

FOR IMMEDIATE RELEASE

**FDA ADVISORY PANEL PROVIDES POSITIVE REVIEW ON SAFETY OF
NEUROSTAR TMS THERAPY™ FOR PATIENTS WITH DEPRESSION**

Panel Requests More Information on Efficacy of Novel, Patented TMS Device

Malvern, PA, January 26, 2007 – Neuronetics, Inc., a privately held medical device company and developer of the NeuroStar TMS (Transcranial Magnetic Stimulation) Therapy system announced today that the U.S. Food and Drug Administration’s (FDA) Neurological Devices Panel agreed that the NeuroStar TMS Therapy system was a safe new treatment option for patients with major depression. The Panel came to this conclusion after evaluating data submitted by Neuronetics, Inc., from the largest study ever conducted with TMS Therapy. The study was conducted in patients who had not received benefit from or were intolerant of previous antidepressant medications. The Panel also requested additional information on efficacy of the new device.

“We are pleased that the FDA Panel recognized the safety benefits that NeuroStar TMS Therapy could bring to patients with major depression, especially those who have been intolerant to medication side effects,” said Neuronetics’ President and CEO, Bruce Shook. “We are confident in the efficacy of our NeuroStar TMS Therapy system, and we look forward to working with the FDA to resolve any remaining questions and make NeuroStar TMS Therapy available for patients suffering with major depression,” said Bruce Shook.

“The randomized, controlled trial clearly demonstrated the efficacy of NeuroStar on many common efficacy measurement tools, including response rates (the rate of patients who had a 50% improvement in symptoms) and remission rates (the rate of patients who had virtually complete symptom resolution),” said Mark A. Demitrack, MD, a psychiatrist and the Chief Medical Officer at Neuronetics, Inc. “The open-label clinical

trial, which is most like real-world clinical practice, demonstrated that approximately one in two patients responded to NeuroStar TMS Therapy and approximately 1 in 3 experienced remission.”

Neuronetics, Inc. is seeking marketing clearance for NeuroStar TMS Therapy, an investigational, non-invasive medical device for patients with major depression. If cleared by the FDA, it will be the first and only treatment of its kind in the US for the treatment of major depression. Today, the panel considered the company’s data submitted in a premarket 510(k) notification. With 510(k) notifications, which differ from premarket approval applications (PMA) for devices, the panel does not vote on whether or not to recommend approval of the device, but reviews the data to assess safety, efficacy, and risk/benefit. A final decision by the FDA is expected within the next few months.

NeuroStar TMS Therapy is a non-invasive outpatient procedure that does not require anesthesia or sedation and can be performed in a psychiatrist’s office. It works by delivering highly focused MRI-strength magnetic field pulses that stimulate nerve cells in the brain that are linked to depression.

“We’ve come a long way in diagnosing and treating depression, but still nearly 30 percent of patients with depression do not benefit from antidepressant medications, or they can’t live with the side effects,” said Mark S. George, MD, Distinguished Professor of Psychiatry, Neurology, and Radiology at the Medical University of South Carolina. Dr. George is a TMS researcher who was involved in the NeuroStar TMS Therapy clinical trials, and he performed the first study with prefrontal TMS for depression 14 years ago. “If this is cleared by the FDA, this would be a welcome new treatment for these patients who currently have few options other than a complex regimen of multiple drugs or, in many cases, more invasive procedures.”

Clinical Highlights to Date

The data submitted to the Panel demonstrated that NeuroStar TMS Therapy was effective, safe and well-tolerated in a six-week randomized, double-blind, sham (placebo)-controlled trial involving 23 research sites in the US, Canada, and Australia.

The study population was 301 patients who were suffering from major depression and who had not responded to at least one, but no more than four, previous antidepressant medications. Results include:

- NeuroStar TMS Therapy treated-patients had statistically significant response and remission rates that were approximately twice the rate of sham-treated patients
- The discontinuation rate due to side effects was less than five percent
- The most commonly reported side effects were mild to moderate headache and local discomfort, which lasted for short periods of time, during or immediately following the treatment session. The incidence of these events declined markedly after the first week of treatment.

During the open-label trial, at the end of nine weeks, 45 percent of patients improved on NeuroStar TMS Therapy, while 31 percent of patients experienced remission (virtually complete symptom resolution). In a six-month extension study, patients received a single medication treatment and, and if needed repeat treatment with NeuroStar TMS Therapy. Among patients who had responded to NeuroStar TMS Therapy less than 10 percent discontinued due to lack of efficacy through six months of follow-up.

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. 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 percent 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, visit www.neuronetics.com.

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NeuroStar TMS Therapy™ system is pending FDA clearance for the treatment of Major Depressive Disorder and is not commercially available. It is an investigational device and limited by federal law to investigational use.

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