

## **NeuroStar® Advanced Therapy Extends Depression Research Leadership with New Data at U.S. Psych Congress**

*The NeuroStar Outcomes Registry surpasses 750 patient milestone and validates real-world outcomes for TMS therapy depression treatment*

**MALVERN, Pa., September 15, 2017** — NeuroStar® Advanced Therapy, the established leader in transcranial magnetic stimulation (TMS), will present clinical data and key findings from its outcomes registry and other data at the 2017 U.S. Psychiatric & Mental Health Congress (Psych Congress) in New Orleans, September 16-19, 2017. Psych Congress, celebrating its 30<sup>th</sup> anniversary, is the nation’s leading independent mental health continuing education conference for advancing psychopharmacology, psychotherapy and wellness.

NeuroStar’s depression outcomes registry, which launched in November 2016 to further investigate and better understand the use of the transcranial magnetic stimulation therapy in a clinical setting, has reached 781 patients across approximately 50 treatment facilities in the United States. The registry is projected to grow to 6,000 patients across 100 different treatment facilities by 2019 — making it one of the largest registries for depression treatment.

“NeuroStar is the leader in clinical research for transcranial magnetic stimulation therapy and is also backed by the largest clinical data set for Major Depressive Disorder of any TMS device. The important research by NeuroStar provides validation for the effectiveness of the therapy in treating chronic depression and offers tremendous potential for treatment advancements and new applications,” said Kimberly Cress, M.D., TMS Serenity Center. “I’m truly excited to be one of the doctors participating in the NeuroStar Outcomes Registry and to have access to pivotal data that helps me better understand and address the needs of my patients. I commend NeuroStar for continuing to deliver powerful research that helps advance the understanding of transcranial magnetic stimulation as a legitimate, second-line treatment option for anyone struggling with depression who isn’t benefitting from antidepressants.”

Three poster presentations will occur during the 2017 Psych Congress (Sunday 1:30, Sunday 5:30, and Monday 1:30). The topics of these posters are:

### **NeuroStar Outcomes Registry**

Results from the NeuroStar Outcomes Registry further validate real-world NeuroStar treatment outcomes seen in open-label clinical trials.<sup>1</sup> On a clinician rating scale (CGI-S), 76 percent of patients responded to the treatment and experienced significant improvement, and 59 percent achieved remission of their depression symptoms — demonstrating the proven efficacy of NeuroStar. The NeuroStar Outcomes Registry is powered by its TrakStar™ technology, which is the only transcranial magnetic stimulation patient data management system that automatically

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<sup>1</sup> Carpenter LL, et al. *Depress Anxiety*, (2012)

\*Treatment time may vary depending on doctor’s recommendation.

tracks treatment information, patient history, and clinical outcomes, maximizing coordination of care.

### **Optimizing TMS Treatment for Depression: The 19-Minute Dash™ Protocol**

NeuroStar conducted an analysis to evaluate a reduced treatment time from 37.5 minutes to under 19 minutes\* by decreasing the time between pulse sequences, which would improve patients' comfort and convenience yet still retain the efficacy and safety of the treatment. NeuroStar's analysis confirmed that the variables which impact treatment efficacy are the number of treatment sessions, the number of pulses per session, and the percent motor threshold. Varying or shortening the length of time between pulses does not negatively impact the safety or efficacy of the NeuroStar treatment.

### **Controlled Trial of NeuroStar in Adolescent Patients**

Major Depressive Disorder is a major health problem for adolescents, yet current treatment options frequently fail to provide adequate clinical improvement or are deemed unacceptable to patients and their families. NeuroStar has launched the first-ever randomized, controlled clinical trial to evaluate this unmet need and the acute and long-term effectiveness of NeuroStar in adolescent and young adult patients ages 12 to 21. The trial will evaluate the safety and efficacy of NeuroStar in approximately 100 patients in study sites across the U.S. , using a six-week acute treatment course with six month follow up. NeuroStar is currently enrolling for this clinical trial ([NCT #02586688](https://clinicaltrials.gov/ct2/show/study/NCT02586688)) and expects enrollment to be completed by the end of 2017.

Approximately 4.3 million Americans treated for depression do not benefit from antidepressant medication.<sup>2</sup> With nearly 1.5 million treatments delivered to date, NeuroStar Advanced Therapy was cleared by the FDA in 2008 as a safe and effective second-line treatment option for adult patients with Major Depressive Disorder who have not seen success with at least one antidepressant medication. It is available by prescription and typically administered daily in a doctor's office for four to six weeks. NeuroStar is improving patient access to this therapy with its widespread insurance coverage and enhanced scheduling convenience as the first FDA-cleared TMS treatment that can be delivered in under 19 minutes. Additionally, there has been a 20 percent increase in the number of NeuroStar systems across the country in the past year. The non-drug, non-invasive treatment uses magnetic pulses to stimulate areas of the brain that are underactive in depression. It is not electroconvulsive therapy (ECT) and uses a different mechanism than ECT. Backed with the most clinical studies for transcranial magnetic stimulation in depression,<sup>1,3,4</sup> NeuroStar Advanced Therapy is free from side effects often associated with antidepressants.<sup>5</sup>

For more information about NeuroStar Advanced Therapy, visit [www.NeuroStar.com](http://www.NeuroStar.com).

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<sup>2</sup> Kessler RC, et al. *JAMA*, (2003)

<sup>3</sup> George MS, et al. *Arch Gen Psychiatry*, (2010)

<sup>4</sup> O'Reardon JP, et al. *Biological Psychiatry*, (2007)

<sup>5</sup> Janicak PG, et al. *J Clin Psychiatry*, (2008)

### **About NeuroStar® Advanced Therapy**

NeuroStar Advanced Therapy is the established leader in transcranial magnetic stimulation (TMS), a non-invasive form of neuromodulation. It is backed by the largest clinical data set for Major Depressive Disorder (MDD) of any TMS device. NeuroStar Advanced Therapy is the #1 physician-preferred TMS treatment for patients with MDD, and there are over 800 NeuroStar systems in 49 states.

With over 300 million covered lives, NeuroStar is widely reimbursed by most commercial and government health plans, including Medicare and Tricare. In addition, there are programs in place, such as NeuroStar Reimbursement Support, to help patients and providers obtain coverage and reimbursement for NeuroStar Advanced Therapy.

NeuroStar is indicated for the treatment of MDD in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode. In an NIMH-funded, independent, randomized controlled trial, patients treated with transcranial magnetic stimulation using a clinical-trial version of the NeuroStar System were four times more likely to achieve remission compared to patients receiving sham treatment ( $P = 0.0173$ ; odds ratio = 4.05).<sup>3</sup> The most common side effect is pain or discomfort at or near the treatment site, which usually resolves within one week. It is contraindicated in people with non-removable conductive metal in or near the head. Long-term durability of effect has not been established in a randomized controlled trial.

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

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