BrainsWay Receives FDA Clearance for Accelerated Deep TMS Protocol for Non-Invasive Treatment of Major Depressive Disorder (MDD)

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Clinical data shows that BrainsWay's new accelerated stimulation protocol is comparable to standard Deep TMS in depression score improvement, response and remission

The accelerated protocol is now commercially available in the United States, expanding patient and provider access

BURLINGTON, Mass. and JERUSALEM, Sept. 16, 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 an expansion of the cleared treatment protocols for the Company's Deep Transcranial Magnetic Stimulation system (Deep TMS™) to include an accelerated protocol for the treatment of patients with major depressive disorder (MDD) including those with comorbid anxiety symptoms.

"We are excited to announce this important FDA clearance of an accelerated treatment protocol for our Deep TMS system, which we are confident will empower providers to treat more patients," said Hadar Levy, BrainsWay's Chief Executive Officer. "More than just another clearance, this marks a pivotal advancement in the treatment of depression with Deep TMS because it expands the ways in which we can use Deep TMS to treat depression. While previously, treatment involved 4 weeks of daily treatment sessions before follow up visits, this newly cleared accelerated protocol includes an acute phase of just 6 treatment days."

"As we look toward introducing the accelerated protocol to patients, we will be providing training to healthcare providers over the coming months. In addition, we are actively seeking updates to reimbursement to match the new accelerated protocol, which will help with patient adoption. As a reminder, the current reimbursement for Deep TMS therapy only allows for up to two treatments per day," continued Mr. Levy.

The expanded clearance protocol was based on clinical data from a multicenter, randomized, blinded, controlled study titled, "Accelerated Deep TMS for Depression: Results from a Multisite, Randomized Non-Inferiority Trial," showing that the accelerated Deep TMS protocol using iTBS to treat patients with MDD resulted in outcomes that were comparable to the standard protocol - while requiring considerably fewer visits to the clinic. For example, HDRS-21 depression scores, after statistical adjustment, were reduced by 19.02 and 19.79 points in the accelerated and standard Deep TMS groups, respectively; and response and remission rates were 87.8% and 78.0%, respectively, for the accelerated group, compared to response and remission rates of 87.5% and 87.5%, respectively, for the standard group. The accelerated protocol comprised of an acute phase of 5 sessions per day for 6 days (over a 14 day period), followed by 2 sessions per day once a week for 4 weeks, with each session lasting less than 10 minutes. This was compared to a standard protocol comprised of an acute phase of 5 daily sessions over 4 weeks, followed by 2 daily sessions per week for 2 weeks, with each session lasting 20 minutes. Median time to remission was 21 days for the accelerated group, versus 28 days for the standard group. Study data also demonstrated the overall safety of BrainsWay's accelerated protocol, with no severe adverse events reported.

The BrainsWay Deep TMS™ System 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. 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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