

# Neuronetics

## NeuroStar® Advanced Therapy for Mental Health Receives FDA Clearance for Treatment of Anxious Depression

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### Indication demonstrates NeuroStar TMS safety and efficacy in improving anxiety symptoms in depressed patients

MALVERN, Pa., July 19, 2022 (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 neurohealth disorders, including drug-resistant depression and obsessive-compulsive disorder (OCD), announced clearance from the U.S. Food and Drug Administration (FDA) for a new indication for its transcranial magnetic stimulation (TMS) system – NeuroStar Advanced Therapy for Mental Health – to treat anxiety symptoms for adult patients who suffer from major depressive disorder (MDD), also known as anxious depression.

“Today, we celebrate a big win for NeuroStar patients and providers,” said Keith J. Sullivan, President and CEO of Neuronetics Inc. “Many people suffering from MDD also experience anxiety symptoms, and these patients with anxious depression are more likely to be severely depressed and to have more thoughts of suicide. This new indication means providers can now describe to MDD patients the benefit of NeuroStar for improving their anxiety symptoms.”

NeuroStar is the leader in patient-focused TMS therapy having treated over 134,000 patients who completed more than 4.8 million treatment sessions. The FDA accepted Neuronetics' use of real-world data analyzed from NeuroStar's proprietary TrakStar® platform in granting clearance for this new indication. The TrakStar database contains digital data from patients treated with NeuroStar at over 1,000 centers. Real-world data from TrakStar is particularly valuable because it provides a large sample from a diverse patient group being treated in a clinical practice setting.

“We would like to acknowledge the contributions of healthcare providers across the country who have partnered with us to help build the world's largest database of depression outcomes,” said Cory Anderson, VP R&D and Clinical. “Not only do we have MDD outcomes, but we also receive data on anxiety outcomes from patients with anxious depression, and these real-world results in anxious depression were an important piece of the FDA clearance.”

The TrakStar results from 664 anxious depression patients demonstrated that 65.5% achieved a clinically meaningful response which exceeded the pre-established overall study success criteria of a minimum 50% response rate ( $p < 0.0001$ ) and indicated a large treatment effect size of 1.4.

“A clinical presentation of anxiety symptoms in patients with MDD is typically more complex to successfully treat with currently available medications,” said Melissa Fickey, MD, founder of Embracing Life Wellness Center. “NeuroStar has presented a robust data set from over 1,300 patients showing safety and efficacy in relieving both depression and anxiety symptoms in patients with anxious depression.”

DASH, [TouchStar™](#), and standard MDD protocols offered by NeuroStar are all now indicated to treat depression with comorbid anxiety. This clearance closely follows after NeuroStar's announcement of an [obsessive compulsive disorder \(OCD\) indication](#), which received FDA clearance in May of this year. For more information about NeuroStar Advanced Therapy for Mental Health, please visit [neurostar.com](#)

### About Anxious Depression

Major depressive disorder (MDD) is a common and serious psychiatric diagnosis among adults with an estimated prevalence of 13.9M patients under treatment in the United States. Anxiety symptoms are a common co-morbidity in patients with MDD, commonly called anxious depression, with an estimated prevalence of more than 50% of MDD patients. The NeuroStar Advanced Therapy System is now indicated for treating anxiety symptoms for those who may exhibit comorbid anxiety and who failed to achieve satisfactory improvement from previous antidepressant medication treatment in the current episode.

### About Neuronetics

Neuronetics, Inc. believes that mental health is as important as physical health. As a global leader in neuroscience, Neuronetics is redefining patient and physician expectations with its NeuroStar Advanced Therapy for Mental Health. NeuroStar is a non-drug, noninvasive treatment that can improve the quality of life for people suffering from neurohealth conditions when traditional medication hasn't helped. NeuroStar is FDA-cleared for adults with major depressive disorder (MDD), as an adjunct for adults with obsessive-compulsive disorder (OCD), and to decrease anxiety symptoms in adult patients with MDD that may exhibit comorbid anxiety symptoms (anxious depression). NeuroStar Advanced Therapy is the leading transcranial magnetic stimulation (TMS) treatment for MDD in adults with over 4.8 million treatments delivered. NeuroStar is backed by the largest clinical data set of any TMS system for depression, including the world's largest depression Outcomes Registry. Neuronetics is committed to transforming lives by offering an exceptional treatment that produces extraordinary results. For safety and prescribing information, [www.neurostar.com](#).

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