Helius Medical Technologies, Inc. Initiates Open-Label Study for Registrational Program in Stroke

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-- Enrollment of at least ten patients at Brooks Rehabilitation will begin this month --
-- Study will evaluate the use of Portable Neuromodulation Stimulator (PoNS®) for gait and balance deficits in chronic stroke survivors --
-- Results will support efforts to achieve U.S. authorization under PoNS's breakthrough designation for stroke --

NEWTOWN, Pa., March 12, 2024 (GLOBE NEWSWIRE) -- Helius Medical Technologies, Inc. (Nasdaq:HSDT) ("Helius" or the "Company"), a neurotech company focused on delivering a novel therapeutic neuromodulation approach for balance and gait deficits, today announced the initiation of an open-label study for its registrational program in stroke. The program was established based on encouraging early trial results as well as real-world evidence from Canada, where PoNS is already authorized for treatment of stroke, and aims to establish the effects of cranial-nerve non-invasive neuromodulation ("CN-NINM"), delivered using PoNS Therapy ®, on gait and dynamic balance in chronic stroke survivors.

Under the direction of Mark Bowden, PT, PhD, Brooks Rehabilitation ("Brooks Rehabilitation") will be the first site to enroll patients. Brooks Rehabilitation is already a participant site to the Company's ongoing investigator-initiated, placebo-controlled study in stroke, led by Dr. Steven Kautz at the Medical University of South Carolina ("MUSC").

"The open-label study will serve as an integral part of our stroke registrational program by bringing the PoNS clinical experience to additional sites in the U.S. We're thrilled to work with Brooks Rehabilitation and Dr. Bowden, a renowned expert in neurorehabilitation and a key contributor to the international guidelines for stroke rehabilitation, to help move PoNS Therapy one step closer to authorization in the U.S.," said Dr. Antonella Favit-Van Pelt, Helius' Chief Medical Officer.

"PoNS Therapy has the potential to meaningfully improve the lives of over five million stroke patients affected by walking and balance disability. In joining the MUSC trial and participating to the open label study, Brooks is very excited to be on the cutting edge in testing this promising technology. We are hopeful that PoNS Therapy can have a meaningful therapeutic effect on chronic stroke survivors and I'm excited about Helius' opportunity to expand the clinical research to other sites," stated Dr. Bowden.

About **Brooks Rehabilitation**

For more than 50 years, the nonprofit Brooks Rehabilitation, headquartered in Jacksonville, Fla., has been a comprehensive system of care for physical rehabilitation. Ranked by U.S. News & World Report as the No. 1 rehabilitation hospital in Florida and one of the top 20 in the nation, Brooks operates three inpatient rehabilitation hospitals – two in Jacksonville, Fla., including one of the nation's largest with 170 beds, and a Center for Inpatient Rehabilitation in partnership with Halifax Health in Daytona Beach, Fla. Brooks also operates one of the region's largest home healthcare agencies; more than 50 outpatient therapy clinics; a physician practice; Clinical Research Center; two skilled nursing facilities; assisted living and memory care. Brooks also provides many low- or no-cost community programs and services to improve the quality of life for people living with physical disabilities. For more information, visit BrooksRehab.org.

About Helius Medical Technologies, Inc.

Helius Medical Technologies is a leading neurotech company in the medical device field focused on neurologic deficits using orally applied technology platform that amplifies the brain's ability to engage physiologic compensatory mechanisms and promote neuroplasticity, improving the lives of people dealing with neurologic diseases. The Company's first commercial product is the Portable Neuromodulation Stimulator. For more information visit www.heliusmedical.com.

About the PoNS Device and PoNS Therapy

The Portable Neuromodulation Stimulator (PoNS) is an innovative, non-implantable, orally applied therapy that delivers neurostimulation through a mouthpiece connected to a controller and it's used, primarily at home, with physical rehabilitation exercise, to improve balance and gait. The PoNS device, which delivers mild electrical impulses to the tongue, is indicated for use in the United States as a short-term treatment of gait deficit due to mild-to-moderate symptoms from multiple sclerosis ("MS") and is to be used as an adjunct to a supervised therapeutic exercise program in patients 22 years of age and over by prescription only.

PoNS has shown effectiveness in treating gait or balance and a significant reduction in the risk of falling in stroke patients in Canada, where it received authorization for sale in three indications: (i) for use as a short-term treatment (14 weeks) of gait deficit due to mild and moderate symptoms from stroke and is to be used in conjunction with physical therapy; (ii) for use as a short-term treatment (14 weeks) of chronic balance deficit due to mild-to-moderate traumatic brain injury ("mmTBI") and is to be used in conjunction with physical therapy; and (iii) for use as a short-term treatment (14 weeks) of gait deficit due to mild and moderate symptoms from MS and is to be used in conjunction with physical therapy. PoNS is also authorized for sale in Australia for short term use by healthcare professionals as an adjunct to a therapeutic exercise program to improve balance and gait. For more information visit www.ponstherapy.com.

Cautionary Disclaimer Statement

Certain statements in this news release are not based on historical facts and constitute forward-looking statements or forward-looking information within the meaning of the U.S. Private Securities Litigation Reform Act of 1995 and Canadian securities laws. All statements other than statements of historical fact included in this news release are forward-looking statements that involve risks and uncertainties. Forward-looking statements are often identified by terms such as "believe," "expect," "continue," "will," "goal," "aim" and similar expressions. Such forward-looking statements include, among others, statements regarding the Company's ability to enroll at least ten patients at the Brooks Rehabilitation Hospital at the beginning of the month, the potential to get U.S. authorization under PoNS's breakthrough designation for stroke, the results of the open-label study, future decisions

and approvals from applicable regulatory entities in the U.S. and Canada, and the uses and effectiveness of PoNS and PoNS Therapy.

There can be no assurance that such statements will prove to be accurate and actual results and future events could differ materially from those expressed or implied by such statements. Important factors that could cause actual results to differ materially from the Company's expectations include uncertainties associated with the Company's capital requirements to achieve its business objectives, disruptions in the banking system and financial markets, the effect of macroeconomic conditions and the Company's ability to access capital markets, the Company's ability to continue to train physical therapists in the supervision of the use of the PoNS Treatment, the Company's ability to secure additional contracts with rehabilitation clinics, the Company's ability to obtain national Medicare coverage and to obtain a reimbursement code so that the PoNS device is covered by Medicare and Medicaid, the Company's ability to build internal commercial infrastructure, secure state distribution licenses, build a commercial team and build relationships with Key Opinion Leaders, neurology experts and neurorehabilitation centers, market awareness of the PoNS device, availability of funds, manufacturing, labor shortage and supply chain risks, our ability to maintain and enforce our intellectual property rights, clinical trials and the clinical development process, the product development process, the regulatory submission review and approval process, our operating costs and use of cash, and our ability to achieve significant revenues, ongoing government regulation, and other risks detailed from time to time in the "Risk Factors" section of the Company's Annual Report on Form 10-K for the year ended December 31, 2022, and its other filings with the United States Securities and Exchange Commission and the Canadian securities regulators, which can be obtained from either at www.sec.gov or www.sedar.com.

The reader is cautioned not to place undue reliance on any forward-looking statement. The forward-looking statements contained in this news release are made as of the date of this news release and the Company assumes no obligation to update any forward-looking statement or to update the reasons why actual results could differ from such statements except to the extent required by law.

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