



Helius Medical Technologies, Inc. Announces Further Expansion of Stroke Clinical Program with the Addition of Brooks Rehabilitation Hospital

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-- Brooks Rehabilitation Hospital adds a second site to the registrational program in stroke, and brings the total number of patients to 100 --

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

-- Results of the study will support efforts to achieve U.S. authorization under PoNS's breakthrough designation for stroke --

NEWTOWN, Pa., Jan. 11, 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 expansion of the registrational program with the addition of Brooks Rehabilitation Hospital ("Brooks Rehabilitation"). The program, structured on the basis of encouraging results from an early trial as well as real-world evidence from Canada, where PoNS is already authorized for treatment of stroke, focuses on establishing the effects of cranial-nerve non-invasive neuromodulation ("CN-NINM"), delivered using PoNS Therapy™, on gait and dynamic balance in chronic stroke survivors. Brooks Rehabilitation will participate as an adjunct site, under the direction of Dr. Mark Bowden, PT, PhD, Vice President of Clinical Integration and Research, to the ongoing investigator-initiated, placebo-controlled study in stroke, led by Dr. Steven Kautz at the Medical University of South Carolina ("MUSC"). Dr. Bowden will also take part in additional clinical activities that, when combined with the randomized controlled study, aim to bring the total number of subjects enrolled in the clinical program to approximately 100.

"The participation of Brooks Rehabilitation marks an important step in the implementation of our clinical program under breakthrough designation for stroke. Dr. Bowden, with his longstanding leadership and contribution to the field of neurorehabilitation for stroke, brings the expertise needed to execute our registrational program. Data from the clinical development activities will contribute invaluable evidence toward our pursuit of regulatory approval in the U.S., and, if successful, provide an impactful therapeutic option for over five million stroke survivors affected by walking and balance disability," said Dr. Antonella Favit-Van Pelt, Helius' Chief Medical Officer.

"We are tremendously excited to be a part of this foundational work using the PoNS device with individuals post-stroke, particularly in light of the emerging success in treating those with multiple sclerosis. The ease of incorporating PoNS into clinical and home-based treatment presents the potential for more efficient clinical translation, and Brooks Rehabilitation is delighted to be at the forefront of testing this innovative technology in partnership with Helius and MUSC," stated Dr. Bowden.

Starting in January 2024, Dr. Bowden anticipates enrolling approximately 40 participants to the development program at Brooks Rehabilitation and expects full enrollment by the end of the year.

About Brooks Rehabilitation Hospital

For more than 50 years, the nonprofit Brooks Rehabilitation Hospital, headquartered in Jacksonville, Fla., has been a comprehensive system of care for physical rehabilitation. Ranked as the No. 1 rehabilitation hospital in Florida and one of the top 20 in the nation by U.S. News & World Report, Brooks Rehabilitation operates two inpatient rehabilitation hospitals in Jacksonville, Fla., and a Center for Inpatient Rehabilitation in partnership with Halifax Health (Daytona Beach). Brooks Rehabilitation also offers one of the region's largest home healthcare agencies; more than 50 outpatient therapy clinics; the Brooks Rehabilitation Medical Group; two skilled nursing facilities; assisted living; memory care; and the Clinical Research Center, which specializes in advanced research to further the science of rehabilitation. In addition, Brooks 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 www.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 ("mTBI") 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 functions and results of the clinical program and Brooks Rehabilitation’s participation in that program, including the timing of enrollment, Helius’ ability to receive authorization for stroke in the U.S. 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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