Neuronetics® Announces First TMS Patient Treated Under New Japan Reimbursement Policy

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Reimbursement for Company's non-drug depression treatment, NeuroStar® Advanced Therapy, enables access for depression sufferers in Japan

MALVERN, Pa., Aug. 1, 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, announced that Kanagawa Psychiatric Center is treating the first patient in Japan using NeuroStar® Advanced Therapy under the newly approved reimbursement listing by Japan'sMinistry of Health, Labour and Welfare (MHLW) and the Central Social Insurance Medical Council (Chuikyo). The reimbursement listing went into effect on June 1, 2019.

As many as 2.4 million adults live with depression in Japan, with approximately 655,000 of them being treated by a doctor. It is estimated that of those receiving treatment, 475,000 patients have failed to achieve remission from depression through antidepressant medications — confirming the importance of safe, effective, non-drug treatment options like NeuroStar Advanced Therapy to address an unmet need in Japan.

"Our initial expansion into Japan, securing reimbursement coverage in the country, our first commercial system installation and now the official treatment of the first patient under the new health policy are such important milestones for us as we work to expand access to people around the world who may benefit from the NeuroStar treatment," said Chris Thatcher, President and CEO of Neuronetics. "We know antidepressants are not a one-size-fits-all solution, and it is crucial that patients with depression and their psychiatrists have access to this alternative option with the potential to transform patients' lives."

According to a survey conducted by the Japanese Society of Psychiatry and Neurology (JSPN), more than half of psychiatric specialists in Japan highly expect to consider TMS for their patients with Major Depressive Disorder (MDD). With NeuroStar now covered by Japan's national public health insurance, this has the potential to transform the treatment of major depression in Japan.[1] Kanagawa Psychiatric Center, the largest psychiatric facility in Yokohama, Japan, is also the first facility in Japan, since the reimbursement listing, to commercially install the Company's NeuroStar Advanced Therapy System for the treatment of MDD.

"Access to and coverage of NeuroStar Advanced Therapy is a positive step forward for depression patients seeking a non-drug option, and their doctors who now have another treatment consideration at their fingertips," said Dr. Motoaki Nakamura, Psychiatrist at Kanagawa Psychiatric Center and Associate Professor at Showa University. "This treatment has the potential to improve the clinical field of depression in Japan, lift the burden of crowded hospitals and facilities since it is a non-invasive option, and can provide hope to the many depression sufferers in our country."

Japan faces one of the highest suicide rates in the world,[2] though the country has an increased focus on addressing mental health and wellness. In recent years, the MHLW amended the Industrial Safety and Health Act to require that companies offer an annual stress check to monitor employees' mental health. The MHLW also continues to promote employment of people with mental disabilities to break the stigma often associated with mental health.

Dr. Nakamura added, "Japan has come a long way in the diagnosis and treatment of mental health. I'm delighted that NeuroStar Advanced Therapy has been recognized and approved as a depression treatment option, and I'm proud to offer it at Kanagawa Psychiatric Center. It gives my patients a chance to achieve remission from depression when antidepressants aren't effective."

About NeuroStar Advanced Therapy

In the United States, NeuroStar Advanced Therapy is the market 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 (PMDA) in 2017 as 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.[3,4] 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.[5]

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 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 Japan as follows: by inducing electrical currents within localized regions of the cerebral cortex and stimulating neurons, using pulsed magnetic fields, the product is used to treat major depression in adult patients (only if they failed to respond to prior treatment with antidepressants).

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).[6] 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.

Neuronetics®, NeuroStar® and TrakStar® are registered trademarks of Neuronetics, Inc. (NASDAQ:STIM). For more information and full safety and prescribing information, visit 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 https://neurostar.com/neuronetics/.

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] Shun, et al. (2017) Psychiatria et neurologia Japonica. 119(7), 472-484

[2] World Health Organization. (2015) Mental Health and Suicide Prevention in Japan. https://www.who.int/mental_health/suicide-prevention/japan_story/en/

[3] Post A, et al. (2001) J Psychiatric Research. 35:193-215

[4] Liston C, et al. (2014) Biol Psychiatry. 76(7):517-26

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

[5] Janicak PG, et al. (2008) J Clin Psychiatry

[6] George MS, et al. Arch Gen Psychiatry, (2010)

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