



## Publication Analyzes Clinical Efficacy of Deep TMS™ in Treating Different Brain Regions Associated with Major Depressive Disorder

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### Study Results Outline a Potential Path to More Personalized Medicine in Noninvasive Brain Stimulation

BURLINGTON, Mass. and JERUSALEM, Jan. 31, 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 a comparative study of BrainsWay's Deep Transcranial Stimulation (Deep TMS™) H1 Coil, which targets the lateral prefrontal cortex, and the Company's H7 Coil, which targets the medial prefrontal cortex. Published in *The Journal of Clinical Investigation (JCI) Insight*, the study, which enrolled 169 treatment-resistant depression patients, validates the efficacy of both BrainsWay coils for depression, and also identifies preliminary predictors that could help optimize treatment based on individual patients' attributes.

The primary endpoint of the study – non-inferiority of the H7 Coil in reducing depressive scores when compared to the H1 Coil – was successfully demonstrated among the overall patient population. This study served as the basis for BrainsWay's August 2022 H7 Coil FDA clearance for depression. This publication of the study also includes a new retrospective analysis of the clinician rating scales and EEG data, revealing intriguing differences between the patient treatment of the two coils. Categorizing patients according to "clusters" of clinical depressive and anxiety baseline symptoms derived from a subset of the Hamilton Depression Rating Scale (HDRS-21) resulted in two subject groups: One with higher severity of the cluster, which on average responded better to the H1 Coil, and another with lower severity of the cluster, which on average responded better to the H7 Coil. This retrospective analysis was referred to in the publication as the "Clinical Differential Predictor" for TMS H-Coils.

Another interesting finding involved retrospective EEG analysis, which showed that brain activity measured during the first treatment session correlated with the clinical outcomes ultimately achieved after the full course of treatment. This finding suggests that specific brain patterns observed in an individual's response to either coil during the early stages of treatment might be predictive of the longer-term outcome of treatment with that coil.

"This study is a significant milestone for depression and anxious depression patients and reinforces our commitment to bring mental health within reach for all," said [Christopher von Jakó](#), Ph.D., President and CEO of BrainsWay.

"This study is an important scientific step forward toward personalized psychiatry," said Prof. Abraham Zangen, Head of the Brain Stimulation and Behavior Lab and the Chair of the PsychoBiology Brain Program at Ben-Gurion University and a scientific consultant for and member of the board of directors of BrainsWay. "Previously published case series had indicated that the H7 Coil was potentially effective in treating depression in patients that did not achieve response or remission after undergoing treatment with TMS coils which target the lateral prefrontal cortex. While the similar reduction in depression scores notably validated the non-inferiority between the H1 and H7 Coils, we were truly inspired by the subsequent retrospective analyses of the clinician rating scales and EEG data. Once we apply the categorization technique employed in this study, the potential exists to increase depression response rates even further. For example, patients categorized as having high cluster severity demonstrated response rates of 95%. We look forward to further validating these preliminary predictors in subsequent research as we continue our quest to optimize patient outcomes."

The paper, "*Pursuing personalized medicine for depression by targeting lateral or medial prefrontal cortex with Deep TMS,*" was published in *The Journal of Clinical Investigation (JCI) Insight*. For more information, please visit: <https://insight.jci.org/articles/view/165271>

### 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](http://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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