NEURONETICS

News Release

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Data Published Online in *The Journal of Clinical Psychiatry* Show Long-Term Benefit of Non-Drug NeuroStar TMS Therapy® in Patients with Treatment Resistant Depression

Largest clinical study evaluating durability of treatment with the NeuroStar shows depression patients maintained remission through 52 weeks

Malvern, Pennsylvania, September 16, 2014 – Neuronetics, Inc., today announced that results of a study designed to assess the long-term effectiveness of NeuroStar TMS Therapy in adult patients with Major Depressive Disorder (MDD) who have failed to benefit from prior treatment with antidepressant medications, were published online in *The Journal of Clinical Psychiatry.* The study found that TMS treatment with the NeuroStar TMS Therapy System induced statistically and clinically meaningful response and remission in patients with treatment resistant MDD during the acute phase of therapy, which were maintained through one year of follow-up. 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 continued antidepressant medication and 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 durability of long-term benefit in patients who have treatment resistant forms of depression,” said Dr. David Dunner, M.D., Director of the Center for Anxiety and Depression in Mercer Island, WA, and Professor Emeritus at the University of Washington in Seattle. “The publication of these findings is an important validation for the sustained efficacy of NeuroStar TMS Therapy in a majority of patients with depression who have not found relief through antidepressant medication.”

With 42 clinical practices participating, 307 patients with a primary diagnosis of unipolar, non-psychotic major depressive disorder and 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 completed their 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 evidence base for the use of NeuroStar TMS Therapy in patients with depression. Most recently, Neuronetics initiated an open-label study to evaluate the safety and efficacy of NeuroStar in patients with MDD who are suffering from post-partum depression. Neuronetics also completed a 12-month randomized study on the utility of TMS as maintenance therapy.

About NeuroStar TMS Therapy®

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.

The NeuroStar TMS Therapy System was FDA-cleared in 2008 on the basis of the largest randomized controlled trial evaluating TMS in depression. In an NIMH-funded, independent, randomized controlled trial, patients treated with TMS using a clinical trial version of the NeuroStar TMS System were four times more likely to achieve remission compared to patients receiving sham treatment (P=0.0173, odds ratio = 4.05). The most common side effect of NeuroStar TMS Therapy is pain or discomfort at or near the treatment site. It is contraindicated in patients with non-removal conductive metal in or near the head. This device has not been evaluated for durability of antidepressant effect in controlled clinical trials.

Over 600 NeuroStar Systems are now in operation across the U.S. and more than 20,000 patients have received treatment. The NeuroStar TMS Therapy System is CE Marked and is approved in several countries worldwide.

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

About Depression

Major depressive disorder is one of the most common mental disorders in the United States. It affects about 25 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 the Study

The study was designed to assess the long-term effectiveness of NeuroStar TMS Therapy in 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 completed 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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