolled more than three hundred patients from more than thirty leading Level 4 Comprehensive Epilepsy Centers in the United States, making it the largest prospectively enrolled trial in the field of neuromodulation for drug-resistant focal epilepsy.

"We are excited to have completed the prospective three-year follow up of patients enrolled in this important study and to have submitted the data to the FDA," said Joel Becker, NeuroPace's Chief Executive Officer. "As the leader in the field of responsive neurostimulation to treat drug-resistant epilepsy, we are committed to studying the impact of RNS System treatment over time in order to continue generating high-quality clinical evidence. This study is a key part of our ongoing commitment to provide physicians the information they need to confidently select and treat their patients with the RNS System."

Focal epilepsy, in which seizures originate from specific areas of the brain, is the most common form of drug-resistant epilepsy. It is typically diagnosed in childhood or adolescence and often results in a lifetime of seizures. 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).

This RNS System PAS study is a five-year prospective, multicenter study required by FDA to gather additional data on the safety and effectiveness of the RNS System as an adjunctive therapy for adult patients with drug-resistant focal epilepsy. The pre-specified primary effectiveness endpoint is at three years of treatment.

"We are excited to reach this important follow up milestone and look forward to FDA review, as well as future peer reviewed publication and presentation of this rigorously collected clinical data," said Martha Morrell, M.D., NeuroPace's Chief Medical Officer. "The RNS System is the only neuromodulation device that provides stimulation and monitors their response over time. The power of this approach was demonstrated in the randomized controlled and long-term treatment trials. Information from the Post-approval Study will further support physicians as they seek to optimize care for drug-resistant focal epilepsy patients," added Dr. Morrell.

The RNS PAS study is planned to continue to a five-year follow-up endpoint as part of the RNS System's initial FDA approval.

About NeuroPace, Inc.
Based in Mountain View, Calif., NeuroPace is a 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 living with 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
This press release may contain forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements may be identified by words such as "aims," "anticipates," "believes," "could," "estimates," "expects," "forecasts," "goal," "intends," "may," "plans," "possible," "potential," "seeks," "will" and variations of these words or similar expressions that are intended to identify forward-looking statements, although not all forward-looking statements contain these words. Forward-looking statements in this press release include, but are not limited to, statements regarding: NeuroPace's current expectations, forecasts and beliefs; future financial performance, including management's outlook for fiscal year 2024; the Company's commitment to effectively managing its operating expenses; ability to capitalize on increased market opportunities by expanding access to treatments; and clinical trial results and indication expansion. NeuroPace may not actually achieve the plans, intentions or expectations disclosed in these forward-looking statements, and you should not place undue reliance on these forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in these forward-looking statements as a result of various factors, including: uncertainties related to market acceptance and adoption of NeuroPace's RNS System; risks related to the pricing of the RNS System and availability of adequate reimbursement for the procedures to implant the RNS System and for clinicians to provide ongoing care for patients treated with the RNS System; the risk that NeuroPace may not realize the intended benefits of its partnership with DIXI Medical; risks related to regulatory compliance and expectations for regulatory approvals to expand the market for NeuroPace's RNS System; NeuroPace's reliance on contractors and other third parties, including single-source suppliers and vendors; and other important factors. 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 Operations" and elsewhere in NeuroPace's public filings with the U.S. Securities and Exchange Commission (SEC), including its Quarterly Report on Form 10-Q for the quarter ended June 30, 2024, filed with the SEC on August 13, 2024, 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

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