Helius Medical Technologies, Inc. Announces Alignment with FDA on Registrational Program for Treatment of Stroke Patients

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-- Studies uses Portable Neuromodulation Stimulator (PoNS®) to evaluate cranial-nerve non-invasive neuromodulation for gait/balance deficits in stroke patients --

-- Interaction with FDA on clinical program feasibility streamlines cost and timeline and leverages trials with the Medical University of South Carolina and Brooks Rehabilitation --

-- Studies and real-world evidence results will be submitted for regulatory authorization under PoNS's breakthrough designation for stroke --

-- Regulatory submission for stroke and marketing authorization expected in 2025 --

NEWTOWN, Pa., Feb. 06, 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, announced today that it has concluded its interaction with the U.S. Food and Drug Administration ("FDA") on optimizing the development plan for its stroke program which aims to evaluate the effects of cranial-nerve non-invasive neuromodulation ("CN-NINM") delivered using PoNS Therapy® on gait and dynamic balance in chronic stroke survivors. Helius' registrational program includes two controlled studies. The clinical program will leverage a randomized, controlled, double blinded investigator-initiated trial ("IIT"), led by Dr. Steven Kautz at the Medical University of South Carolina ("MUSC") and a Company-sponsored study to enroll approximately 100 subjects. Dr. Kautz's IIT began enrollment of 60 participants in September 2023 with the collaboration of Dr. Mark Bowden at Brooks Rehabilitation as a second site.

"Vetting the registrational program and design of our clinical studies with the FDA is an important milestone for Helius and meeting the agency's expectations will give us the most efficient path to delivering PoNS Therapy to stroke patients," said Dr. Antonella Favit-Van Pelt, Helius' Chief Medical Officer. "This development plan, which leverages early study results and real-world evidence from Canada, allows us to streamline the size, timeline, and cost of the registrational program and positions Helius on the best course toward potential FDA authorization under PoNS's breakthrough designation for stroke."

When evaluated in a real-world evidence (RWE) database analysis of Canadian stroke patients with gait or balance deficit, PoNS Therapy demonstrated a significant and clinically meaningful improvement in gait, averaging a 6.74-point improvement in the functional gait assessment (FGA) score over a 14-wk treatment period (95% CI: 4.85 to 8.63). Before starting PoNS Therapy, over 93% of patients were considered at risk of falling, as determined by an FGA<23 score at baseline. After a 14-week treatment regimen with PoNS, 28% of patients were no longer at fall risk, a considerable result given that, in routine clinical practice, rehabilitative physical therapy alone decreases the risk of falling in only 1-3% of patients. Across all stroke patients in the database, 69.2% of patients experienced at least a 5-point FGA improvement, which is larger than the 4.2-point minimal detectable change usually seen in stroke patients.

"One of our chief objectives is to optimize access to PoNS Therapy for stroke patients suffering from gait and balance deficit in North America. We recently announced collaborations with the University of Montreal and the Quebec Ministry of Health to evaluate the health economic benefits of PoNS Therapy in these patients and hope that our development approach will not only save several millions of dollars in healthcare burden cost but also lead us on the most expedited pathway toward authorization in the U.S., where an estimated 80% of the seven million stroke patients experience impaired walking," stated Helius' President and Chief Executive Officer, Dane Andreeff. "We are now targeting regulatory submission by early 2025 with the goal of receiving marketing authorization later in the same year."

If authorized to treat stroke in the U.S., PoNS would be eligible for coverage under the proposed Transitional Coverage of Emerging Technologies (TCET) pathway, which would expedite Medicare coverage of certain breakthrough devices by allowing manufacturers the opportunity for increased premarket engagement with the Centers for Medicare & Medicaid Services (CMS). Under the new guidelines, qualifying breakthrough designations would have temporary coverage within six months after FDA market authorization. PoNS received breakthrough designations in both multiple sclerosis and stroke in the United States, potentially benefiting, with a new indication, an estimated 90% of stroke patients who are covered by Medicare.

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 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 receive authorization for stroke in the U.S., the success of the Company's developmental, regulatory and commercialization efforts, the Company's ability to be eligible for coverage under the proposed Transitional Coverage of Emerging Technologies (TCET) pathway, 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 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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