BrainsWay Announces Successful Results in Pivotal Multicenter Study Evaluating Deep Transcranial Magnetic Stimulation System as an Aid in Smoking Cessation

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Primary and secondary endpoint achieved with statistical significance

Company intends to meet with FDA shortly to discuss planned regulatory submission and potential clearance pathway

JERUSALEM, Dec. 02, 2019 (GLOBE NEWSWIRE) -- BrainsWay Ltd. (NASDAQ & TASE: BWAY) ("BrainsWay") today announced final positive results from its pivotal multicenter trial assessing the safety and efficacy of the Company's H4 Deep transcranial magnetic stimulation system (Deep TMS) as an aid in smoking cessation in adults suffering from chronic smoking addiction. This trial represents the first multicenter pivotal study conducted with any non-invasive brain stimulation device in the addiction space.

The results reported are from a randomized, double-blind, multicenter study designed to evaluate the safety and efficacy of H4 Deep TMS treatment as an aid in reducing cigarette smoking in individuals suffering from chronic smoking addiction. The trial was conducted at 14 sites, primarily in the U.S., and enrolled 262 eligible subjects randomized into two groups: an active treatment group treated with BrainsWay's proprietary H4 coil targeting addiction-related brain circuits, and a sham (placebo) control group. The primary endpoint of the study was a comparison between the two groups of the four-week continuous quit rate (CQR), representing abstinence during a consecutive four-week period. Weekly abstinence was defined as a subject's self-report (in a diary) of no smoking, confirmed by urine tests indicating abstinence from smoking. The participants in the study were highly addicted to smoking, with a history of smoking on average for over 26 years and multiple failed attempts to quit.

Of the 168 participants in the study who actually completed three weeks of H4 Deep TMS or sham treatment, plus the mandatory additional three weeks of follow-up (reaching the six-week endpoint), the CQR was 28.4% in the treatment group compared to 11.7% in the sham group (p=0.0063). The primary endpoint was defined based on the CQR among those subjects who received at least one H4 Deep TMS (or sham) treatment session and had at least one post-baseline assessment, even if not completing the treatment period. Within this cohort (which consisted of 234 participants and included dropouts) the CQR was 19.4% in the treatment group and 8.7% in the sham group (p= 0.0174).

An important secondary endpoint was the reduction in the number of cigarettes smoked. At baseline, the average number of cigarettes smoked per week was 132 for the active group and 127 for the sham group. After 3 weeks of treatment, the average number of cigarettes smoked per week was reduced to 38 in the active group and 57 in the sham group (p= 0.0018, active vs. sham). By the sixth week of the study, the average number of cigarettes smoked per week declined to 31 for the active group and 48 for the sham group (p=0.0125, active vs. sham).

"The data from this large randomized pivotal study indicate that our Deep TMS can play an important role in treating cigarette smokers who seek to quit," said David Zacut, Chairman and Interim Chief Executive Officer of BrainsWay. "We are very encouraged by these clinical results and look forward to meeting with the U.S. Food and Drug Administration (FDA) shortly to discuss our planned regulatory submission and the potential clearance pathway for this important treatment. If cleared, we believe that smoking cessation could be a significant market opportunity for Deep TMS and BrainsWay. Moreover, the success demonstrated in this study in treating patients addicted to cigarettes strengthens our optimism with respect to the potential for the use of our platform technology to treat other addictions as well."

"These are exciting and important results," said Professor Mark S. George, M.D., Distinguished Professor of Psychiatry, Radiology and Neurosciences and Director of the Brain Stimulation Laboratory at the Medical University of South Carolina in Charleston, SC, and Co-Principal Investigator of the study, along with Prof. Abraham Zangen. "Smoking tobacco is an enormous burden for patients and society, and we do not have enough good treatment options. H4 Deep TMS combined with induced smoking cues was found to be effective in helping smokers quit in a large sample of smokers who had smoked, on average, for 26 years with numerous prior failed attempts to quit. Additionally, when compared to sham, receiving Deep TMS therapy for 3 weeks more than doubled subjects' chances of quitting cigarettes. These results are clinically meaningful. I hope this study serves to provide smokers with another option that can help them quit, improving their own health dramatically and driving down the overall cost of medical care."

BrainsWay's Deep TMS system uses best-in-class technology to effectively stimulate areas of the brain at a greater depth and breadth than any other commercially available TMS device. The BrainsWay H4 helmet used in this study is different than the Company's FDA-cleared H1 and H7 coils (cleared for the treatment of major depressive disorder and obsessive-compulsive disorder, respectively) and is designed to non-invasively stimulate brain networks known to be associated with addictions, including the bilateral insula and prefrontal cortex, using brief electromagnetic pulses.

Overall, the treatment was found to be well-tolerated by participants in the study, and no seizures were reported. The results of the study, including patient safety information and adverse event data, remain subject to completion of analysis of the underlying data.

More About the Pivotal Study:

The trial was a randomized, double-blind, multicenter study designed to evaluate the safety and efficacy of Deep TMS as an aid in smoking cessation in heavy smokers. The multicenter study was conducted at 14 sites, primarily in the U.S. All of the subjects in the study had at least one prior unsuccessful attempt to quit smoking before being enrolled in the trial. Over 80% of the subjects, had undertaken at least two prior unsuccessful attempts, and over 25% had undertaken at least five prior unsuccessful attempts.

Participants received three weeks of daily H4 Deep TMS (or sham) treatment followed by one session per week for three more weeks (for a total of 18

treatments over six weeks). Assessment visits, including questionnaires and the collection of urine samples, were performed weekly from week two until week six. In addition, subjects were asked to keep a record of their smoking behavior on a diary card.

Only participants who reported zero cigarettes in their diary card at the week six assessment were invited to an additional follow-up visit three months following the completion of the Deep TMS (or sham) treatment. Among the participants who managed to meet the 4-week CQR within the first 6 weeks of the study, 73% in the active group and 60% in the sham group did not return to smoking at all by the time of this final follow up visit.

About Smoking Addiction:

Smoking is one of the leading causes of death in developed countries. The addiction to nicotine, similar to the addiction to drugs and alcohol, involves modulation of the brain reward system and causes uncontrollable desire to smoke. Approximately 38 million U.S. adults smoke cigarettes, and 480,000 die from smoking each year. Cigarette smoking has been found to harm nearly every organ system in the body and is the leading cause of preventable death in the U.S. and of disease burden worldwide (Brian L et al., JAMA Intern Med 2014).

About BrainsWay

BrainsWay is a commercial stage medical device company focused on the development and sale of non-invasive neuromodulation products using the Company's proprietary Deep Transcranial Magnetic Stimulation (Deep TMS) technology for the treatment of major depressive disorder (MDD) and obsessive-compulsive disorder (OCD), for which BrainsWay received marketing authorization from the U.S. Food and Drug Administration (FDA) in 2013 (for MDD) and in August 2018 (for OCD). BrainsWay is currently conducting and planning additional clinical trials of Deep TMS in various psychiatric, neurological and addiction disorders.

About Dr. Mark S. George, MD, Co-PI of the Study

Dr. George is Distinguished Professor of Psychiatry, Radiology and Neurosciences and Director of the Brain Stimulation Laboratory at the Medical University of South Carolina in Charleston, SC, USA. He is the Editor-in-Chief of the journal Brain Stimulation. He was an enrolling physician in the study but otherwise did not receive compensation for his role as PI. For the past 15 years he has not personally accepted funds from, and owns no equity or stock in any brain stimulation device company, including BrainsWay.

Forward Looking Statements and Risks

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. This data, including patient safety information and adverse event data, remain subject to further analysis and may be subject to further modification. 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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