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New Trial Data Confirm Clinical Effectiveness and Good Adherence Rates with NeuroStar TMS Therapy in Patients with Major Depressive Disorder Treated in a Real World Practice Setting

– New Results Presented at American Psychiatric Association Meeting in Hawaii –

HONOLULU, Hawaii – May 14, 2011 – Results of a Neuronetics-sponsored, multisite observational study of patients with major depressive disorder (MDD) treated with Neuronetics' NeuroStar Transcranial Magnetic Stimulation (TMS) Therapy in clinical practice showed outcome and adherence rates that were consistent with those observed in patients treated in controlled clinical trial settings. Ninety-nine patients, with a primary diagnosis of major depressive disorder and who had previously been treated with antidepressant medications without benefit, were studied. The study was conducted in 40 clinical practices in the United States. The findings were presented today at the American Psychiatric Association meeting in Honolulu, Hawaii.

“In conjunction with data from randomized controlled clinical trials, information obtained from observational studies of patients treated in real world settings provides an important perspective on how research-based findings translate to treatment in clinical practice,” said Mark A. Demitrack, M.D., Chief Medical Officer at Neuronetics. “There are few studies that have examined the effectiveness of TMS Therapy in a large sample of patients across multiple real world practice settings, and we are pleased that the results validate the data of prior controlled studies and support the use of NeuroStar TMS as an effective treatment for patients who have failed to receive benefit from initial antidepressant medication.”

In the overall study population, as measured by the Inventory of Depressive Symptoms Self-Report scale (IDS-SR) criteria, 53.6 percent – or one in two patients – achieved response and 35.1 percent – or one in three patients – achieved remission by the end of acute treatment. Similarly, using the Patient Health Questionnaire Nine item scale (PHQ-9), 66.7 percent – or two in three patients – reported no or only mild depression scores (a PHQ-9 total score of less than 10) at the end of acute treatment. Similar to these patient-rated outcomes, forty-four percent of patients – or nearly one in two – achieved a final score of one (normal, not at all ill) or two (borderline ill) out of seven (extremely ill) using the physician-rated Clinician Global Impressions Severity of Illness scale (CGI-S). Thus, patient self-report measures were consistent with physician observation.

“These data add to the impressive body of evidence that support the positive impact that TMS Therapy may have on patients living with major depression,” said Karl Lanocha, M.D., Medical Director of The TMS Center of New England.

About the Study

Patients with a primary diagnosis of MDD, who had failed to receive adequate benefit from prior antidepressant medication, sought acute treatment with NeuroStar TMS Therapy in a clinical practice. NeuroStar TMS was provided as clinically determined by the evaluating physician and outcome assessments were performed prior to initiation of the first TMS treatment; at two weeks after treatment began; at the point at which the physician determined that maximal acute treatment had been reached; and, at six weeks if the final acute treatment was longer than six weeks. Assessments included the CGI-S, the PHQ-9, and the IDS-SR.

About NeuroStar TMS Therapy

Neuronetics' NeuroStar TMS Therapy system was cleared by the U.S. Food and Drug Administration (FDA) in October 2008 for the treatment of adult patients with Major Depressive Disorder 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 typically administered daily for four to six weeks.

In clinical trials, patients treated with active NeuroStar TMS Therapy experienced an average reduction in their depression symptom score of 22.1 percent compared to a 9 percent reduction in patients receiving inactive treatment. In an open-label clinical trial, which is most like real world clinical practice, approximately one in two patients experienced significant improvement in symptoms, and one in three experienced complete symptom resolution¹. There were no systemic side effects such as those experienced with some antidepressant medications. The most common adverse event related to treatment was scalp pain or discomfort at the treatment area during active treatment. There is a rare risk of seizure with TMS Therapy (0.1 percent of patients under general clinical use).

NeuroStar TMS Therapy is contraindicated in patients with non-removable metallic objects in or around the head. It is not indicated or effective for all patients with depression and it is available only upon the prescription of a psychiatrist. For full safety and prescribing information, visit www.NeuroStar.com.

Availability of NeuroStar TMS Therapy

Treatment with NeuroStar TMS Therapy is available at more than 300 treatment centers in 38 states. For information on specific treatment centers that offer NeuroStar TMS Therapy, please visit www.NeuroStar.com or call Neuronetics Customer Service Center at (877) 600-7555.

About Major Depressive Disorder

Major depression is a serious medical illness affecting more than 14 million American adults every year. Of those suffering from depression, 6.8 million do not even seek treatment². Often a debilitating disorder, depression results in a persistent state of sadness that interferes with an individual's thoughts, behavior, mood, and physical health. It is important to recognize the symptoms and seek treatment as soon as possible.

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, Penn., Neuronetics is the leader in the development of TMS Therapy, a non-invasive form of neuromodulation. Neuronetics was created as a spinout of The Innovation Factory, a medical device incubator in Duluth, Ga. For more information, please visit www.neuronetics.com.

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1. Demitrack MA, Thase ME, Psychopharmacology Bulletin 2009; 42(2):5-38.
2. Kessler, RC, et al. Prevalence, severity, and comorbidity of twelve-month DSM-IV disorders in the National Comorbidity Survey Replication (NCS-R). Archives of General Psychiatry, 2005 Jun; 62 (6):617-27.