BrainsWay Announces FDA Approval of Neurolief's Proliv™Rx Neuromodulation System for Major Depressive Disorder (MDD)

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BrainsWay's strategic investment in Neurolief paved the way for the first and only FDA approved at-home neuromodulation device with Class III Premarket Approval labeling for MDD patients who failed one or more prior antidepressants

BURLINGTON, Mass. and JERUSALEM, Jan. 12, 2026 (GLOBE NEWSWIRE) -- BrainsWay Ltd. (NASDAQ & TASE: BWAY) ("BrainsWay" or the "Company"), a global leader in advanced noninvasive brain stimulation technologies, today announced that the U.S. Food and Drug Administration (FDA) has granted Premarket Approval (PMA) for Neurolief's Proliv™Rx system, a Class III device, as an adjunctive treatment for adult patients suffering from major depressive disorder (MDD) who have failed to achieve satisfactory improvement from at least one previous antidepressant medication, for use at home or in the clinic.

This approval represents a significant regulatory milestone, making Proliv™Rx the first and only at-home neuromodulation treatment with FDA labeling applicable to treatment refractory MDD patients. The approval expands the clinical landscape beyond traditional in-clinic care and reflects growing regulatory recognition of advanced neuromodulation solutions designed for use in the home setting.

"Our strategic investment in Neurolief, which includes an option to acquire Neurolief, positions us to both enhance our current value proposition to our existing market as well as potentially increase our total addressable market by enabling care for patients who may not be able to easily access the clinic. We are currently working on meaningful synergistic approaches that include the commercial and research infrastructures of both companies," stated Hadar Levy, Chief Executive Officer of BrainsWay. "This FDA approval represents an exciting early validation of our investment strategy and reinforces our conviction in data-driven, technology-enabled mental health care. Our work with Neurolief, which is singular among TMS manufacturers, further strengthens our leadership position and advances our long-term vision to become the only company in the mental health space offering data-based integration of multiple treatment modalities across multiple care settings," concluded Mr. Levy.

About Neurolief
Neurolief is a pioneering neuromodulation company committed to developing breakthrough therapies for mental health and neurological disorders. The company has developed the world's first wearable, non-invasive, multi-channel brain neuromodulation system, that is designed for use at home, engineered to simultaneously stimulate key neural pathways in the head in order to modulate brain regions involved in regulation of mood and pain. Neurolief's Proliv™Rx device was granted Premarket Approval by the U.SFood and Drug Administration (FDA), and is indicated as an adjunctive treatment for Major Depressive Disorder (MDD) in adults who failed to achieve satisfactory improvement from at least one previous antidepressant medication, for use at home or in clinic. Its Relivion® MG device is currently FDA-cleared and CE-marked for the treatment of migraine. Learn more at: www.neurolief.com.

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 clinical studies demonstrating clinically proven efficacy. Current indications include major depressive disorder (including reduction of anxiety symptoms, commonly referred to as anxious depression), 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 operations in the United States and Israel, BrainsWay is committed to increasing global awareness of 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," "targets," "believes," "hopes," "potential" or similar words, and also includes any financial guidance and projections contained herein. 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. In addition, historical results or conclusions from scientific research and clinical studies – especially preliminary data which remains subject to peer-review – 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: the failure to realize anticipated synergies and other benefits of the proposed transaction; the failure of our investments in management services organizations and/or other clinic-related entities to produce profitable returns; 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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