FDA Grants NeuroStar® Advanced Therapy System Breakthrough Device Designation to Treat Bipolar Depression

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NeuroStar, developed by Neuronetics, Inc., is the first transcranial magnetic stimulation (TMS) device to receive Breakthrough Device Designation for bipolar depression

MALVERN, Pa., March 06, 2020 (GLOBE NEWSWIRE) -- 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, announced today that the U.S. Food and Drug Administration (FDA) has recently granted Breakthrough Device Designation for the Company's NeuroStar Advanced Therapy System for the treatment of bipolar depression.

The FDA's Breakthrough Device Program is intended to help patients and healthcare providers receive more timely access to breakthrough technologies that have the potential to provide more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. The program creates an expedited pathway for prioritized FDA review of the NeuroStar Advanced Therapy clinical trial program. Neuronetics has submitted initial clinical plans for discussion with the FDA.

"We are delighted that the FDA has accepted our application for Breakthrough Device Designation and look forward to working closely with them to provide a potential solution for people with bipolar depression. This potential new treatment indication for NeuroStar means that millions of people with bipolar disorder who do not respond to medications may have a proven, non-drug treatment available to them," said Yelena Tropsha, Vice President, Commercial Access. "The Breakthrough Device Designation is an important milestone that further supports our mission of renewing lives by transforming neurohealth."

Bipolar I and II disorder cause recurrent, dramatic shifts in mood, energy, and activity levels. Bipolar disorder affects approximately 6.5-7 million U.S. adults annually.[1,[2]] Focus for therapies has been on treating the mania and hypomania phase of the disorder with only a few medications approved for the depression phase associated with these disorders. With the Breakthrough Device Designation, NeuroStar Advanced Therapy — the market leader in transcranial magnetic stimulation (TMS) for unipolar major depression — could potentially provide more effective treatment with limited safety concerns to this additional patient population.

In 2008, NeuroStar Advanced Therapy was the first TMS device to receive FDA clearance for adults with Major Depressive Disorder who have not seen success with at least one antidepressant medication. NeuroStar is a non-invasive form of neuromodulation that uses magnetic pulses to stimulate areas of the brain that are underactive in depression.[3,[4]] It is now the first TMS device to receive Breakthrough Device Designation for bipolar depression in adult patients with Bipolar I or Bipolar II disorders that have failed to receive satisfactory improvement from prior pharmacological therapy.

About NeuroStar® Advanced Therapy
NeuroStar® Advanced Therapy is the market leader in transcranial magnetic stimulation (TMS), a non-invasive form of neuromodulation, and the #1 TMS choice of doctors for patients with Major Depressive Disorder (MDD). Widely available across the United States, NeuroStar is reimbursed by most commercial and government health plans, including Medicare and Tricare. In the US, 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. NeuroStar is also available in other parts of the world, including Japan, where it is listed under Japan's national health insurance.

In an 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.

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

About Neuronetics
Neuronetics, Inc. (or the "Company") 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. Its first commercial product is a transcranial magnetic stimulation (TMS) device called the NeuroStar® Advanced Therapy System. Additional information can be found at www.neuronetics.com.

Forward-Looking Statements
Statements in this press release 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 relate to future events that are by their nature uncertain, and 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 are subject to significant risks and uncertainties and actual results could differ materially from those projected. For further discussion of the uncertainties that may cause our actual results to be materially different from those expressed in our forward-looking statements, please refer to the Company's recent SEC filings which are available at www.sec.gov as well as at www.ir.neurostar.com. Except as required by law, the Company undertakes no duty or obligation to update forward-looking statements in this press release to reflect events after the date of this press release.

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[1] https://biomedtracker.com/indicationreport.cfm?indid=168 (Pharma Intelligence BioMed Tracker) based on U.S. adult population, Census July 2018
[2] National Institute of Mental Health https://www.nimh.nih.gov/health/statistics/bipolar-disorder.shtml
[3] Post A, et al. *J Psychiatric Research*, (2001)
[4] Liston C, et al. *Biol Psychiatry*, (2014)
[5] George MS, et al. *Arch Gen Psychiatry*, (2010)

Source: Neuronetics