



News Release

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Neuronetics, Inc. Receives CE Mark Approval for NeuroStar TMS Therapy

Non-Invasive, Non-Drug Solution Offers Hope to Millions of Adults Living with Depression

MALVERN, PA, June 4, 2012 – Neuronetics, Inc. announced today the receipt of CE Mark approval for its NeuroStar TMS Therapy[®] System for the treatment of Major Depressive Disorder (MDD) in adult patients who have failed to receive satisfactory improvement from antidepressant medications. The decision is based on data from five studies, collectively representing the largest clinical data set for a therapeutic use of TMS, that demonstrate the safety and efficacy of NeuroStar TMS Therapy in depressed patients across a broad range of antidepressant treatment resistance. One of the five studies has shown a sustained benefit through six months of follow-up in a majority of patients, with only eleven percent of patients experiencing a relapse of illness.

“There is a significant need to extend non-drug treatment options to patients with depression outside the U.S., as not all patients respond to drug therapy,” said Dr. Mark Demitrack, Chief Medical Officer for Neuronetics, Inc. “The CE Mark for NeuroStar TMS Therapy is an important milestone for Neuronetics as it signifies that we have met the requirements of the European Union authorities with extensive clinical efficacy and safety evidence to support the role of TMS in treating depression, while demonstrating our commitment to advance treatment options for patients around the world.”

NeuroStar TMS Therapy is a non-invasive, non-systemic therapeutic device that delivers magnetic resonance imaging (MRI)-strength, pulsed, magnetic fields to induce an electric current in a localized region of the cerebral cortex, the part of the brain that controls mood. NeuroStar is a highly-targeted therapy for adults living with MDD without the systemic side effects commonly associated with oral antidepressant medications.

Recent studies conducted using the NeuroStar TMS Therapy System, include a published, National Institute of Mental Health funded, and company-independent research study evaluating NeuroStar TMS Therapy in patients with major depression (George, et al 2010). This study replicated and extended the results reported in Neuronetics’ multicenter, controlled trial and further validated TMS Therapy as an effective and safe treatment option without the systemic side effects of drug treatment.

In the recent Treatment Utilization and Outcomes Study conducted by Neuronetics, one out of two patients responded to NeuroStar TMS Therapy, defined as experiencing a decrease in symptoms by at least 50 percent. One out of three patients achieved remission, defined as experiencing the absence of any clinically meaningful illness symptoms. These results replicate the results of two prior open-label clinical trials of NeuroStar TMS Therapy and verify that these outcomes are achieved with the NeuroStar TMS Therapy System during general clinical practice (Neuronetics data on file, 2012).

Since its U.S. FDA clearance in 2008, NeuroStar TMS Therapy has been administered to over 8,000 patients through more than 250,000 treatments at 400 centers in the U.S.

About Depression

Depression is a serious illness that affects about 121 million people worldwide, according to the World Health Organization. People with depression may experience a range of physically and emotionally debilitating symptoms, including anxiety, sadness, irritability, fatigue, changes in sleep patterns, loss of interest in previously enjoyable activities and digestive problems.

About NeuroStar TMS Therapy®

NeuroStar TMS Therapy is a non-systemic (does not circulate in the bloodstream throughout the body) and non-invasive (does not involve surgery) form of neuromodulation. It stimulates nerve cells in an area of the brain that has been linked to depression by delivering highly- focused MRI-strength magnetic field pulses. The treatment is typically administered daily for 4-6 weeks. NeuroStar TMS Therapy is available by prescription only. There is a rare risk of seizure associated with TMS (0.1% per acute treatment course). For full safety and prescribing information, visit www.NeuroStar.com.

About Neuronetics

Neuronetics, Inc. is a privately-held medical device company focused on developing non-invasive therapies for psychiatric and neurological disorders using MRI-strength magnetic field pulses. Based in Malvern, PA, Neuronetics is the leader in the development of TMS Therapy, a non-invasive form of neuromodulation. Neuronetics was created as a spin-out of The Innovation Factory, a medical device incubator in Duluth, GA. For more information, please visit www.neuronetics.com.

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