

Neuronetics

NeuroStar Achieves Milestone Regulatory Clearance in South Korea

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First International Approval for Expanded Indication and Certification for MT Cap and D-Tect™ Technologies

MALVERN, Pa., July 17, 2023 (GLOBE NEWSWIRE) -- Neuronetics, Inc. (NASDAQ: STIM), a medical technology company focused on designing, developing, and marketing products that improve the quality of life for patients who suffer from neurohealth disorders, announced that the Ministry of Food and Drug Safety (MFDS) in South Korea has authorized multiple features of NeuroStar TMS (transcranial magnetic stimulation) for sale and distribution in the country – including an expansion of the indication to now include patients with major depressive disorder (MDD) that exhibit [comorbid anxiety](#) symptoms, the [NeuroStar 3.7](#) platform, [MT Cap](#), and [D-Tect™](#) MT Accessory. This marks the first international market where NeuroStar has obtained marketing authorization for the expanded indication and cutting-edge technologies.

MT Cap and D-Tect optimize efficiency for providers and patients by shortening the time and reducing the number of steps involved in determining a patient's motor threshold (MT), which is a critical step to establishing the patient's prescription prior to starting treatment. The NeuroStar 3.7 platform standardizes the NeuroStar hardware globally and includes advancements designed to streamline a clinician's workflow, such as a touchscreen display with a biometric fingerprint reader.

"The regulatory milestone, which came several months ahead of schedule, is a notable achievement for NeuroStar," stated Keith J. Sullivan, President, and CEO of Neuronetics Inc. "It affirms our commitment and strategy toward providing groundbreaking medical technologies to healthcare professionals worldwide. The approval in South Korea, along with our recent [EU-MDR and MDSAP](#) certifications, solidifies our position as a leader in the international medical device industry and underscores our mission to enhance patient care globally."

Patients in South Korea with depression, just like in the United States, struggle with the side effect burden of systemic medications that are used as 2nd, 3rd, and 4th line therapy. The lifetime prevalence of MDD in the country is 6.7%, representing nearly 3.5M adults struggling with depression among the population of 51M¹. South Korea was also reported to have the greatest suicide rate among nations of the Organization of Economic Cooperation and Development (OECD)².

As a market leader in TMS within the South Korean market, NeuroStar aims to fill this unmet need and has partnered with distributor DK Healthcare to expand access to NeuroStar TMS. Further, NeuroStar continues its strategy to advance mental health care globally in strategically selected international markets by seeking clearance for new technological innovations and new indications as the supporting data become available.

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 5.4 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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¹ Shin C, et al. (2017) Assessment of Depression in General Population of Korea. *J Korean Med Sci* 32: 1861-1869. doi: 10.3346/jkms.2017.32.11.1861

² Jang, H, et al. (2022) Suicide rate and social environment characteristics in South Korea: the roles of socioeconomic, demographic, urbanicity, general health behaviors, and other environmental factors on suicide rate. *BMC Public Health* 22, 410. <https://doi.org/10.1186/s12889-022-12843-4>

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