BrainsWay Reports Positive Results from Multicenter Randomized Study of Accelerated Deep TMS for Major Depressive Disorder (MDD)

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Improvement in depression scores, response and remission were all found to be comparable with standard Deep TMS in non-inferiority trial

BURLINGTON, Mass. and JERUSALEM, June 11, 2025 (GLOBE NEWSWIRE) -- BrainsWay Ltd. (NASDAQ & TASE: BWAY), a global leader in advanced noninvasive neurostimulation treatments for mental health disorders, today announced preliminary results from a multicenter, randomized controlled trial titled, *"Accelerated Deep TMS for Depression: Results from a Multisite, Randomized Non-Inferiority Trial."* The results suggest that the accelerated Deep Transcranial Magnetic Stimulation (Deep TMS™) protocol using intermittent theta burst stimulation (iTBS) to treat patients with major depressive disorder (MDD) resulted in outcomes that are comparable to the standard once-daily TMS protocol — while requiring considerably fewer visits to the clinic.

The trial, which enrolled 104 adult patients diagnosed with depression across eight sites, is the largest randomized, controlled, blinded, multicenter trial of an accelerated Deep TMS protocol. Patients from the study were divided into two active treatment groups, with one group receiving treatment under the standard Deep TMS protocol and the other group receiving treatment under the accelerated Deep TMS protocol.

Patients in the accelerated group completed five sessions per day over six treatment days, followed by a brief continuation phase of eight sessions over the subsequent four weeks. This protocol was designed to significantly reduce treatment burden. The primary endpoint of the study was the change in depressive symptoms as measured using the HDRS-21 scale, and secondary endpoints included response and remission rates.

Key Points from the Study:

- **Comparable Efficacy**: The accelerated Deep TMS group achieved significant improvement that was comparable to the standard Deep TMS group:
  - HDRS depression scores were reduced by 18.9 and 19.9 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.
- **Shorter Sessions**: Accelerated Deep TMS sessions lasted less than 10 minutes, compared to 20 minutes for standard treatment sessions.
- **Time to Remission**: Median time to remission was 21 days for the accelerated group v. 28 days for the standard group.
- **Safety and Tolerability**: The accelerated protocol was well-tolerated, with no reported serious adverse events. Side effects, such as headache and site discomfort, were mild and consistent with standard TMS treatments.
- **No Reliance on fMRI Imaging**: The study was conducted using BrainsWay's H1 Coil with standard targeting, without reliance on any neuronavigation equipment.

"Throughout psychiatry, we see patients who are motivated to get better but simply cannot make it to a clinic five days a week for six weeks straight," said Dr. Russ Voltin, a board-certified psychiatrist at PsyCare, a participating site in the study. "This accelerated treatment approach appears to preserve efficacy while making the logistics far more manageable. For many patients, it could be the difference between getting treated and not receiving the treatment."

"Innovation in mental health care is not only about new technology, it is also about advancing how care is delivered," noted Dr. Colleen Hanlon, Vice President of Medical Affairs at BrainsWay. "This study reflects our commitment to expanding access to Deep TMS and driving the field forward through compelling scientific research."

The accelerated protocol tested in the study is investigational in nature and not yet FDA-cleared. The preliminary results remain subject to additional analysis and peer-review.

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," "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. 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 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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