Helius Medical Technologies, Inc. Expands Stroke Trial at the Medical University of South Carolina

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-- Number of subjects increased from 12 to 60 --
-- Portable Neuromodulation Stimulator (PoNS®) will be used to evaluate cranial-nerve non-invasive neuromodulation and dynamic gait/balance in stroke patients --

NEWTOWN, Pa., July 27, 2023 (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 expansion of the previously announced trial in stroke from 12 to 60 patients. This ongoing investigator-initiated study, led by Dr. Steven Kautz at the Medical University of South Carolina ("MUSC"), will evaluate the effects of cranial-nerve non-invasive neuromodulation ("CN-NINM"), delivered using PoNS Therapy™, on gait and dynamic balance in chronic stroke survivors.

"PoNS is already authorized for stroke in Canada, and patients using PoNS Therapy to treat symptoms have seen significant improvement in gait and a reduced risk of falling. Based on this meaningful data, Helius has welcomed the opportunity to support Dr. Kautz's stroke study by expanding the sample size from twelve to sixty patients," said Antonella Favit-Van Pelt, M.D., Ph.D., Helius' Chief Medical Officer. "This is a significant step toward our efforts to leverage the breakthrough designation granted in August 2021 and pursue approval for stroke in the U.S. in the near future."

"Improving dynamic balance is critical for reducing stroke-related morbidity, and analysis of real-world evidence from Canada has given us great confidence to open the study to more patients. We are excited to begin enrolling patients next month," stated Steven Kautz, Ph.D., Chair, Department of Health Sciences and Research, College of Health Professions, MUSC.

The study will be a placebo-controlled experimental design in which stroke survivors will undergo a total of twelve weeks of a gait and balance physical therapy training program, performed both in clinic (four weeks) supervised by a physical therapist trained on PoNS therapy and at home (eight weeks) unsupervised with an individualized gait and balance training regimen. MUSC anticipates enrollment of the sixty participants will begin in August 2023, with expected completion by the end of 2024.

About MUSC

Founded in 1824 in Charleston, South Carolina, MUSC is the state's only comprehensive academic health system, with a unique mission to preserve and optimize human life in South Carolina through education, research and patient care. Each year, MUSC educates more than 3,200 students in six colleges – Dental Medicine, Graduate Studies, Health Professions, Medicine, Nursing and Pharmacy – and trains more than 900 residents and fellows in its health system. MUSC brought in more than $298 million in research funds in fiscal year 2022, leading the state overall in research funding. MUSC also leads the state in federal and National Institutes of Health funding with more than $220 million. For information on academic programs, visit musc.edu.

As the health care system of the Medical University of South Carolina, MUSC Health is dedicated to delivering the highest-quality and safest patient care while educating and training generations of outstanding health care providers and leaders to serve the people of South Carolina and beyond. Patient care is provided at 16 hospitals (includes owned and affiliated), with approximately 2,700 beds and four additional hospital locations in development; more than 350 telehealth sites and connectivity to patients' homes; and nearly 750 care locations situated in all regions of South Carolina. In 2022, for the eighth consecutive year, U.S. News & World Report named MUSC Health University Medical Center in Charleston the No. 1 hospital in South Carolina. To learn more about clinical patient services, visit muschealth.org.

MUSC has a total enterprise annual operating budget of $5.1 billion. The nearly 26,000 MUSC family members include world-class faculty, physicians, specialty providers, scientists, students, affiliates and care team members who deliver groundbreaking education, research, and patient care.

About Helius Medical Technologies, Inc.

Helius Medical Technologies is a leading neurotech company in the medical device field focused on neurologic deficits using non-implantable platform technologies that amplify the brain's ability to compensate and promotes neuroplasticity, aiming to improve the lives of people dealing with neurologic diseases. The Company's first commercial product is the Portable Neuromodulation Stimulator (PoNS). For more information, visit www.heliusmedical.com.

About the PoNS Device and PoNS Therapy

The Portable Neuromodulation Stimulator (PoNS) is an innovative orally-applied, non-implantable medical device, inclusive of a controller and mouthpiece, which delivers electrical stimulation to the surface of the tongue to improve balance and gait. The PoNS device 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 is also authorized for sale in Canada for three indications: (i) 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 (ii) 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; and (iii) for use as a short-term treatment (14 weeks) of gait deficit due to mild and moderate symptoms from stroke, 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 obtain approval for stroke in the U.S., the uses and effectiveness of PoNS and PoNS Therapy, the stroke study led by Dr. Kautz and the Company’s strategic operating plans.

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, lingering impacts of the COVID-19 pandemic, the effect of macroeconomic conditions and the Company’s ability to access capital markets, the Company’s ability to train physical therapists in the supervision of the use of the PoNS Treatment, the Company’s ability to secure 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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