



**NEUROSTAR<sup>®</sup> TMS THERAPY DEMONSTRATED SAFETY AND TOLERABILITY  
IN DEPRESSION CLINICAL TRIALS ACCORDING TO  
RECENT PEER-REVIEWED PUBLICATION**

*Data From Over 10,000 Treatment Sessions Suggest NeuroStar TMS Therapy May Offer a Novel, Safe, and Tolerable Treatment Option for Patients with Major Depression*

Malvern, PA – February 28, 2008 – Neuronetics, Inc. announced today that an integrated summary of safety for its NeuroStar TMS (transcranial magnetic stimulation) Therapy system was published in *The Journal of Clinical Psychiatry*, the official peer-reviewed journal of the American Society for Clinical Psychopharmacology. NeuroStar TMS Therapy<sup>®</sup> is a non-systemic, non-invasive investigational medical device currently under review by the FDA for the treatment of depressed patients who failed to receive benefit from and/or tolerate antidepressant medications. These data represent the most comprehensive and largest experience to date regarding the safety and tolerability of TMS Therapy<sup>®</sup>.

"For patients with depression, tolerability of treatment is a major concern. This integrated safety summary demonstrated that treatment with TMS Therapy was well tolerated by depressed patients and was absent the systemic side effects that are frequently associated with antidepressant drugs," said psychiatrist Phil Janicak, M.D., Professor of Psychiatry at Rush University-Chicago, a principal investigator of the trial, and the lead author of the safety analysis. "Coupled with the growing body of evidence demonstrating its efficacy, these safety data demonstrate that TMS Therapy is uniquely well tolerated and safe, particularly when compared to pharmacologic antidepressant options or electroconvulsive therapy (ECT)," Janicak added.

NeuroStar TMS Therapy is administered as an outpatient procedure, 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 thought to be linked to depression. In clinical trials, NeuroStar TMS Therapy demonstrated statistically and clinically significant improvements in depression symptoms<sup>1</sup>.

Neuronetics, Inc. is seeking marketing clearance for NeuroStar TMS Therapy in patients with major depression who have failed to receive adequate benefit from and/or tolerate previous treatment. If cleared by the FDA, it will be the first and only treatment of its kind in the U.S. for the treatment of major depression.

### **About the Integrated Safety Summary for NeuroStar TMS Therapy**

Aggregate safety data were obtained from a comprehensive clinical development program examining the use of NeuroStar TMS Therapy in the treatment of major depressive disorder. There were 3 separate clinical protocols, including 325 patients from 23 clinical sites in the US, Australia, and Canada. Adverse events were assessed at each study visit by review of spontaneous reports with separate reporting of serious adverse events. Safety assessments were also completed for cognitive function and auditory threshold. Assessment of disease-specific risk included the potential for worsening of depressive symptoms. The time course and accommodation to the most commonly appearing adverse events were considered.

### **Results from the Integrated Safety Summary for NeuroStar TMS Therapy**

Throughout the NeuroStar TMS Therapy studies, more than 10,000 active TMS treatments were safely performed. The following are the safety results observed<sup>2</sup>:

- No systemic side effects, such as weight gain, sexual dysfunction, sedation, nausea, or dry mouth
- No seizures
- No evidence of emergent suicidal ideation
- No negative effects on cognition
- No negative effects on auditory threshold
- No drug interactions were observed
- The most common adverse event related to treatment was scalp discomfort 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
- During a 6-month follow-up period, there were no new safety observations

### **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, visit [www.neuronetics.com](http://www.neuronetics.com).

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**Caution: Investigational device. Limited by federal law to investigational use.**

<sup>1</sup> 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.

<sup>2</sup> 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.

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