



News Release

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New Data Show Long-Term Benefit of Transcranial Magnetic Stimulation in Difficult-to-Treat Patients with Depression using NeuroStar TMS Therapy System

Largest clinical study evaluating durability of Transcranial Magnetic Stimulation (TMS) shows depression patients maintained remission through 52 weeks with the NeuroStar

SAN FRANCISCO, May 21, 2013 – New data released today at the annual meeting of the American Psychiatric Association show that the NeuroStar TMS Therapy System® induced statistically and clinically meaningful response and remission in patients with Major Depressive Disorder (MDD) during the acute phase of therapy, which were maintained through one year of treatment. At the end of acute treatment, 62 percent of patients achieved symptomatic improvement while 41 percent reported complete remission. At 12 months, 68 percent of patients achieved symptomatic improvement while 45 percent reported complete remission. Maintenance of benefit was observed under a pragmatic regimen of continuation antidepressant medication and access to TMS reintroduction for symptom recurrence.

“The durability of NeuroStar TMS Therapy demonstrated by this robust, real-world study is remarkable, as it’s not typical to see long-term benefit in patients who have treatment resistant forms of depression,” said Dr. Philip Janicak, M.D., Professor of Psychiatry at Rush University, and Medical Director of the Rush Psychiatric Clinical Research Center. “The study reinforces the sustained efficacy of NeuroStar TMS Therapy in a majority of patients with depression who have not found relief through oral antidepressant medication.”

With 42 clinical practices participating, 307 patients with a primary diagnosis of unipolar, non-psychotic major depressive disorder, who had failed to receive benefit from prior antidepressant medication, received NeuroStar TMS Therapy.

The objectives of this study were to assess the change in depressive symptomatology and functional capacities across the duration of acute and long-term follow-up treatment with NeuroStar TMS. Of the patient population, 257 patients received benefit with acute TMS treatment, then were tapered from their acute treatment regimen and consented to long-term observation over 52 weeks.

Clinical assessments were based on data obtained at three, six, nine and twelve months using the clinician-rated Clinical Global Impression Severity of Illness (CGI-S), and the patient-rated Patient Health Questionnaire (PHQ-9) and Inventory for Depressive Symptomatology-Self Report (IDS-SR).

Neuronetics, Inc. is building upon the robust clinical profile of NeuroStar TMS Therapy System. Most recently, Neuronetics initiated an open-label study to evaluate the safety and efficacy of the NeuroStar® in patients with MDD who are living with post-partum depression. In addition, Neuronetics is also conducting a randomized study on durability of TMS as a maintenance therapy.

About NeuroStar TMS Therapy System®

Neuronetics' NeuroStar TMS Therapy System was cleared by the FDA in October 2008 for the treatment of Major Depressive Disorder (MDD). NeuroStar TMS Therapy is indicated for the treatment of MDD in adult patients who have failed to achieve satisfactory improvement from one prior antidepressant medication at or above the minimal effective dose and duration 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 an area of the brain that has been linked to depression by delivering highly-focused MRI-strength magnetic field pulses. The treatment is available by prescription and typically administered daily for 4-6 weeks.

Nearly 500 NeuroStar Systems are now in operation across the U.S. and more than 12,000 patients have received treatment since clearance by the U.S. Food & Drug Administration in 2008. In June 2012, Neuronetics received the CE Mark for the NeuroStar TMS Therapy System.

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

About Depression

Depression is a serious illness that affects about 20 million Americans annually. 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. It is estimated that about four million patients do not benefit from standard treatments for depression, even after repeated treatment attempts.

About the Study

The study was designed to assess the long-term effectiveness of NeuroStar TMS Therapy in a naturalistic clinical practice settings over 52 weeks following a clinically beneficial acute treatment course. The study population spanned 42 clinical practices with a cumulative total of 307 patients with a primary diagnosis of unipolar, non-psychotic major depressive disorder, who had failed to receive benefit from prior antidepressant medication.

NeuroStar TMS Therapy was administered to patients as determined by the evaluating physician, consistent with labeled use. Patients who received benefit from acute NeuroStar TMS Therapy were tapered from their TMS regimen and observed through 52 weeks of follow-up. Clinical assessments (CGI-Severity of Illness, PHQ-9 and IDS-SR) were obtained at three, six, nine and twelve months. Concurrent medication use and TMS reintroduction for recurrent symptoms was recorded and summarized during the long-term follow up.

Compared with baseline, there was a statistically significant reduction in mean [SD] CGI-S, PHQ-9 and IDS-SR total scores at the end of acute treatment (5.1 [0.9] versus 3.2 [1.5], 18.3 [5.2] versus 9.6 [7.0], and 45.7 [11.0] versus 27.4 [15.8], all $P < 0.0001$), which was sustained throughout the 52 week follow-up (3.0 [1.5], 9.4 [7.2], and 27.3 [16.1], all $P < 0.0001$), respectively.

About Neuronetics, Inc.

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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