BrainsWay Receives FDA Clearance for Smoking Addiction in Adults

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Company Intends to Execute a Controlled U.S. Market Release in Early 2021

This is the Company's third FDA-cleared indication for its Deep TMS System, and is the first FDA clearance in the addiction space for any TMS device

CRESSKILL, N.J. and JERUSALEM, Aug. 24, 2020 (GLOBE NEWSWIRE) -- BrainsWay Ltd. (NASDAQ & TASE: BWAY) ("BrainsWay" or the "Company"), a global leader in the advanced non-invasive treatment of brain disorders, today announced that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for the Company's deep transcranial magnetic stimulation (Deep TMS) system for its use as an aid in short-term smoking cessation in adults.

"This FDA clearance represents a significant milestone for BrainsWay and our Deep TMS platform technology," stated Christopher von Jako, Ph.D., President and Chief Executive Officer of BrainsWay. "Smoking is one of the leading causes of death in the U.S. and also leads to other serious conditions, such as lung cancer and heart disease. While other therapies are currently available, a substantial medical need continues to exist for treatments that can increase the continuous quit rate among smokers. Based on the compelling data from our large, randomized pivotal study of 262 subjects, we are confident that our Deep TMS technology can play an important role in treating cigarette smokers who seek to quit. We look forward to executing a controlled U.S. market release of our newly cleared and proprietary H4 Deep TMS coil for this indication early next year."

Dr. von Jako added, "Importantly, this is the first FDA clearance in the addiction space for any TMS device, and it represents BrainsWay's third FDA-cleared coil and indication, following the clearance of our H1-coil for patients suffering from major depressive disorder and the H7-coil as an adjunct therapy for the treatment of OCD. This latest clearance cements BrainsWay's status as an industry leader, and further demonstrates our commitment to leveraging our platform technology to advance innovative therapeutic solutions across multiple patient populations."

About the Pivotal Study
The efficacy of the BrainsWay Deep TMS System with H4-coil as an aid to short-term smoking cessation was demonstrated in a prospective, double blind, randomized, sham controlled, multi-center trial which enrolled 262 eligible subjects randomized into two groups: an active treatment group treated with BrainsWay's H4 Deep TMS coil which was designed to target addiction-related brain circuits, and a sham (placebo) control group. Subjects were randomly assigned to either the active Deep TMS group or the sham group. The treatments were performed daily, five days a week for 3 weeks, followed by an additional 3 sessions once a week for 3 weeks (for a total of 18 sessions over the course of 6 weeks).

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, at any point between the start of treatment and the follow up visit four months thereafter. 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 an average of over 26 years and multiple failed attempts to quit.

When analyzing the primary endpoint in the 262 participants comprising the full intention to treat (ITT) population (which also included subjects who did not complete the entire treatment period), the CQR was 17.1% in the active Deep TMS group and 7.9% in the sham group (p=0.0238). When analyzing subjects with 4 weeks of treatment, diary records, and confirmatory urine samples (i.e., completers), the CQR was 28.4% in the active Deep TMS group compared to 11.7% in the sham group (p=0.0063). Based on the primary efficacy analysis of the study, BrainsWay's H4 Deep TMS coil led to a positive treatment outcome and demonstrated a beneficial effect in short-term smoking cessation.

An important secondary endpoint was the number of cigarettes smoked per day (CPD), per diary entry. The difference in the average number of CPD per subject from baseline to the end of the study (4-month follow-up for quitters and 6 weeks follow-up for smokers) was statistically significantly lower in the active Deep TMS group compared to the sham group (p=0.0311).

No seizures were reported in the study, and the most common adverse event reported was headaches, which was not statistically different between the active and sham groups. Other side effects that were reported included application site discomfort, back pain, muscle twitching, and discomfort.

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 neurostimulation products using the Company's proprietary Deep Transcranial Magnetic Stimulation (Deep TMS) platform 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 2018 for OCD. BrainsWay is currently conducting clinical trials of Deep TMS in various psychiatric, neurological, and addiction disorders.

Forward Looking Statements
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. 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, and the effect of the global COVID-19 health pandemic on our business and continued uncertainty and market impact relating thereto.

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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