

Depression Patients Who Are Successfully Treated With NeuroStar TMS Therapy May Not Need Antidepressant Medications

Data Published in Brain Stimulation Show 12-month Outcomes with NeuroStar TMS Therapy® Comparing Two Maintenance TMS Approaches in Medication-free MDD Patients

MALVERN, Pa., March 24, 2016 – Neuronetics, Inc. announced today the publication of a recent study in *Brain Stimulation* - “Can Medication Free, Treatment-Resistant, Depressed Patients Who Initially Respond to TMS Be Maintained Off Medications?” Nearly 4 million people in the United States live with depression and are not helped by antidepressant medications. The study focused on this treatment resistant population. Previous studies have demonstrated that over half of these patients experienced improvement in their symptoms and over one third experience complete remission from their depression when treated with NeuroStar TMS Therapy.¹

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 the brain by delivering highly focused MRI-strength magnetic field pulses which lead to activation of cortical and deep brain structures known to be involved in mood regulation. The treatment is available by prescription and typically administered daily for 4-6 weeks.

A key question in the medical community is whether or not the patients who respond to NeuroStar TMS Therapy need to remain on antidepressant medications post-treatment in order to maintain their response. The objective of this study was to evaluate the efficacy of NeuroStar TMS Therapy as the sole maintenance therapy to prevent relapse of depression for patients who initially responded to NeuroStar TMS Therapy. The study examined efficacy over one year of once-monthly scheduled maintenance treatment with NeuroStar TMS Therapy, as compared to monthly observation, for the prevention of symptomatic worsening in medication-free patients who had shown a clinical response to acute treatment. The study demonstrated that treatment-resistant depressed patients treated with NeuroStar TMS Therapy may maintain their clinical benefit with occasional reintroduction only, and do not require antidepressant medication. A secondary finding of the study also revealed a high remission rate of 61.2% among patients from the acute treatment phase, prior to randomization.

“While data has been published on the efficacy of repetitive TMS therapy for acute treatment of resistant MDD, until now there has been limited prospective data about using TMS in medication-free patients to maintain clinical improvement after an initial response,” said Noah S. Philip, MD (representing the study site at Butler Hospital in Providence, RI), Assistant Professor of Psychiatry and Human Behavior at the Alpert Medical School of Brown University. “This study addressed an important question about whether a once-per-month TMS regimen would prolong the time until depressive relapse. Although this schedule was not optimal for the sample we studied, publication of this data in *Brain Stimulation* shows that re-introduction of TMS has a high likelihood of “rescuing” patients who may be at the brink of slipping back into a major depressive episode.”

¹ Carpenter LL, et al. (2012). Transcranial Magnetic Stimulation (TMS) for Major Depression: A Multisite, Naturalistic, Observational Study of Acute Treatment Outcomes in Clinical Practice. *Depress Anxiety* 29(7):587–596.

In this study, about one-third of patients continued to receive benefit from NeuroStar TMS Therapy after acute treatment without the need for treatment with antidepressant medication during the 12-month duration of the study. These results suggest that long term management for patients after initial treatment may require a sequenced approach, for example, observation at first, moving to maintenance NeuroStar TMS Therapy as a second stage, and perhaps combination with pharmaceuticals as a last step. The findings of this study are consistent with other studies of long term outcome data for NeuroStar TMS Therapy that suggest a durable benefit of acute remission in long term follow up.

This 12-month study enrolled 67 patients with pharmacoresistant MDD who were treated with an acute course of NeuroStar TMS Therapy administered for six weeks. Forty-nine patients who completed the 6-week treatment were then randomized to either maintenance treatment with a single session given once every four weeks, or to monthly observation with no additional NeuroStar TMS Therapy treatment. NeuroStar TMS reintroduction was available for symptomatic worsening for either group. All patients were maintained *without* antidepressant medications for the duration of the study. Of the 49 randomized patients, sixteen (32.7%) completed all 53 weeks of the study. Although there was no statistical advantage of monthly maintenance treatment to observation alone, both groups yielded similar stability of outcome over time.

To access the online version of the published manuscript, visit the [Brain Stimulation website](#).

About NeuroStar TMS Therapy

The NeuroStar TMS Therapy System is indicated for the treatment of Major Depressive Disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode.

The NeuroStar TMS Therapy System was initially FDA-cleared in 2008 on the basis of the largest randomized controlled trial evaluating TMS in depression.² In a second independent randomized controlled trial, sponsored by the NIMH, patients treated with TMS using a clinical trial version of the NeuroStar TMS System were four times more likely to achieve remission compared to patients receiving sham treatment ($P=0.0173$, odds ratio=4.05).³ The most common side effect of NeuroStar TMS Therapy is pain or discomfort at or near the treatment site. It is contraindicated in patients with non-removable conductive metal in or near the head.

Nearly 250 million people in the U.S. have access to insurance covering NeuroStar TMS Therapy.

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 700 treatment centers in 49 states. For information on specific treatment locations that offer NeuroStar TMS Therapy, please visit www.NeuroStar.com or call Neuronetics Customer Service Center at (877) 600-7555.

² O'Reardon JP, et al. (2007). Efficacy and Safety of Transcranial Magnetic Stimulation in the Acute Treatment of Major Depression: A Multisite Randomized Controlled Trial. *Biol Psychiatry*, 62(11):1208-1216

³ George MS, et al. (2010). Daily Left Prefrontal Transcranial Magnetic Stimulation Therapy for Major Depressive Disorder: A Sham-Controlled Randomized Trial. *Arch Gen Psychiatry*, 67(5):507-516.

About Neuronetics, Inc.

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 or www.neurostar.com.

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