

## Neuronetics Announces Launch of First Ever Randomized, Controlled Clinical Trial to Evaluate Non-Drug NeuroStar TMS Therapy® in Adolescent Patients with Major Depressive Disorder

*Study will Examine Acute and Long-Term Benefits of NeuroStar TMS,  
Including Symptom Reduction and Remission Rates*

**MALVERN, Pa., Nov. 2, 2015** – Neuronetics, Inc., the market leader in transcranial magnetic stimulation (TMS) technology, announced today the start of enrollment for a randomized controlled clinical trial to evaluate the acute and long-term effectiveness of NeuroStar TMS Therapy® in adolescent patients 12-21 years of age living with major depressive disorder (MDD). This is the first randomized, controlled clinical trial to investigate treatment with TMS in adolescent patients with treatment resistant depression.

Approximately 11 percent of adolescents living in the U.S. have been diagnosed with a depressive disorder<sup>1</sup>. Although the disease state is a continuum into adulthood, symptoms in adolescents can differ from those seen in adult patients. Recognizable symptoms include complaints of feeling sick, refusal to participate in daily activities like going to school, misbehavior in the classroom and excessive worry of losing a caregiver.<sup>2</sup>

“The physical and emotional strain of major depressive disorder can be debilitating for the youth living with it and for their families,” said Christopher Thatcher, President and CEO of Neuronetics. “We are thankful that funding from a Series F Financing Round earlier this year, from GE Ventures and our other investors, will enable us to conduct this important clinical trial, which will further our understanding of the potential role of NeuroStar TMS Therapy in treating depression in adolescents.”

The trial will evaluate the safety and efficacy of NeuroStar TMS in approximately 100 adolescent patients in study sites across the U.S and Canada, using a six-week acute treatment course with follow-up after six-months. Patients who do not improve have the option to enter the open-label phase and receive known active TMS treatment. All who improve will then continue in the follow-up phase for 6 months, with TMS retreatment as necessary.

“It is our hope that NeuroStar TMS Therapy will prove to be an effective treatment for managing the troubling symptoms and impairment associated with adolescent Major Depressive Disorder (MDD), which affects approximately 2.6 million young people in the United States. TMS is an appealing non-pharmacologic option with a promising tolerability profile that we hope to confirm in this study,” said Dr. John Campo, Chair of the Department of Psychiatry and Behavioral Health at The Ohio State University College of Medicine and Wexner Medical Center. “Patients or their parents and caregivers should speak with a healthcare provider if they are interested in learning more about how to participate in this clinical trial.”

For more information about the trial and enrollment, see [ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/NCT02586688?term=neurostar&rank=1), identifier: NCT02586688  
<https://clinicaltrials.gov/ct2/show/NCT02586688?term=neurostar&rank=1>.

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<sup>1</sup> *J Am Acad Child Adolesc Psychiatry*. 2010 October ; 49(10): 980–989. doi:10.1016/j.jaac.2010.05.017.

<sup>2</sup> National Institute of Mental Health. (2014). Depression in Children and Adolescents Fact Sheet.

# NEURONETICS

## **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. 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.

The NeuroStar TMS Therapy System was initially FDA-cleared in 2008 on the basis of the largest randomized controlled trial evaluating TMS in depression<sup>3</sup>. In an independent NIMH-sponsored randomized controlled trial, 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)<sup>4</sup>. 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.

More than 240 million people in the U.S. have access to insurance covering NeuroStar TMS Therapy.

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

## **About Depression**

Major depressive disorder is one of the most common mental disorders in the United States. It affects about 25 million Americans, and it's estimated that about four million patients do not benefit from standard treatments for depression, even after repeated treatment attempts. People with depression may experience a range of physically and emotionally debilitating symptoms, including anxiousness, sadness, irritability, fatigue, changes in sleep patterns, loss of interest in previously enjoyable activities and digestive problems.

## **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<sup>®</sup>, a non-invasive form of neuromodulation. For more information, please visit [www.neuronetics.com](http://www.neuronetics.com) or [www.neurostar.com](http://www.neurostar.com).

NeuroStar<sup>®</sup>, NeuroStar TMS Therapy<sup>®</sup> and TMS Therapy<sup>®</sup> are registered trademarks of Neuronetics, Inc.

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<sup>3</sup> 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

<sup>4</sup> 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.