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Neuronetics Announces FDA Clearance to Expand Indication for NeuroStar TMS Therapy to Broader Population of Adults with Major Depressive Disorder

Label expansion is supported by largest body of clinical data of any Transcranial Magnetic Stimulation (TMS) system for depression

MALVERN, Pa., April 7, 2014 – Neuronetics, Inc. announced today that it has received clearance from the U.S. Food and Drug Administration (FDA) for its premarket notification to expand the indication for its novel, non-drug depression treatment, NeuroStar TMS Therapy, to treat adult patients with Major Depressive Disorder (MDD) who have failed to benefit from any number of antidepressant medications. The label expansion was based on new clinical data from a large, prospectively randomized, sham controlled clinical trial that found that TMS delivered by the NeuroStar TMS Therapy System produced statistically significant and clinically meaningful antidepressant therapeutic effects greater than sham treatment.

"Achieving this label expansion is a significant milestone for Neuronetics, further demonstrating our commitment to providing a noninvasive depression therapy to millions of patients who don't respond to antidepressant medication and who could benefit from a non-drug treatment option like NeuroStar," said Judy P. Ways, Ph.D., VP Regulatory Affairs and Quality Assurance at Neuronetics. "This second RCT added a sophisticated sham condition and demonstrated that patients treated with active NeuroStar TMS Therapy are four times more likely to achieve remission of their depression symptoms as compared to patients receiving sham treatment. Additionally, the safety, efficacy and long term durability of NeuroStar TMS Therapy is backed by the largest clinical data set of any TMS product for depression."

The NeuroStar TMS Therapy System is the only TMS system evaluated in seven studies of major depression, completed with 800 patients. One recent study was a multicenter (42 centers), naturalistic, observational study that evaluated the acute efficacy and long term durability of NeuroStar TMS Therapy in adult patients with major depression. In this study, more than half of patients achieved responder status at the end of acute treatment and approximately one third of patients achieved remission. Cumulatively, the NeuroStar clinical studies have resulted in 11 peer-reviewed publications that provide the most comprehensive evidence of safety and efficacy for TMS in the treatment of major depression.

Over 550 NeuroStar Systems are now in operation across the U.S. and more than 18,000 patients have received treatment since clearance by the FDA in 2008. It is a safe and effective outpatient procedure, requiring no sedation and performed in a physician's office with each treatment lasting about 37 minutes daily for four to six weeks.

About NeuroStar TMS Therapy®

Neuronetics' NeuroStar TMS Therapy System was the first TMS system cleared by the FDA in the United States for the treatment of Major Depressive Disorder (MDD). The NeuroStar TMS Therapy System is indicated for the treatment of Major Depressive Disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode. 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 the brain by delivering highly-focused MRI-strength magnetic field pulses which lead to activation of cortical and deep brain structures known to be involved in mood regulation. The treatment is available by prescription and typically administered daily for 4-6 weeks.

For full safety and prescribing information, visit www.NeuroStar.com.

About Depression

Depression is a serious illness that affects about 14 million Americans, and it's estimated that about four million patients do not benefit from standard treatments for depression, even after repeated treatment attempts. People with depression may experience a range of physically and emotionally debilitating symptoms, including anxiousness, sadness, irritability, fatigue, changes in sleep patterns, loss of interest in previously enjoyable activities and digestive problems.

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. For more information, please visit www.neuronetics.com or www.neurostar.com.

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