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Data Published in *CNS Spectrums* Indicate Acute Transcranial Magnetic Stimulation (TMS) with NeuroStar TMS Therapy® Improves Quality of Life in Patients with Depression

Non-drug Treatment with NeuroStar TMS Led to Significant Symptom Improvement in Patients Not Benefitting from Prior Antidepressant Medication

MALVERN, Pa., September 16, 2013 – Neuronetics, Inc., today announced that results of a naturalistic, observational study from 42 clinical trial sites in the United States, which examined the efficacy of acute treatment with NeuroStar TMS Therapy®. in patients with Major Depressive Disorder (MDD), were published in the July 2013 issue of *CNS Spectrums*. In the study, patients who experienced persistent symptoms of MDD without benefit from concurrent antidepressant pharmacotherapy reported statistically and clinically meaningful improvement in quality of life (QOL) symptoms and functional status following acute treatment with NeuroStar TMS Therapy. Acute efficacy results of this trial were previously reported, showing statistically significant improvement from baseline in depression symptoms including 58% response and 37% remission rates as rated by the clinician using the CGI-Severity of Illness scale under conditions of general clinical use (Carpenter, et al, 2012).

MDD is a debilitating condition in which nearly two-thirds of patients do not benefit adequately from antidepressant medications, and continue to experience life-altering symptoms and functional impairment.

“The publication of these findings is an important validation that NeuroStar TMS Therapy is effective in improving quality of life measures during acute treatment of MDD, particularly in patients with greater disease severity who have not benefitted from treatment with oral antidepressant medication,” said Philip Janicak, M.D., first author, Professor of Psychiatry at Rush University Medical Center. “Patients reported improvement in QOL outcomes after just six weeks of treatment with NeuroStar TMS, which is faster than results we typically see with pharmacotherapy. These data offer hope to people living with MDD and reinforce TMS as a viable treatment option that induces symptom relief and improves overall well-being.”

The published observational study, entitled “Transcranial Magnetic Stimulation (TMS) for Major Depression: A Multisite, Naturalistic, Observational Study of Quality of Life Outcome Measures in Clinical Practice”, involved 307 outpatients across 42 clinical TMS practice sites in the United States with a primary diagnosis of MDD who had failed to benefit from antidepressant medication. A recurrent course of illness was reported in 93 percent of patients and 44 percent had previously been hospitalized for depression. A significant level of treatment resistance was present.

At the end of the acute phase of NeuroStar TMS treatment, statistically significant improvements across physical health and mental health components variables were observed, as measured by the Short Form 36-Item Questionnaire (SF-36). Severely depressed patients experienced the most robust improvement in a relatively short time frame (six weeks). The largest treatment effects were observed on those subscale scores associated with improvements in mental health and social functioning. In addition, 37 percent (N=114) of study patients achieved remission during acute NeuroStar treatment and experienced a superior improvement in QOL compared with non-remitters. Patients with moderately severe to severe depression had the most robust improvement in QOL.

The vitality, social functioning, role-emotional, and mental health perceptions subscales of SF-36 showed a statistically significant improvement of 12-14.8 points or 1.2-1.5 standard deviations (SDs) in the normed score. The mean mental component summary (MCS) score improved by 16.8 points to 33.5 (± 15.06), which is comparable to previous studies showing an improvement in the MCS scores following nine months of treatment with paroxetine (15.8), fluoxetine (15.1), or sertraline (17.4). The subpopulation of remitters showed a much more robust improvement of 27.4 to 30.9 points, reaching scores that are close to the general population norms and are only 0.13 to 0.55 SDs lower.

While the Factors Influencing Depression Endpoints Research (FINDER) Study, a European, prospective, observational trial in 3,468 patients, reported that severely depressed patients had significantly worse SF-36 MCS outcomes, the *CNS Spectrums’* published study demonstrated that acute NeuroStar TMS treatment produced a pronounced QOL improvement in moderately severely- and severely-ill patients compared with the mildly- and moderately-ill groups.

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). 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.

In a controlled trial, patients treated with active NeuroStar TMS Therapy received greater than 3 times the improvement in depressive symptoms compared to placebo at four weeks (MADRS, -7.1 vs -2.1, *P*=0.0006). 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 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

Forty-two clinical TMS practice sites across the United States treated 307 outpatients with a primary diagnosis of MDD and persistent symptoms despite adequate antidepressant pharmacotherapy. Treatment parameters were based on individual clinical considerations and followed the labeled procedures for use of the NeuroStar TMS Therapy System. Functional status was ascertained using the Medical Outcome Study Short-Form Health Survey (SF-36), comprised of eight subscales that measure physical and role functioning: bodily pain, general health, vitality, social and role functioning, and mental health. The physical component summary (PCS) score and a mental component summary (MCS) score integrate information from all eight of the subscales. Patient-reported QOL was also characterized using the EuroQol 5-Dimension Questionnaire (EQ-5D), which contains five dimensions measuring the degree of impairment in the domains of mobility, self-care, usual activities, pain/discomfort, and anxiety/depression.

Patient-reported outcome measures of functional status and QOL were obtained at baseline prior to the initial TMS treatment, and again at the end of acute treatment. The study is posted on www.clinicaltrials.gov, listing number NCT 01114477.

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.

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