BrainsWay Receives FDA Clearance of Deep TMS™ as Adjunct Therapy for Major Depressive Disorder (MDD) in Adolescents Aged 15 to 21

November 13, 2025

Deep TMS™ becomes first and only TMS device cleared in treatment of patients aged 15 to 86 suffering from depression

BURLINGTON, Mass. and JERUSALEM, Israel, Nov. 13, 2025 (GLOBE NEWSWIRE) -- BrainsWay Ltd. (NASDAQ & TASE: BWAY) ("BrainsWay" or the "Company"), a global leader in advanced noninvasive neurostimulation treatments for mental health disorders, today announced that the U.S. Food and Drug Administration (FDA) has granted a label expansion for the Deep Transcranial Magnetic Stimulation (Deep TMS™) system making the treatment available as an adjunct therapy for adolescents aged 15 to 21 years suffering from major depressive disorder (MDD).

"The FDA's clearance of this expanded label enables access to Deep TMS™ for the critically important adolescent patient population, which is often underserved by traditional pharmacological options to manage major depressive disorder," said Dr. Colleen Hanlon, VP of Medical Affairs, BrainsWay Ltd. "The 510(k) clearance was supported by our submission of one of the largest real-world adolescent neuromodulation datasets ever presented to the U.S. FDA, which demonstrated compelling efficacy and safety in reducing depressive symptoms, as well as substantial improvements in comorbid anxiety. This reinforces BrainsWay's position in the market as the leader of evidence-based, noninvasive treatment for depression across all age groups."

The 510(k) clearance followed BrainsWay's submission of a robust data set, including real-world evidence collected from 1,120 adolescents (aged 15–21) treated across 35 TMS centers in the U.S. between 2012 and 2024. Data from high-frequency (18 Hz) and iTBS (intermittent theta-burst) Deep TMS protocols were included. Using the self-administered Patient Health Questionnaire-9 (PHQ-9) rating scale, the results demonstrated, following 36 treatment sessions, an average improvement of 12.1 points and a 66.1% response rate (defined as an improvement from baseline of 50% or greater). In addition, meaningful reductions in anxiety symptoms were observed using the self-administered Generalized Anxiety Disorder (GAD-7) scale, consistent with prior adult studies. Safety outcomes were consistent with previous adult studies.

"We are excited at the opportunities this clearance can bring, for both the young people suffering from this often debilitating condition, and for their parents who have struggled for so long to find treatment solutions that can bring some joy and hope back into their family life," said Hadar Levy, BrainsWay's Chief Executive Officer. "This clearance will allow us to reach the broadest age range of any TMS system for the treatment of depression. With approximately 5 million adolescents in the U.S. estimated to have experienced a major depressive episode within the past year, this represents a significant milestone for us to be able to address an important segment of the MDD patient population. Clinicians can now treat both adults and adolescents using the same Deep TMS™ system and established stimulation protocols."

The BrainsWay Deep TMS™ System is now indicated for the treatment of depressive episodes and for decreasing comorbid anxiety symptoms in adults suffering from MDD who have failed to achieve satisfactory improvement from previous antidepressant medication treatment in the current episode, and as an adjunct therapy for adolescent patients (aged 15-21). MDD is a leading cause of disability globally, with millions of people affected. The situation is especially dire for those patients who fail to respond to traditional treatments, facing prolonged suffering, higher healthcare costs, and a heightened risk of comorbid conditions such as substance abuse and suicide. Despite the global impact of MDD, there is a critical gap in accessible, effective therapies, particularly for these patients.

About BrainsWay
BrainsWay is a global leader in advanced noninvasive neurostimulation treatments for mental health disorders. The Company is boldly advancing neuroscience with its proprietary Deep Transcranial Magnetic Stimulation (Deep TMS™) platform technology to improve health and transform lives. BrainsWay is the first and only TMS company to obtain three FDA-cleared indications backed by pivotal clinical studies demonstrating clinically proven efficacy. Current indications include major depressive disorder (including reduction of anxiety symptoms, commonly referred to as anxious depression), obsessive-compulsive disorder, and smoking addiction. The Company is dedicated to leading through superior science and building on its unparalleled body of clinical evidence. Additional clinical trials of Deep TMS in various psychiatric, neurological, and addiction disorders are underway. Founded in 2003, with operations in the United States and Israel, BrainsWay is committed to increasing global awareness of and broad access to Deep TMS. For the latest news and information about BrainsWay, please visit www.brainsway.com.

Forward-Looking Statement
This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements may be preceded by the words "intends," "may," "will," "plans," "expects," "anticipates," "projects," "predicts," "estimates," "aims," "targets," "believes," "hopes," "potential" or similar words, and also includes any financial guidance and projections contained herein. These forward-looking statements and their implications are based on the current expectations of the management of the Company only and are subject to a number of factors and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. While the clinical study described in this release found a higher incidence of certain adverse events such as headaches and application site discomfort/pain in the accelerated group when compared to the standard of care group, none of these events was classified as severe, and they were comparable to previous TMS clinical studies. In addition, historical results or conclusions from scientific research and clinical studies – especially preliminary data which remains subject to peer-review – do not guarantee that future results would suggest similar conclusions or that historical results referred to herein would be interpreted similarly in light of additional research or otherwise. The following factors, among others, could cause actual results to differ materially from those described in the forward-looking statements: the failure to realize anticipated synergies and other benefits of the proposed transaction; the failure of our investments in management services organizations and/or other clinic-related entities to produce profitable returns; inadequacy of financial resources to meet future capital requirements; changes in technology and market requirements; delays or obstacles in launching and/or

successfully completing planned studies and clinical trials; failure to obtain approvals by regulatory agencies on the Company's anticipated timeframe, or at all; inability to retain or attract key employees whose knowledge is essential to the development of Deep TMS products; unforeseen difficulties with Deep TMS products and processes, and/or inability to develop necessary enhancements; unexpected costs related to Deep TMS products; failure to obtain and maintain adequate protection of the Company's intellectual property, including intellectual property licensed to the Company; the potential for product liability; changes in legislation and applicable rules and regulations; unfavorable market perception and acceptance of Deep TMS technology; inadequate or delays in reimbursement from third-party payers, including insurance companies and Medicare; inability to commercialize Deep TMS, including internationally, by the Company or through third-party distributors; product development by competitors; inability to timely develop and introduce new technologies, products and applications, which could cause the actual results or performance of the Company to differ materially from those contemplated in such forward-looking statements.

Any forward-looking statement in this press release speaks only as of the date of this press release. The Company undertakes no obligation to publicly update or review any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by any applicable securities laws. More detailed information about the risks and uncertainties affecting the Company is contained under the heading "Risk Factors" in the Company's filings with the U.S. Securities and Exchange Commission.

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