Neuronetics® Receives FDA Clearance for Three-Minute TouchStar™ Treatment Protocol

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TouchStar theta burst protocol leverages NeuroStar® Advanced Therapy's patented Contact Sensing technology to help ensure the optimum prescribed treatment dose to patients

MALVERN, Pa., Nov. 23, 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 the U.S. Food and Drug Administration (FDA) granted clearance for the Company's TouchStar treatment, a three-minute intermittent theta burst (iTBS) protocol with its NeuroStar Advanced Therapy System, administered with patented Contact Sensing technology.

The new protocol arms physicians with the ability to now offer a third FDA-cleared treatment protocol with NeuroStar Advanced Therapy – a non-drug, non-invasive transcranial magnetic stimulation (TMS) treatment for Major Depressive Disorder (MDD) that uses magnetic pulses to stimulate areas of the brain that are underactive in depression. The three-minute TouchStar protocol allows clinicians to further customize treatments to best suit patient needs while increasing utilization of the NeuroStar Advanced Therapy System and expanding its benefits to more patients.

TouchStar with Contact Sensing provides physicians and their patients with the option of shorter treatment sessions using higher frequency pulses while helping ensure that the proper dose is being given at every session. The Contact Sensing technology monitors NeuroStar Advanced Therapy's contoured coil, which is designed with a curve to fit the head and provides continuous real-time feedback about the coil's angle and contact with the head.

"The TouchStar protocol is particularly impactful when paired with our patented Contact Sensing precision technology that provides clinicians with the confidence of knowing they are giving patients the right dose at the exact location," said Greg Harper, Vice President of Product Development and Operations at Neuronetics. "A faster solution to target depression is certainly a benefit, but when we're shortening those treatment times it is even more critical that proper coil position is maintained. With TMS systems, if coil contact with the head is off by just 1mm, up to 40 percent of the required dosage can be lost[1] – Contact Sensing monitors coil position and helps ensure patients get the full prescribed treatment dosage every session."

TouchStar is the latest advancement designed to enhance treatment options and expand access and availability of NeuroStar Advanced Therapy for patients. The system now has three treatment variations: standard, which offers treatments at 37.5 minutes per session; DASH, which offers treatments as little as 19 minutes per session; and TouchStar, which offers treatments at three minutes per session. TouchStar will be available to NeuroStar providers in the first quarter of 2021.

"TouchStar protocol clearance is an especially relevant milestone as depression rates continue to rise and providing access to proven depression treatments remains more critical than ever before," said Keith J. Sullivan, President and CEO of Neuronetics. "Our hope is that this third treatment protocol will mean even more patients in need will have access to NeuroStar Advanced Therapy to help them in their battle with this debilitating disease."

Neuronetics remains committed to gathering real world outcomes for treatment through the NeuroStar Outcomes Registry and will include TouchStar data as part of the largest outcomes registry in the world for MDD. Visit www.neurostar.com for more information.

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. Its 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.

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[1] Data on file. Neuronetics, Inc.

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