# BrainsWay Announces Data Published in World Psychiatry on Deep Transcranial Magnetic Stimulation (Deep TMS™) for Smoking Addiction

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*Evidence Supports Use of Deep TMS as a Safe and Effective Treatment for Smoking Addiction*

BURLINGTON, Mass. and JERUSALEM, Sept. 30, 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 data published in World Psychiatry, the official publication of the World Psychiatric Association, from a pivotal, multicenter, placebo-controlled, double-blind clinical trial, supporting the use of Deep TMS™ as a safe and effective treatment for tobacco use disorder – one of the most common substance use disorders and leading cause of preventable death worldwide.

The study is the first large multicenter randomized controlled trial to examine the safety and efficacy of brain stimulation in addiction medicine and was conducted across 12 U.S. sites and two Israel sites among 262 chronic smokers, who reported at least one previous failed attempt to quit.

"Publishing the findings of Deep TMS and its success as a treatment for smoking addiction in a peer-reviewed medical journal like World Psychiatry not only allows us to enrich the evidence around the treatment, but also further disseminate this critical information to providers who are seeking effective, noninvasive options to help their patients," said Christopher von Jako, Ph.D., President and Chief Executive Officer of BrainsWay. "We remain deeply committed to helping patients who suffer from mental health disorders and addictions, like tobacco use disorder, and are proud to offer a clinically-proven and noninvasive solution that can change their lives."

The Company is currently conducting a controlled market release (CMR) to further define the most relevant messaging, business model for clinics, addressable patient population, and to collect post-marketing data to support reimbursement. With 15 sites enrolled in the CMR, BrainsWay has also transitioned to the limited rollout of systems to existing customers to support growing demand.

"It is exciting to see years of work and focus come to fruition with the publication of these results, the FDA Clearance last summer, and the increasing requests to adopt the technology clinically," said Prof. Abraham Zangen, Head of the Brain Stimulation and Behavior Lab and the Chair of the PsychoBiology Brain Program at Ben-Gurion University and a scientific consultant for and member of the board of directors of BrainsWay. "Advances in neuroscience continue to show growing promise in the field of addiction medicine, and we are excited to be at the forefront of those efforts. There is still much work to be done to explore the full utility of Deep TMS in the field of addiction."

**About the Study**

Participants were treated with BrainsWay's Deep TMS System, the first noninvasive medical device cleared by the U.S. Food and Drug Administration (FDA) to aid in short-term smoking cessation. Treatment was conducted using BrainsWay's proprietary H4 Coil, which targets the bilateral insula and prefrontal cortex - regions associated with addiction behaviors.

A total of 262 participants were enrolled in the study, with 123 randomized to receive active Deep TMS and 139 sham (placebo) stimulation. Patients received three weeks of 18-min daily Deep TMS sessions, followed by once a week treatment for three weeks.

Greater than 1 in 4 patients that completed treatment achieved the primary outcome measure of four or more continuous weeks of abstinence from smoking. Of those patients, approximately 2 in 3 maintained abstinence through week 18 demonstrating at least a 4-month durability of Deep TMS treatment. The average number of cigarettes smoked per week was reduced substantially by treatment - 128 at baseline to 32 by week 6. 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.

While not measured head to head, the results of the study generally compare favorably to other common treatments of smoking addiction, such as medications including bupropion and varenicline, nicotine-replacement therapy, and psychotherapy.

**About Smoking Addiction**

Smoking continues to be the leading cause of preventable illness worldwide despite continued cessation efforts. In the United States, 14% of all adults smoke cigarettes (34.1 million) with an economic burden of nearly $400 billion annually: $225 billion for direct medical care and over $156 billion in lost productivity. 480,000 deaths are attributed to cigarette smoking in the US each year. Worldwide, more than 1.3 billion people use tobacco products, and more than 8 million people die annually from direct and indirect exposure. The global economic burden of smoking is estimated to be $1.852 trillion every year: nearly 2% of the World GDP.

**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 and/or in this release: 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; statistical penalties which may apply to any data expressed for secondary outcomes and/or subgroups within primary outcome measures, 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.

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