Neuronetics Receives MDSAP Certification and CE Mark Certification under New MDR

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Achievement demonstrates Company's commitment to rigorous standards for safe and effective products

MALVERN, Pa., May 08, 2023 (GLOBE NEWSWIRE) -- Neuronetics, Inc. (NASDAQ: STIM), a commercial stage medical technology company focused on designing, developing, and marketing products that improve the quality of life for patients who suffer from neurohealth disorders, announced its certification in two enhanced compliance programs. The Company has received CE Mark Certification for NeuroStar Advanced Therapy under the new Medical Device Regulation (MDR) in the European Union (EU) and the Medical Device Single Audit Program (MDSAP) certification.

"Underscoring our commitment to rigorous regulatory and quality standards, our team has worked tirelessly to achieve these certifications from global regulatory agencies," said Keith J. Sullivan, President and CEO of Neuronetics. "These enhanced compliance standards lay the foundation for the company's future as a global organization with the potential to help patients worldwide."

The EU MDR is a more stringent certification process that replaces the European Medical Device Directive. The process is designed to improve patient safety and ensure the effectiveness and quality of medical devices sold in the EU. It sets rigid requirements for developing, manufacturing, and marketing medical devices. The CE Mark is a symbol that indicates conformity with EU regulations, and it is a mandatory requirement for medical devices to be sold in the EU.

MDSAP certification covers distribution in five countries, including the U.S., Japan, Canada, Australia, and Brazil. Once a company is registered in the country, MDSAP certification streamlines the audit process by allowing medical device manufacturers to undergo a single regulatory audit of their quality management system that fulfills the requirements of multiple regulatory jurisdictions.

For more information about NeuroStar, please visit neurostar.com.

About Neuronetics
Neuronetics, Inc. believes that mental health is as important as physical health. As a global leader in neuroscience, Neuronetics is redefining patient and physician expectations with its NeuroStar Advanced Therapy for Mental Health. NeuroStar is a non-drug, noninvasive treatment that can improve the quality of life for people suffering from neurohealth conditions when traditional medication hasn't helped. NeuroStar is FDA-cleared for adults with major depressive disorder (MDD), as an adjunct for adults with obsessive-compulsive disorder (OCD), and to decrease anxiety symptoms in adult patients with MDD that may exhibit comorbid anxiety symptoms (anxious depression). NeuroStar Advanced Therapy is the leading transcranial magnetic stimulation (TMS) treatment for MDD in adults with over 5.3 million treatments delivered. NeuroStar is backed by the largest clinical data set of any TMS system for depression, including the world's largest depression Outcomes Registry. Neuronetics is committed to transforming lives by offering an exceptional treatment that produces extraordinary results. For safety and prescribing information, **www.neurostar.com**.

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Source: Neuronetics