



BrainsWay Post-Marketing Study Confirms Substantial Clinical Benefits of Deep TMS™ in Treating Depression and Anxious Depression

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Real-World Evidence Demonstrates the Highest Response and Remission Rates Observed to Date for Deep

BURLINGTON, Mass. and JERUSALEM, March 28, 2023 (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 the publication of an expansive post-marketing data analysis demonstrating high response and remission rates for depression and anxious depression patients undergoing Deep Transcranial Magnetic Stimulation (Deep TMS™) treatment. The data, published in *Psychiatry Research*, showed the substantial benefits of Deep TMS treatment for depression, with patients who had received 30 or more treatments achieving an 82% response rate and a 65% remission rate.

"BrainsWay is pleased to share this real-world evidence on Deep TMS, as it further validates the immense potential of this treatment in addressing the global mental health crisis," said Hadar Levy, Chief Executive Officer of BrainsWay. "The average patient in this data analysis had already failed more than seven medication trials in their lifetime, and it is exciting to see that patients undergoing a full course of treatment achieved such significant outcomes. These results embolden us in our mission to improve health and transform lives."

"These findings are truly notable," said Aron Tendler, M.D., Chief Medical Officer of BrainsWay. "Keeping in mind that these are patients who have not had success with other treatment modalities, it is compelling to see that four out of five patients in real-world settings achieved at least a 50% reduction in their depression symptoms. Furthermore, nearly three out of four were found to have reached remission based on the Hamilton Depression Rating Scale, a gold standard clinician-administered measurement tool."

[In the study](#), BrainsWay collected an aggregate data set from 1,753 patients across 21 clinics, of which 1,351 patients met the inclusion criteria for the analysis. All patients were treated with the Deep TMS H1 Coil utilizing either a standard protocol (typically 18Hz, 20-minutes long) or a shorter intermittent theta burst (iTBS) protocol. Outcomes were measured with clinician-based scales (HDRS-21) and/or patient self-administered questionnaires designed specifically for depression (PHQ-9, BDI-II). This analysis showed that the average patient achieved sustained response at 16 sessions, or 21 days after beginning treatment. The evidence also showed that efficacy rates were similar between the standard and iTBS protocols. Data from questionnaires which are not specific to depression, and thus less relevant for assessing depression changes, were intentionally excluded.

"BrainsWay would like to thank all of the valued customers, partners, and patients involved in collecting, compiling, and analyzing this data. While the lifesaving nature of this therapy has been known for years, until this study it was only anecdotally known just how effective Deep TMS really is in real-world settings for depression patients that have had limited success with other treatment options," said Levy.

About Major Depressive Disorder and Anxious Depression

Major depressive disorder (MDD) is a common and debilitating form of depression characterized by physiological, emotional, and cognitive symptoms. According to the World Health Organization (WHO), depression affects approximately 264 million people worldwide, and the U.S. National Institute of Mental Health (NIMH) estimates that 21 million adults in the United States suffer from an MDD episode within a given year. Common symptoms of MDD include loss of interest, depressed mood, reduced energy, disturbed sleep, and changes in appetite. 60-90% of depression patients also exhibit comorbid moderate to severe anxiety, a condition commonly referred to as anxious depression. These anxiety symptoms include nervousness, feelings of panic, increased heart rate, rapid breathing, sweating, insomnia, trembling, and difficulty focusing or thinking clearly. The economic burden in the United States for major depressive disorder totaled \$326 billion prior to the recent COVID pandemic.

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 offices in Burlington, MA and Jerusalem, 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," "believes," "hopes," "potential" or similar words. 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. In addition, historical results or conclusions from scientific research and clinical studies 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: 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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