NeuroStar® Advanced Therapy Receives FDA Clearance as a First-Line Add-On Treatment for Adolescents with Depression

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NeuroStar is the first and only TMS therapy cleared as an adjunct treatment for patients ages 15 and older

MALVERN, Pa., March 25, 2024 (GLOBE NEWSWIRE) -- Neuronetics, Inc. (NASDAQ: STIM), a medical technology company focused on designing, developing, and marketing products that improve the quality of life for patients who suffer from neurohealth disorders, announced clearance from the U.S. Food and Drug Administration (FDA) for NeuroStar Advanced Therapy for use as an adjunct for the treatment of major depressive disorder (MDD) in adolescent patients aged 15-21. NeuroStar is the first and only transcranial magnetic stimulation (TMS) treatment FDA-cleared for this age group, making it the fourth FDA-cleared indication for NeuroStar.

"The prevalence of depression in adolescents and young adults has been accelerating since the COVID-19 pandemic. The current treatment options available for adolescents are extremely limited, compared to those available for adults," according to Dr. Kenneth Pages, Medical Director of TMS of South Tampa. "NeuroStar's TMS therapy now offers a promising first-line treatment for adolescents, backed by real-world data and impressive response rates consistent with response rates for adults. This advancement has the potential to set a new treatment paradigm for how we address depression in our youth."

The FDA's decision to grant clearance for this new indication is based in part on analyzing real-world data collected through NeuroStar's proprietary TrakStar® platform. This platform provided crucial insights into the treatment's effectiveness and safety profile in adolescents. Among the 1,169 adolescents in the data analysis, 78% achieved clinically meaningful improvement in their depression severity. The FDA reviewed the comprehensive data set from TrakStar, along with clinical data from the published literature, and concluded that NeuroStar TMS was substantially equivalent in terms of safety and effectiveness when used as an adjunct to antidepressant therapy over antidepressant therapy alone in this population.

“Receiving FDA-clearance to treat the adolescent segment aged 15 and up is a treatment solution that is long overdue in the mental health industry,” said Keith J. Sullivan, President and CEO of Neuronetics. “We are excited to offer NeuroStar TMS therapy as a new option for young people and for their concerned parents who have struggled to find a treatment they can be confident in. As a company, we will be focused on driving even more awareness and education about NeuroStar given that this new clearance grows our total addressable market in MDD by 35%.”

NeuroStar is harnessing the versatility of its coil design, enabling providers to address the treatment needs of adolescents with MDD symptoms immediately, all without requiring additional hardware upgrades or purchases. For more information about NeuroStar TMS Therapy, please visit **www.neurostar.com**.

About Adolescent Depression
Adolescent depression is a complex and challenging mental health condition that affects young individuals during the crucial period of adolescence. An estimated 4.3 million U.S. adolescents aged 15-21 are affected by MDD. Depression amongst adolescents can disrupt crucial aspects of development, such as academic performance, relationships with peers and family members, and overall emotional well-being.

NeuroStar Advanced Therapy is indicated as an adjunct for the treatment of MDD in adolescent patients aged 15-21.

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 indicated for the treatment of depressive episodes and for decreasing anxiety symptoms for those who may exhibit comorbid anxiety symptoms in adult patients suffering from MDD and who failed to achieve satisfactory improvement from previous antidepressant medication treatment in the current episode. It is also FDA-cleared as an adjunct for adults with obsessive-compulsive disorder and for adolescent patients aged 15-21 with MDD. NeuroStar Advanced Therapy is the leading TMS treatment for MDD in adults with over 6.1 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, visit **www.neurostar.com**.

Cautionary statement under the Private Securities Litigation Reform Act of 1995:

Statements in the press release regarding 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 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: the Company’s ability to execute its business strategy; the Company’s ability to achieve or sustain profitable operations due to its history of losses; the terms of the Company’s credit facility; the Company’s reliance on the sale and use of its NeuroStar Advanced Therapy system to generate revenues; the scale and efficacy of the Company’s salesforce; the Company’s ability to retain talent; availability 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 competing technologies and therapies for the indications that the Company’s products treat; product defects; the Company’s ability to obtain and maintain intellectual property protection for its technology; developments in clinical trials or regulatory review of NeuroStar Advanced Therapy system for additional indications; developments in regulation in the U.S.

and other applicable jurisdictions; our ability to successfully roll-out our Better Me Guarantee Provider Program on the planned timeline; our self-sustainability and existing cash balances; and our ability to achieve cash flow break-even on a full-year basis in 2025. For a discussion of these and other related risks, please refer to the Company's recent filings with the U.S. Securities and Exchange Commission (SEC), 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.

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