FOR IMMEDIATE RELEASE

FDA CLEARS NEUROSTAR® TMS THERAPY FOR THE TREATMENT OF DEPRESSION

First and Only Non-systemic and Non-invasive Treatment Cleared for Patients Who Have Not Benefited From Prior Antidepressant Treatment

Malvern, PA, [October 8, 2008] – Neuronetics, Inc., a privately-held medical device company and a leader in the field of neuromodulation, announced today that the U.S. Food and Drug Administration (FDA) has cleared its NeuroStar TMS (Transcranial Magnetic Stimulation) Therapy system for the treatment of depression. NeuroStar TMS Therapy® is specifically indicated for the treatment of Major Depressive Disorder 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. In clinical trials with NeuroStar TMS Therapy, these patients had been treated with a median of 4 medication treatment attempts, one of which achieved criteria for adequate dose and duration.

"Clinical neuroscience advances have greatly improved the diagnosis and treatment of depression, but much more is needed. These disorders lead the world in producing disability, and more than half of the millions being treated for clinical depression currently fail to achieve wellness," said John Greden, MD, Professor of Psychiatry & Clinical Neurosciences and Executive Director of the University of Michigan Comprehensive Depression Center. "Before now, few options have been available for them other than complex and often unproven combinations of medications. Now, with the FDA clearance of NeuroStar TMS Therapy, there is new hope."

The NeuroStar TMS Therapy system is the first and only TMS Therapy® device cleared by the FDA for the treatment of depression. 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 which stimulates nerve cells in an area of the brain that is linked to depression, by delivering highly focused MRI-strength magnetic pulses. Patients being treated by NeuroStar TMS Therapy do not require anesthesia or sedation and remain awake and alert. It is a 40-minute outpatient procedure that is prescribed by a psychiatrist and performed in a psychiatrist's office. The treatment is typically administered daily for 4-6 weeks.

"In the randomized controlled trial conducted for FDA clearance, NeuroStar TMS Therapy demonstrated statistically and clinically significant treatment effects," said Phil Janicak, MD, Professor of Psychiatry at Rush University-Chicago and a Principal Investigator in the NeuroStar TMS Therapy clinical trials. "It's particularly noteworthy that these outcomes were achieved without systemic side effects, such as weight gain and sexual dysfunction."

Clinical Trials Demonstrated Efficacy and Safety of NeuroStar TMS Therapy

NeuroStar TMS Therapy was evaluated for efficacy, safety, and tolerability in the acute treatment of major depression in patients who had failed to receive benefit from prior antidepressant medications. A 6-week, randomized, placebo-controlled, double-blind, study[1] was conducted to evaluate the safe and effective use of NeuroStar TMS as a monotherapy. An analysis for predictors of response demonstrated that the patients with the best response to NeuroStar TMS Therapy were those who had not benefited from one prior antidepressant medication at an adequate dose and duration in the current episode[2]. These are the patients for whom NeuroStar TMS Therapy has been cleared by the FDA.

This clinical study population[2] was comprised of 164 patients with unipolar, non-psychotic major depressive disorder. Almost all of them (97%) had suffered previous depression episodes. These patients also had an extensive treatment history without a satisfactory improvement. They had received a median of 4 total prior antidepressant treatment attempts in the current episode, one of which achieved treatment adequacy at or above the minimal effective dose and duration. Forty-eight percent were unemployed due to their depression, 35% had a co-morbid anxiety disorder, and all had moderate to severe depressive symptoms.

In the indicated patient population, the following efficacy results were observed in the randomized, controlled study:

- The primary efficacy measure, the Montgomery-Asberg Depression Rating Scale (MADRS) symptom score change at 4 weeks, was statistically significantly superior to placebo (p=0.0006), among NeuroStar-treated patients. Similar results were observed with the Hamilton Depression Rating Scale (HAMD) [3].
- NeuroStar TMS Therapy-treated patients had statistically significant response[3] and remission[4] rates, which were approximately twice the rate of placebo-treated patients. The response rate is the percentage of patients who had a ≥50% improvement in symptoms, and the remission rate is the percentage of patients who achieved virtually complete symptom resolution.
- NeuroStar TMS Therapy also produced statistically significant improvements on the HAMD factor scores for core depression symptoms, anxiety symptoms, somatization, and psychomotor retardation.[4]

Throughout the NeuroStar TMS Therapy studies, more than 10,000 active TMS treatments were safely performed. The following were the safety results observed[5]:

- No systemic side effects, such as weight gain, sexual dysfunction, sedation, nausea, or dry mouth
- No adverse effects on concentration or memory
- No seizures
- No device-drug interactions
- The most common adverse event related to treatment was scalp pain or discomfort at the treatment area during active treatments, which was transient and mild to moderate in severity. The incidence of this side effect declined markedly after the first week of treatment.
- There was a less than 5% discontinuation rate due to adverse events.
- During a 6-month follow-up period, there were no new safety observations compared to those seen during acute treatment.

NeuroStar TMS Therapy is contraindicated in patients with implanted metallic devices or non-removable metallic objects in or around the head. As with any antidepressant treatment, patients should be monitored for symptoms of worsening depression. NeuroStar TMS Therapy has not been studied in patients who have not received prior

antidepressant treatment. Efficacy has not been established in patients who have failed to receive benefit from two or more prior antidepressant treatments at minimal effective dose and duration in the current episode.

“Depression is a debilitating illness, and existing treatment options are frequently ineffective or intolerable due to side effects,” said Neuronetics’ President and CEO, Bruce Shook. “The availability of NeuroStar TMS Therapy means that patients suffering from this disease now have an entirely new non-systemic and non-invasive treatment option that has been proven safe and effective.”

Availability of NeuroStar TMS Therapy

Initially, NeuroStar TMS Therapy will only be available in a limited number of treatment centers around the country. For specific information on treatment locations with NeuroStar TMS Therapy, please visit www.NeuroStarTMS.com or call the Neuronetics Customer Service Center at (877) 600-7555.

About Depression

Depression affects at least 14 million American adults each year. Researchers estimate that by the year 2020, depression will be the second leading cause of disability worldwide. Each year, over 30,000 people in the US commit suicide, 60% of which suffer from depression. The economic burden of depression in 2000 was estimated at $83.1 billion in the US. Women are almost twice as likely as men to suffer from depression. However, some experts feel that depression in men is under-reported. Depression has no racial, ethnic, or socioeconomic boundaries. About two-thirds of those who experience an episode of depression will have at least one other episode in their lives. Despite major advances in treating this debilitating illness, nearly 30% of patients with depression do not benefit from or are intolerant of antidepressant therapy.

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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[1] O'Reardon, J, et al. Efficacy and Safety of Transcranial Magnetic Stimulation Therapy in the Acute Treatment of Major Depression: A Multi-site Randomized Controlled Trial. *Biological Psychiatry*, December 2007; 62:1208-1216.

[2] Lisanby, S, et al. Daily Left Prefrontal Repetitive Transcranial Magnetic Stimulation (rTMS) in the Acute Treatment of Major Depression: Clinical Predictors of Outcome in a Multisite, Randomized Controlled Clinical Trial. *Neuropsychopharmacology*, advance online publication, 13 August 2008; doi:10.1038/npp.2008.118.

[3] Thase M, Demitrack M. Evaluating Clinical Significance of Treatment Outcomes in Studies of Resistant Major Depression, *Biological Psychiatry*, April, 2008; Vol. 63:7s, pg. 138s.

[4] Data on file.

[5] Janicak, P, et al. Transcranial Magnetic Stimulation (TMS) in the Treatment of Major Depression: A Comprehensive Summary of Safety Experience from Acute Exposure, Extended Exposure and During Reintroduction Treatment. *Journal of Clinical Psychiatry*, February 2008; 69:2:222-232.

NEUROSTAR®
TMS THERAPY

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