Helius Medical Technologies, Inc. Partners with the Medical University of South Carolina in Pilot Trial on Stroke

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-- PoNS ® to be used in study of cranial-nerve non-invasive neuromodulation and dynamic gait balance in stroke patients --

-- Collaboration will inform Helius's registrational program in stroke --

NEWTOWN, Pa., Dec. 17, 2021 (GLOBE NEWSWIRE) -- Helius Medical Technologies, Inc. (Nasdaq:HSDT) ("Helius" or the "Company"), a neurotech company focused on neurological wellness, today announced its partnership with Dr. Steve Kautz, on an investigator-initiated study, conducted at the Medical University of South Carolina ("MUSC"), to evaluate cranial-nerve non-invasive neuromodulation ("CN-NINM") and dynamic balance in chronic stroke survivors. As part of the study, some patients will receive CN-NINM, which will be delivered using PoNS therapy.

"Falls are a major post-stroke complication and developing an optimal rehabilitation program to improve dynamic balance is critical for reducing stroke related morbidity and economic burdens," stated Steve Kautz, Ph.D., Chair, Department of Health Sciences and Research, College of Health Professions, MUSC. "Our study aims to evaluate the effects of PoNS therapy on the recovery of gait and postural stability and, in teaming with Helius, we hope to provide a framework for an innovative rehabilitation protocol."

"MUSC is at the forefront of research in rehabilitation for stroke and other disabling neurologic conditions and we are delighted to support this pilot trial in stroke with our PoNS devices," said Antonella Favit-Van Pelt, M.D., Ph.D., Helius' Chief Medical Officer. "Now that the FDA has granted Breakthrough Designation to PoNS for the treatment of dynamic gait and balance deficits in patients with stroke, this collaboration will provide important information to inform our clinical research and upcoming registrational program, allowing us to observe the functional outcomes of PoNS therapy in stroke patients in a real-world clinical setting. We look forward to working with Dr. Kautz and MUSC on this and future studies."

The study will be a placebo-controlled experimental design in which stroke survivors will participate in balance and gait training for 3 sessions per week, 40 minutes per session, for 4 weeks. MUSC anticipates enrolling twelve participants beginning in early 2022.

About MUSC

Founded in 1824 in Charleston, MUSC is home to the oldest medical school in the South as well as the state's only integrated academic health sciences center, with a unique charge to serve the state through education, research and patient care. Each year, MUSC educates and trains more than 3,000 students and nearly 800 residents in six colleges: Dental Medicine, Graduate Studies, Health Professions, Medicine, Nursing and Pharmacy. MUSC brought in more than $328 million in biomedical research funds in fiscal year 2021, continuing to lead the state in obtaining this funding. For information on academic programs, visit www.musc.edu.

As the clinical health system of the Medical University of South Carolina, MUSC Health is dedicated to delivering the highest quality and safe patient care while training generations of compassionate, competent health care providers to serve the people of South Carolina and beyond. Close to 25,000 care team members provide care for patients at 14 hospitals with approximately 2,500 beds and 5 additional hospital locations in development, more than 300 telehealth sites and nearly 750 care locations situated in the Lowcountry, Midlands, Pee Dee and Upstate regions of South Carolina. In 2021, for the seventh consecutive year, U.S. News & World Report named MUSC Health the No. 1 hospital in South Carolina. To learn more about clinical patient services, visit www.muschealth.org.

MUSC and its affiliates have collective annual budgets of $4.4 billion. The more than 25,000 MUSC team members include world-class faculty, physicians, specialty providers and scientists who deliver groundbreaking education, research, technology 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 non-surgical 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. Helius is advancing PoNS post-approval research in MS through a recently launched Therapeutic Experience Program (TEP) designed to partner with neurologists and neurorehabilitation therapists at 10-12 US centers of excellence, who express an interest in becoming "early adopters" of PoNS therapy.

PoNS is also authorized for sale in Canada for two indications: (i) PoNS is authorized 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) PoNS is authorized 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.

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 expected enrollment, timing and other details of the investigator-initiated study, its ability to provide a framework for an innovative rehabilitation protocol and important information to inform the clinical research and upcoming registrational program, expected enrollment, patient participation, centers of excellence and other details of the TEP study and expected time to begin commercialization of the PoNS device in the U.S.

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, the impact of the COVID-19 pandemic, 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, future clinical trials and the clinical development process, manufacturing and supply chain risks, the product development process and FDA regulatory submission review and approval process, other development activities, 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, 2020, its Quarterly Report on Form 10-Q for the quarter ended September 30, 2021 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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