FDA Clears BrainsWay Deep TMS™ System for Decreasing Anxiety Symptoms in Depressed Patients

August 18, 2021

Expanded Depression Indication Further Demonstrates Company's Leadership Position

BURLINGTON, Mass. and JERUSALEM, Aug. 18, 2021 (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 that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) allowing the Company to market its Deep Transcranial Magnetic Stimulation (Deep TMS™) System for the reduction of comorbid anxiety symptoms in adult patients with depression, also known as anxious depression.

"This clearance expands upon BrainsWay's depression indication, and represents yet another in a series of firsts for the Company," said Christopher von Jako, Ph.D., President and Chief Executive Officer of BrainsWay. "Many patients suffering from major depression experience anxiety symptoms. This most recent regulatory achievement further establishes BrainsWay's leadership position at the forefront of bringing transformative solutions to advance patient wellness."

Data from 573 patients who had undergone Deep TMS treatment in 11 studies, including both randomized controlled trials (RCT) and open-label studies, was submitted by BrainsWay in support of its application to the FDA. The data demonstrated a treatment effect that was consistent, robust, and clinically meaningful for decreasing anxiety symptoms in adult patients suffering from major depressive disorder. An analysis of the BrainsWay data found favorable outcomes with Deep TMS when compared to sham or medication as standard of care. For example, using the Cohen's d statistical method, data from the 3 RCT studies of Deep TMS demonstrated effect sizes ranging from 0.34 (when compared to sham) to 0.90 (when compared to medication), and an overall weighted, pooled effect size of 0.55.

As a reference, published articles from approximately 16,000 subjects in over 70 studies of drug-based anxiety treatments – including studies of standard-of-care medications frequently prescribed for patients suffering from anxious depression and general anxiety disorder – report effect sizes ranging from 0.2 – 0.37.

"This clearance is confirmation of what many have believed anecdotally for years – that Deep TMS is a unique form of therapy that can address comorbid anxiety symptoms using the same depression treatment protocol," said Aron Tendler, MD, Chief Medical Officer of BrainsWay. "We look forward to continuing to work with our providers to bring the very best in care to the patients that have come to rely on BrainsWay's deeper and broader neurostimulation and our groundbreaking approach to mental health disorder treatment."

The expanded FDA labeling now allows BrainsWay to market its Deep TMS System for the treatment of depressive episodes and for decreasing anxiety symptoms for those who may exhibit comorbid anxiety symptoms in adult patients suffering from major depressive disorder and who failed to achieve satisfactory improvement from previous antidepressant medication treatment in the current episode.

About Anxious Depression
Comorbid anxiety symptoms are common in patients with major depressive disorder. Between 60-90% of patients with depression have moderate anxiety, and 20-25% have more severe anxiety. In the United States, 17.3 million adults experience at least one major depressive episode per year. Considering the rate of comorbidity, 10 to 16 million adults experience moderate to severe anxiety in addition to their primary diagnosis of depression. Common 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 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 studies demonstrating clinically proven efficacy. Current indications include major depressive disorder, 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 and broad access to Deep TMS. For the latest news and information about BrainsWay, please visit www.brainsway.com.

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, and include, but are not limited to, statements about the expected proceeds, use of proceeds and closing of the underwritten offering. 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, including the Company's Annual Report on Form 20-F. Investors and security holders are urged to read these documents free of charge on the SEC's web site at http://www.sec.gov.

Contacts:
BrainsWay:
Scott Areglado
SVP and Chief Financial Officer
844-386-7001
SAreglado@brainsway.com

Investors:
Bob Yedid
LifeSci Advisors
646-597-6989
Bob@LifeSciAdvisors.com

Media Contact:
Will Johnson
Antenna
201-465-8019
BrainsWay@antennagroup.com