

# Neuronetics

## NeuroStar® Patient Outcomes Registry Has Now Surpassed 3,000 Evaluable Patients, Making It The World's Largest in Major Depressive Disorder

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**Data reinforces NeuroStar® Advanced Therapy as effective non-drug treatment to battle depression; registry surpasses number of evaluable patients in STAR\*D**

MALVERN, Pa., July 8, 2019 /PRNewswire/ -- **Neuronetics, Inc. (NASDAQ: STIM)** – Neuronetics, Inc., the developer of NeuroStar® Advanced Therapy, announced today that its depression outcomes registry has reached 3,223 evaluable patients, making it the largest outcomes registry in the world for Major Depressive Disorder (MDD). Launched in November 2016 for the purpose of collecting and analyzing outcomes data from treatment with NeuroStar Advanced Therapy in real-world clinical settings, the registry has surpassed the number of evaluable patients in the STAR\*D study (n=2,876), making it the largest registry focused on therapies for the treatment of depression. STAR\*D was previously the largest long-term study directly comparing treatment strategies for patients with depression. The NeuroStar outcomes registry includes data from 100 clinical practice sites across the United States and reveals that the majority of patients (63 percent) treated with NeuroStar Advanced Therapy experienced significant improvement\* in their depression symptoms, supporting real-world outcomes consistent with those results seen in an open-label clinical trial (Carpenter 2012) in which 58 percent of patients experienced significant improvement.<sup>1</sup> Safety data reported in the registry is also consistent with the findings of previously conducted clinical trials.

"This clinical evidence continues to indicate that NeuroStar is an effective, non-drug depression treatment option. As MDD continues to be a major issue for people in the U.S. and across the globe, a proven option like this is more critical than ever," said Dr. Todd Hutton of Southern California TMS Center and 2019-2020 President of the International Clinical TMS Society. "I am extremely proud to be a part of the NeuroStar outcomes registry and helping to achieve this milestone, as it further underscores a commitment to understanding safe and effective treatment strategies with the potential to help millions achieve remission. It is exciting to use NeuroStar to transform lives and to contribute to an outcomes registry that could provide insight into potential future TMS applications and development."

Depression impacts more than 17 million adults in the U.S.<sup>2</sup> For many people, antidepressant medication is ineffective, demonstrating the importance of breakthrough treatment options and innovative research to address the unmet needs of this population. The NeuroStar outcomes registry aims to investigate and better understand the use of NeuroStar, a non-drug depression treatment, in a clinical setting.

"Surpassing this 3,000-patient milestone in the registry further validates NeuroStar Advanced Therapy's efficacy for patients struggling with depression and as a viable clinical treatment alternative for psychiatrists to treat patients with major depressive disorder," said Chris Thatcher, President and CEO of Neuronetics, Inc. "This large subset of patients from the 66,000 patients treated worldwide provides us insights into potential new research, and for advancements in treatment protocols and patient selection."

### About NeuroStar® Advanced Therapy

NeuroStar® Advanced Therapy is the established leader in transcranial magnetic stimulation (TMS), a non-invasive form of neuromodulation. NeuroStar was the first TMS device to receive United States Food and Drug Administration, or FDA, clearance in 2008 and the first to receive Shonin approval from Japan's Pharmaceuticals and Medical Devices Agency in 2017, and is a proven treatment for adults with MDD for whom medication has not worked. It uses magnetic pulses to stimulate areas of the brain that are underactive in depression.<sup>3,4</sup> With more than 2.3 million treatments delivered to more than 66,000 patients worldwide to-date, NeuroStar Advanced Therapy is the #1 TMS choice of doctors in the United States, and is widely available across the United States. It is typically administered daily in a doctor's office for 19 to 37 minutes\*\* over four to six weeks. Unlike electroconvulsive therapy (ECT), NeuroStar is non-invasive and allows patients to resume daily activities immediately following treatment sessions. As a non-drug treatment, it is also free from systemic side effects often associated with antidepressant medications.<sup>5</sup>

NeuroStar is reimbursed by most commercial and government health plans in the United States, 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. Visit [www.NeuroStar.com](http://www.NeuroStar.com) for more information about NeuroStar Advanced Therapy and [click here](#) to locate a NeuroStar doctor in the United States.

NeuroStar is also available in Japan and select other countries. NeuroStar became listed for reimbursement under Japan's national health insurance on June 1, 2019. NeuroStar is exclusively distributed in Japan by Teijin Pharma Limited.

NeuroStar is indicated in the United States 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 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>6</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.

NeuroStar® is a registered trademark of Neuronetics, Inc. (NASDAQ:STIM). For more information and full safety and prescribing information, visit [www.neurostar.com](http://www.neurostar.com).

### About Neuronetics

Neuronetics, Inc. is a commercial-stage medical technology company focused on designing, developing, and marketing products that improve the quality of life for patients who suffer from psychiatric disorders. Our first commercial product, the NeuroStar® Advanced Therapy System, is a non-invasive and non-systemic office-based treatment that uses transcranial magnetic stimulation, or TMS, to create a pulsed, MRI-strength magnetic

field that induces electrical currents designed to stimulate specific areas of the brain associated with mood. The system is cleared by the FDA for the treatment of major depressive disorder in adult patients who have failed to achieve satisfactory improvement from prior antidepressant medication in the current episode. NeuroStar is also available in other parts of the world, including Japan, where it is listed under Japan's national health insurance. Additional information can be found at [www.neuronetics.com](http://www.neuronetics.com).

#### Forward-Looking Statements

Statements in the press regarding Neuronetics, Inc. (the "Company") that are not historical facts constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements may be identified by terms such as "outlook," "potential," "believe," "expect," "plan," "anticipate," "predict," "may," "will," "could," "would" and "should" as well as the negative of these terms and similar expressions. These statements include those relating to: the Company's expectations regarding the build out of and demand for its NeuroStar Advanced Therapy System, including with respect to trends in the incidence of depression, and its expectations or beliefs regarding future applications and development of the System; and any statements of assumptions underlying any of the foregoing items. These statements are subject to significant risks and uncertainties and actual results could differ materially from those projected. The Company cautions investors not to place undue reliance on the forward-looking statements contained in this release. These risks and uncertainties include, without limitation, risks and uncertainties related to: continued availability and adequacy of coverage and reimbursement from third-party payors for treatments using the Company's products; physician and patient demand for treatments using the Company's products; developments in respect of competing technologies and therapies for the indications that the Company's products treat, including depression; product defects; the Company's ability to obtain and maintain intellectual property protection for its technology; and developments in regulation in the United States, Japan and other applicable jurisdictions. For a discussion of these and other related risks, please refer to the Company's recent SEC filings which are available on the SEC's website at [www.sec.gov](http://www.sec.gov). These forward-looking statements are based on the Company's expectations and assumptions as of the date of this press release. Except as required by law, the Company undertakes no duty or obligation to update any forward-looking statements contained in this press release as a result of new information, future events or changes in the Company's expectations.

\* Response rate defined as PHQ-9 score less than 10

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

<sup>2</sup> National Institute of Mental Health. (2019). Mental Health Information: Major Depression. <https://www.nimh.nih.gov/health/statistics/major-depression.shtml>


<sup>3</sup> Post A, et al. (2001) *J Psychiatric Research*. 35:193-215

<sup>4</sup> Liston C, et al. (2014) *Biol Psychiatry*. 76(7):517-26

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

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

<sup>6</sup> George MS, et al. *Arch Gen Psychiatry*, (2010)

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Meagan Dominick, Office: 610.455.2779, [mdominick@vaultcommunications.com](mailto:mdominick@vaultcommunications.com)