

Subject: Important TMS Therapy Study Results Press Release

As you may be aware, the results of an independent multicenter research study on TMS therapy, funded by the National Institute of Mental Health (NIMH), was published in this month's *Archives of General Psychiatry*<sup>1</sup>. Given the relevant nature of the study findings, we are providing a copy of the press release issued by the publishing journal on May 4 that contains a summary overview and commentary by the investigators regarding their study data.

This study provides a rigorous and independent validation of prior TMS clinical research and confirms the value of TMS Therapy as an effective and safe treatment for adult patients with major depression who have failed to benefit from prior antidepressant drug therapy.

We appreciate the scientific rigor with which the study was designed and conducted. While the study was completely independent from Neuronetics, we are pleased that the NeuroStar TMS Therapy system was utilized for this trial. As you know, TMS Therapy is the only non-systemic and non-invasive treatment for depression, and the NeuroStar system is the *only* TMS device that is cleared by the FDA for this clinical use\*.

The results of this important study will be presented at the upcoming American Psychiatric Association (APA) meeting in New Orleans this month. We look forward to the presentation of these data which add additional evidence of the valid role of TMS therapy as a safe and effective treatment option for patients suffering from major depression.



Bruce Shook  
President and CEO  
Neuronetics, Inc.

\*NeuroStar TMS Therapy<sup>®</sup> is 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.

The referenced study included some patients with depression who are not within the FDA-cleared indication for NeuroStar TMS Therapy. Efficacy has not established in patients with 2 or more prior antidepressant medication failures of adequate dose and duration in the current episode.

For full prescribing and safety information, visit [www.NeuroStarTMS.com](http://www.NeuroStarTMS.com).

References: 1. George et al. *Arch Gen Psychiatry*, 2010;67[5]:507-516.

From the *Archives of General Psychiatry*:

### **Brain-Stimulation Method Appears to Help Induce Remission in Some Patients With Depression**

CHICAGO—Daily transcranial magnetic stimulation—an intervention that uses magnetic currents to activate certain brain areas—appears to help induce remission in patients with treatment-resistant depression, according to a report in the May issue of *Archives of General Psychiatry*, one of the *JAMA/Archives* journals.

Major depression is common, disabling and expensive, and more effective treatments are needed, according to background information in the article. Some patients experience little or no improvement after medication, psychotherapy or both. Transcranial magnetic stimulation has shown potential as a depression treatment, but there is concern regarding the quality of existing research.

Mark S. George, M.D., of the Medical University of South Carolina, Charleston, and colleagues conducted a randomized controlled trial of repetitive transcranial magnetic stimulation among 190 patients with depression who were not taking medication. Of these, 92 were randomly assigned to receive the intervention, which involved stimulating the left prefrontal cortex with an electromagnetic coil for 37.5 minutes daily for three weeks. The other 98 received a sham treatment that mimicked the sensory experience of stimulation using a similar coil and scalp electrodes but with the magnetic field blocked.

A total of 90 percent of patients in the sham group and 86 percent in the treatment group completed the study. Among these, depression remitted in 14.1 percent in the transcranial magnetic stimulation group, compared with 5.1 percent in the sham group. The odds of achieving remission were 4.2 times greater in the active treatment group.

"One of the most important aspects of the study was ensuring that no one who knew the randomization status of the patient ever came in contact with the patient or interacted with the data," the authors write. "We developed a new active sham transcranial magnetic stimulation system that simulated the repetitive transcranial magnetic stimulation somatosensory experience and effectively masked the patients, the raters and, to a large extent, the treaters." At the end of the treatment phase, patients, treaters and clinical raters were asked to guess whether they were in the active or treatment group. Only treaters were able to guess at a rate more accurate than chance, and they were not very confident of their responses.

The researchers calculated that for every 12 patients treated with transcranial magnetic stimulation, one would remit from depression. Most remissions occurred among individuals with low antidepressant treatment resistance.

"The results of this study suggest that prefrontal repetitive transcranial magnetic stimulation is a monotherapy with few adverse effects and significant antidepressant effects for unipolar depressed patients who do not respond to medications or who cannot tolerate them," the authors conclude.

([Arch Gen Psychiatry. 2010;67\[5\]:507-516](#). Available to the media pre-embargo at [www.jamamedia.org](http://www.jamamedia.org)).