Neuronetics® Unveils Promising New Depression Research Data at Psych Congress

October 3, 2019

New findings confirm safety and efficacy of NeuroStar® Advanced Therapy, a non-drug depression treatment, setting the stage for future indications

MALVERN, Pa., Oct. 3, 2019 /PRNewswire/ -- Neuronetics, Inc. (NASDAQ: STIM), 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, will present its latest patient treatment data and key findings at the 32nd Annual Psych Congress in San Diego, October 3-6, 2019. Psych Congress is a leading independent mental health continuing education conference for advancing psychopharmacology, psychotherapy and wellness.

Neuronetics will share new data from its depression outcomes registry, the largest in the world for Major Depressive Disorder (MDD), which recently surpassed 3,300 evaluable patients. The latest data from patients evaluated using the clinician rating scale of CGI-S (N=1078) shows more than three quarters of patients (76 percent) respond to an acute course of NeuroStar transcranial magnetic stimulation (TMS) treatment and 54 percent achieve remission. This further validates efficacy results shown in a prior open-label study, which showed a 58 percent response rate, and 37 percent remission using the same rating scale.[1]

The depression outcomes registry was launched in 2016 to collect and analyze outcomes data from treatment with NeuroStar Advanced Therapy in real-world clinical settings, and now includes data from 100 clinical practice sites across the country. The NeuroStar outcomes registry has surpassed the number of evaluable patients in the Sequenced Treatment Alternatives To Relieve Depression (STAR*D) study (n=2,876), which was previously the largest long-term study of drug treatment strategies for patients with depression.

"The clinical evidence we're seeing continues to validate NeuroStar as an effective treatment option," said Dr. Todd Hutton of Southern California TMS Center and 2019-2020 President of the International Clinical TMS Society. "I'm proud of my participation in the NeuroStar outcomes registry and know the work we are doing and data we uncover is helping to change lives and shape potential future TMS applications to better serve MDD sufferers across the nation, and the globe."

An additional poster presentation will include clinical research supported by Neuronetics as part of its investigator-initiated trials program, which is focused on post-traumatic stress disorder (PTSD) and traumatic brain injury (TBI). The poster session will showcase preliminary data from researchers at the Uniformed Services University of the Health Sciences, which suggests TMS therapy may be a safe treatment option for military patients with diagnosed TBI and symptoms of PTSD. According to Mental Health America, PTSD affects more than 12 million American adults in any given year. This data will be presented by Jared Garland, Clinical Research Assistant at the Henry M. Jackson Foundation for the Advancement of Military Medicine.

"The registry results further underscore the proven efficacy of NeuroStar," said Chris Thatcher, President and CEO of Neuronetics, Inc. "And, we are excited about the potential of bringing life-changing NeuroStar TMS treatment to patients suffering from complex and difficult diagnoses like PTSD. These early insights are helpful as we embark on clinical work that will set the stage for expanded indications."

Neuronetics will also share findings on the safety profile of the NeuroStar system, with data showing lower than the already low estimated risk of seizure for the NeuroStar system, at only 0.001 percent of treatments (1 in 89,000).

Poster sessions during the 2019 Psych Congress will be presented on Friday, October 4, 1:30 PM – 3:00 PM, Friday, October 4, 6:00 PM – 7:30 PM and Saturday, October 5, 1:30 PM – 2:30 PM. Posters will remain on display during all hours that the Exhibit Hall is open. Additional details are included below:

The NeuroStar Outcomes Registry (Poster Number 150)
Poster Co-authors: Todd Hutton, M.D; Miriam Mina, B.S.; Karen Heart, MBA
Presented By: Todd Hutton, M.D., Southern California TMS Center, USC Keck School of Medicine, Pasadena, CA and Miriam Mina, Neuronetics, Inc.

Post Marketing Rate of Seizures During Transcranial Magnetic Stimulation (TMS) Treatment With NeuroStar® Advanced Therapy Appears to be Lower Than Previously Estimated (Poster Number 220)
Poster Co-authors: Philip Janicak, M.D.; Karen Heart, MBA; Bridget McGugan, PharmD, MBA
Presented By: Bridget McGugan, PharmD, MBA, Neuronetics, Inc.

Evolution of a Study of Bilateral Prefrontal Transcranial Magnetic Stimulation to Treat the Symptoms of Mild TBI and PTSD: Research Methods, Participant Demographics, and Tolerability (Poster Number 139)

Poster Co-authors: Paul F. Pasquina, MD, Professor and Chair of the Department of Physical Medical and Rehabilitation at Uniformed Services University of the Health Sciences and Chief of Rehabilitation Medicine Service at Walter Reed National Military Medical Center, and his colleague Mr. Jared Garland, Clinical Research Assistant at the Henry M. Jackson Foundation for the Advancement of Military Medicine in Support of the Center for Rehabilitative Sciences Research at Uniformed Services University of the Health Sciences
Presented By: Jared Garland

NeuroStar Advanced Therapy was the first TMS device to receive FDA clearance in 2008 as a safe and effective option for adult patients with MDD. NeuroStar has been a trailblazer in the treatment of depression and offers hope to the 5.5 million adults in the U.S. with depression who do not see relief from antidepressant medication.[2,3,4] NeuroStar is backed with the most clinical studies for TMS in depression and has proven efficacy for patients with MDD.[5,6,7]

In honor of National Depression Awareness Month observed throughout October, Neuronetics will share and celebrate patient advocates who have received NeuroStar treatment and achieved remission from their depression. These devoted individuals will align with NeuroStar to educate the public on transcranial magnetic stimulation as an innovative depression treatment option through their first-person stories and perspective.

For more information about NeuroStar Advanced Therapy, visit www.NeuroStar.com.

About NeuroStar® Advanced Therapy
NeuroStar® Advanced Therapy is the market leader in transcranial magnetic stimulation (TMS), a non-invasive form of neuromodulation. NeuroStar Advanced Therapy is the #1 TMS choice of doctors for patients with MDD, and is widely available across the United States.

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 a NIMH-funded, independent, randomized controlled trial, patients treated with TMS using a clinical-trial version of the NeuroStar TMS System were 4.2 times more likely to achieve remission compared to patients receiving sham treatment (P = 0.02; odds ratio = 4.05)[5]. 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.

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 United States Food and Drug Administration, or 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.

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. 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.

[1] Carpenter LL, et al. Depress Anxiety, (2012)
[2] Kessler RC, et al. JAMA, (2003)
[3] https://factfinder.census.gov/faces/nav/jsf/pages/index.xhtml, accessed 1/16/2018
[4] Gaynes BN et al. Cleveland Clinic Journal of Medicine, (2008)
[5] Carpenter LL, et al. Depress Anxiety, (2012)
[6] George MS, et al. Arch Gen Psychiatry, (2010)
[7] O'Reardon JP, et al. Biological Psychiatry, (2007)

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