



## NeuroPace Announces Preliminary Results from One-Year Data in NAUTILUS Study

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- NeuroPace has completed the primary endpoint analysis of the one-year data from the first and only clinical study to evaluate neuromodulation therapy for idiopathic generalized epilepsy
- Study met the 12-week post-implant primary safety endpoint, demonstrating excellent safety outcomes and confirming favorable safety profile of the RNS® System
- Primary effectiveness endpoint did not reach statistical significance in overall study population but showed a statistically significant response in a subset, which represents the majority of participants
- Preliminary data illustrates the overall value of the RNS System to individualize patient treatment over time, showing more favorable rates of median seizure reduction than observed in the Company's randomized controlled trial supporting its current indication in focal epilepsy

MOUNTAIN VIEW, Calif., May 27, 2025 (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 preliminary primary endpoint one-year results of the two-year NAUTILUS study evaluating safety and effectiveness of the RNS System for treatment of individuals with drug-resistant idiopathic generalized epilepsy (IGE).

### NAUTILUS Study Results

The study successfully met its primary 12-week post-implant safety endpoint, demonstrating a low rate of serious adverse events related to the device and implant procedure, consistent with the established safety profile of the RNS System.

The study did not reach statistical significance for the primary effectiveness endpoint in the overall study population, which was to show a longer time to a second generalized tonic-clonic seizure in the active stimulation group compared to the sham stimulation group. Importantly, however, the data did show a clinically meaningful and highly statistically significant response in the primary effectiveness endpoint within a subgroup of patients with lower baseline frequency of generalized tonic-clonic seizures which represented the majority of trial participants. While the study is not powered to show effectiveness in subgroups, this analysis suggests that there is a therapeutic and clinically meaningful benefit of the RNS System in a substantial subpopulation.

Additionally, within the entire trial population, clinically relevant data, including median percent seizure reduction, responder rates and improvement in seizure free days showed numerically robust and clinically meaningful improvements over the first year of treatment and continued in those who have progressed to the second year. Notably, in a more challenging epilepsy syndrome which was studied in an ethical and novel study design for medical devices, preliminary data at one-year illustrates the value of the RNS System technology to individualize patient treatment through programming over time. While a distinct study design, these metrics were favorable and higher than rates observed in the Company's randomized controlled trial in focal epilepsy that led to FDA approval. In the patients that have completed more than 12 months in the study, preliminary metrics showed continued clinical improvement over time, which aligns with prior findings from the RNS System in the focal epilepsy population, including the FDA-reviewed three-year data from the Company's Post-Approval Study.

"We are very encouraged by the NAUTILUS study results, which demonstrated statistically significant seizure reduction in a key and substantial patient subgroup along with durable improvements across multiple secondary endpoints," said Dr. Martha Morrell, M.D., NeuroPace Chief Medical Officer. "These findings further validate the RNS System's ability to provide personalized therapy, especially when compared to our focal epilepsy pivotal trial that led to our initial approval, while also reinforcing our commitment to expanding access to RNS therapy. We are pleased with the results to date and are confident in our potential for future indication expansion into IGE, as we continue our engagement with the U.S. Food and Drug Administration."

"We view the totality of the data in the NAUTILUS study as a meaningful catalyst that adds to the growing body of evidence and momentum in our business," said Joel Becker, Chief Executive Officer. "With a strong base business growing over 20% year over year, we remain confident in our long-term growth strategy and excited by the opportunity ahead."

The [NAUTILUS Study](#) is a prospective, multicenter, randomized, single-blind, sham-stimulation controlled study that enrolled 100 participants, with 87 undergoing implantation of the RNS Neurostimulator and Leads across 23 epilepsy centers within the US. Patients had drug-resistant idiopathic generalized epilepsy with a high burden of generalized tonic-clonic seizures, the most severe and dangerous seizure type. NeuroPace received [FDA Breakthrough Device Designation](#) status in 2021 for the potential use of its RNS System to treat IGE. Patients in the NAUTILUS trial continue to participate in the study through the completion of two years after the device implant, with prespecified collection of safety and effectiveness data.

The Company plans to submit the full dataset to FDA and for peer-reviewed publication. The Company will engage with the FDA to discuss regulatory pathways based on the data. These discussions may include the possibility of utilizing the overall median seizure reduction data across the full study population, as well as pursuing a more targeted indication focused on patients with lower baseline seizure frequency who may represent a majority of patients with IGE.

### Full-Year 2025 Financial Guidance

The Company reaffirms its previously issued full-year 2025 financial guidance.

### Conference Call Information

NeuroPace will host a conference call at 8:30 a.m. Eastern Time to discuss these results. Investors interested in listening to the conference call may do so by accessing a live and archived webcast of the event at ([click here](#)). Individuals interested in participating in the call via telephone may access the call by dialing +1-877-407-3982 and referencing Conference ID 1375410. The webcast will be archived on the Company's investor relations website at <https://investors.neuropace.com/news-and-events/events> and will be available for replay for at least 90 days after the event.

#### **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. 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. Forward-looking statements in this press release include, but are not limited to, statements regarding: NeuroPace's expectations, forecasts and beliefs with respect to its plans to expand its clinical indication to additional patient populations; NeuroPace's engagement with the FDA regarding regulatory pathways and indication expansion for its RNS System; NeuroPace's plans to submit the full dataset from its ongoing NAUTILUS clinical study for publication; and NeuroPace's expectations regarding its full-year 2025 financial guidance. 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: actual operating results may differ significantly from any guidance provided; uncertainties related to market acceptance and adoption of NeuroPace's RNS System and impacts to NeuroPace's revenue for 2025 and in the future; risks that NeuroPace's operating expenses could be higher than anticipated and that it could use its cash resources sooner than expected; risks that NeuroPace's gross margin may be lower than forecast; 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; risks related to regulatory compliance and expectations for regulatory submissions and approvals to expand the market for NeuroPace's RNS System; risks related to clinical development, including risks related to unfavorable or inconsistent clinical data from ongoing clinical studies; 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 March 31, 2025, filed with the SEC on May 13, 2025, 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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