NEURONETICS

News Release

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Non-Drug NeuroStar TMS Therapy Shows Favorable Outcomes Compared to Oral Anti-Depressants in Treating Major Depressive Disorder

Companion health economics analysis shows Transcranial Magnetic Stimulation (TMS) is cost-effective among patients who fail to benefit from prior antidepressant medication

NEW YORK, May 6, 2014 – Neuronetics, Inc. announced today a new analysis of data at the annual meeting of the American Psychiatric Association that shows Transcranial Magnetic Stimulation (TMS) administered with the NeuroStar TMS Therapy System resulted in greater symptom improvement than next-choice conventional antidepressant medication among patients with Major Depressive Disorder (MDD) who failed to benefit from prior antidepressant medication. In a propensity-score matched analysis of data from two independent studies, patient-reported symptom outcomes measured by the Quick Inventory of Depressive Symptomatology-Self Report (QIDS-SR), showed that after 6 weeks of acute phase treatment, 53 percent of patients treated with NeuroStar TMS Therapy reported no or mild depression. In contrast, the propensity-score matched population of patients treated with next-choice antidepressant medication showed improvement among 38 percent of patients (P<0.0001 for the contrast between the two groups, favoring NeuroStar TMS Therapy).

“This comparative, propensity-score matched analysis is important because it demonstrates that a higher proportion of patients with major depressive disorder are likely to achieve greater symptom relief by six weeks with NeuroStar TMS Therapy when compared to the improvement seen with the conventional next-choice approach with oral antidepressants,” said Mark A. Demitrack M.D., Vice President and Chief Medical Officer, Neuronetics. “As successive medication attempts fail to produce relief for a patient, later treatments are increasingly

associated with poorer tolerability, further complicating the course of this disabling illness. This latest data analysis is very encouraging and consistent with previous studies that show NeuroStar TMS Therapy is a safe and effective non-drug treatment option that offers relief and possible remission for patients."

In this report, researchers used a rigorous statistical analysis called propensity score matching to create a comparison population in order to analyze the differences across two independent studies: the TMS Outcomes Study and the Sequenced Treatment Alternatives to Relieve Depression (STAR*D) Study. The STAR*D Study is a landmark report, and remains among the largest and longest studies ever conducted to evaluate depression treatment outcomes using medication and was independently sponsored by the National Institute of Mental Health. Comparison between the groups was based on categorical outcomes using the QIDS-SR definitions for remission (0-5), mildly ill (6-10), moderately ill (11-15) or severely to very severely ill (16-27) depression and showed that the TMS group experienced a greater clinical improvement at six weeks (P<0.0001) compared to the STAR*D study population.

A companion study also presented today found that NeuroStar TMS Therapy is cost-effective for patients who fail to benefit from prior antidepressant medication, with mean annual costs of $11,886 and $10,888 for TMS and STAR*D patients, respectively. Based on these data, researchers estimated that the per member-per month (PMPM) cost to payors of including TMS as a covered benefit range from $0.17 - $0.24, suggesting that the clinical outcome provided by TMS Therapy represents a good value for money in health economic terms.

"NeuroStar TMS Therapy is cost effective compared to standard drug treatment for MDD. This economic advantage of TMS over standard drug therapy is due to the substantially larger proportion of patients who get better with TMS during acute treatment and who maintain those results long-term," said Kit Simpson, Dr. P.H., Professor of Health and Science Research, Medical University of South Carolina. "NeuroStar TMS Therapy is non-systemic, so it doesn't have the side effects associated with pharmacotherapy; therefore, it is well-tolerated by patients, which promotes treatment adherence."

About NeuroStar TMS Therapy®

Neuronetics' NeuroStar TMS Therapy System was cleared by the FDA in October 2008 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 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.

In an NIMH-funded, independent, randomized controlled trial, patients treated with TMS using 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. NeuroStar TMS Therapy compared to antidepressant medication has not been studied in prospective head-to-head clinical trials.
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 Studies
A propensity score algorithm was performed to match the patient populations of the TMS study and STAR*D study in analyzing clinical outcomes and cost-efficacy of treatment.

TMS Outcomes Study
In a multisite, naturalistic, observational study of acute treatment outcomes in clinical practice, 42 US-based clinical TMS practice sites treated 307 outpatients with Major Depressive Disorder (MDD) and persistent symptoms despite antidepressant pharmacotherapy. Treatment was administered with the NeuroStar TMS Therapy System based on the labeled procedure. Assessments were performed at baseline, week 2, at the point of maximal acute benefit, and at week 6 when the acute course extended beyond 6 weeks. The primary outcome was change in the Clinician Global Impressions-Severity of Illness from baseline to end of acute phase. Secondary outcomes were change in continuous and categorical outcomes on self-report depression scales (9-Item Patient Health Questionnaire [PHQ-9], and Inventory of Depressive Symptoms-Self Report [IDS-SR]).

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.

Sequenced Treatment Alternatives to Relieve Depression (STAR*D)[i]
The Sequenced Treatment Alternatives to Relieve Depression (STAR*D) Study, funded by the National Institute of Mental Health, was a nationwide public health clinical trial. The purpose of the trial was to determine the effectiveness of different treatments for people with Major Depressive Disorder (MDD) who have not responded to initial treatment with an antidepressant medication. A broadly representative adult outpatient sample with nonpsychotic major depressive disorder received one (N=3,671) to four (N=123) successive acute treatment steps.

Those not achieving remission with or unable to tolerate a treatment step were encouraged to move to the next step. Those with an acceptable benefit, preferably symptom remission, from any particular step could enter a 12-month naturalistic follow-up phase. A score of ≤5 on the Quick Inventory of Depressive Symptomatology–Self-Report (QIDS-SR16) (equivalent to ≤7 on the 17-item Hamilton Rating Scale for Depression [HRSD17]) defined remission; a QIDS-SR16 total score of ≥11 (HRSD17≥14) defined relapse.

In a separate analysis, the comparative health economic value between TMS and STAR*D was evaluated. Cost of medical care, drug utilization and clinical outcomes were quantified for each health state, according to the QIDS-SR scores. A Markov model was used to estimate total cost and quality-adjusted life years for each treatment over a two-year time horizon.

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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[i] *Am J Psychiatry 2006; 163: 1905-1917.* Available at: http://ajp.psychiatryonline.org/article.aspx?articleid=97282.