BrainsWay Announces Data from Feasibility Study of Deep Transcranial Magnetic Stimulation System in the treatment of Adults with ADHD

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Results demonstrate increased activity in attention-related brain networks treated with BrainsWay's H6-coil, which correlate with observed improvement in ADHD symptoms

PATTERSON, N.J., Feb. 10, 2020 (GLOBE NEWSWIRE) -- BrainsWay Ltd. (NASDAQ & TASE: BWAY) ("BrainsWay") today announced results from a randomized controlled double-blind clinical trial (NCT01196910) assessing the safety and efficacy of the Company's proprietary H6-coil deep transcranial magnetic stimulation (dTMS) System for the treatment of adults with attention deficit hyperactivity disorder (ADHD). Researchers at Tel Aviv Sourasky Medical Center, Tel Aviv University, Ben Gurion University and BrainsWay conducted the study, which used functional magnetic resonance imaging (fMRI) to assess the effect of dTMS on clinical, cognitive and neural activity in adults with ADHD. Results showed a statistically significant improvement in patient-reported assessments of inattention, together with a significant increase in activity that was observed within the dorsolateral prefrontal cortex (DLPFC), a brain area previously shown to express reduced activity in adults with ADHD.

"Reduced activity of the DLPFC, a brain region that controls the ability to respond to changing attentional demands, has previously been observed in patients with ADHD," said Dr. Maya Bleich-Cohen, senior investigator at Tel Aviv Sourasky Medical Center and an investigator on the study. "The results of this initial study indicate that dTMS can be effective in modulating the DLPFC and that this may be a feasible technique to improve attention symptoms in adults with ADHD. Additional study of this non-invasive treatment approach in this population is warranted."

About the Study
The study enrolled 75 adults, ages 18-60 years, with ADHD who had not previously received TMS. The study included one treatment group with the dTMS coil targeting the right prefrontal cortex (N=27), a second group with the dTMS coil targeting the left prefrontal cortex (N=28), and a control group with a sham coil (N=20). Participants underwent a treatment phase consisting of 15 daily dTMS sessions, which were conducted five days a week for three consecutive weeks using the BrainsWay dTMS H6 (or sham) coil. Each patient underwent fMRI before and after the treatment phase. Two additional treatment sessions were performed at the second and third follow-up visits, which were performed one and two months after completion of the acute treatment phase, respectively. At each treatment session, subjects also performed six minutes of computerized cognitive training consisting of an immediate recall task and a sustained attention task, each of three-minute duration. Patients underwent clinical evaluation at screening, after the three-week treatment phase and then at four and eight weeks after completion of the treatment phase, which included symptom assessment using validated questionnaires, and a full cognitive assessment including evaluation of memory, executive function and attention skills.

Topline findings from the study include:

- Significant improvements were observed in the Inattention/Memory Problems subscale of the Conners' Adult ADHD Rating Scale (CAARS) self-report questionnaire, in both right and left treatment arms compared with the sham control group (p=.033)
    - In a post-hoc analysis, improvements in the right and left stimulation groups were each significantly greater than that of the sham group (p<0.00005 and p<0.05, respectively)
- Interestingly, increased fMRI brain activation in the right DLPFC during a working memory task were only apparent following treatment in the right stimulation group (p=0.01)
    - In a post-hoc analysis, activation in the right stimulation group was greater than that of the left stimulation or sham groups (p<0.005)
    - Additionally, this increased right DLPFC activation was associated with larger symptom improvement exclusively in the right stimulation group (p<0.05)
    - Other regions associated with the brain's attentional network showed similar increased activation during the task in the right stimulation group (i.e. Right Inferior Parietal Sulcus, Right Inferior Frontal Gyrus)
- The response rates (defined as at least a 25% reduction in the CAARS observer questionnaire) measured one month following treatment were 26%, 23% and 18% for the right, left and sham arms, respectively. These differences, however, were not statistically significant in the limited sample size of this feasibility study
- No serious adverse events were reported in the study

The authors, led by principal investigator Elissa L. Ash, MD, from Tel Aviv Sourasky Medical Center and Sackler Faculty of Medicine at Tel Aviv University, are preparing the data for publication in a peer-reviewed forum.

"The medications commonly used to treat adults with ADHD have adverse side effects that may lead to treatment discontinuation have been reported in approximately 50% of patients," said Christopher R. von Jako, president and CEO of BrainsWay. "dTMS with our H1 and H7-coils has been shown to provide benefit in the treatment of major depressive disorder and obsessive-compulsive disorder, respectively, and this initial feasibility study with our proprietary H6-coil suggests that it may provide benefit in the treatment of adults with ADHD. This study underscores our ability to innovate new coils and technologies that can potentially be optimized to the specific neurologic features of particular diseases. We are excited for the potential of

dTMS in the treatment of adults with ADHD and will continue to evaluate this non-invasive approach in this patient population."

This study adds to the growing body of clinical evidence demonstrating the potential clinical benefits of dTMS in the treatment of ADHD. A prior study, results of which were reported in 2016, compared dTMS using the BrainsWay H6-coil targeting the right prefrontal cortex with focal TMS using a figure-8 coil or sham TMS. In that study, the percentage of patients who showed a reduction of 30% or more in the CAARS observer questionnaire was 33% in the dTMS group, 8% in the sham group, and 15% in the focal TMS group. A significant average improvement of 8.25 points (p=0.0001) was observed in total CAARS scores in the dTMS group compared with pre-treatment baseline values, and no significant changes were observed in the focal TMS or sham groups. These findings correlated with electrophysiological activity in the right prefrontal cortex and suggested a substantial therapeutic advantage for deep and widespread stimulation of the right prefrontal cortex with BrainsWay's proprietary H6-coil over stimulation with a focal figure-8 coil in patients with ADHD. The study was recently published in the *Neuroimage Clinical* scientific journal.

About ADHD
ADHD is characterized as a disorder with an ongoing pattern of inattention and/or hyperactivity that can negatively impact a person's quality of life and how they function at school, work and socially. It is estimated that ADHD affects nearly 1-in-10 adults in the United States in their lifetimes. Current treatments for ADHD are primarily stimulant medications that are often associated with risks and side effects, especially if misused or abused. It is estimated that approximately 5 million American adults are misusing prescription stimulants.

About BrainsWay
BrainsWay is engaged in the research, development and sales and marketing of a medical system for non-invasive treatment of common brain disorders. The medical system developed and manufactured by the company is based on a unique breakthrough technology called Deep TMS, which can reach significant depth and breadth of the brain and produce broad stimulation and functional modulation of targeted brain areas. In the U.S., the Company's device has been FDA cleared for the treatment of major depressive disorder (MDD) and of Obsessive Compulsive Disorder (OCD). The Company's systems have also received CE clearance and are used worldwide for the treatment of various brain disorders.

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. Moreover, the data presented herein represent the company's description of the preliminary analysis following completion of the study. The data has not been subject to FDA review in the United States and certain results as expressed herein may be subject to further analysis, modification and/or statistical penalties. 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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