



## Helius Medical Technologies, Inc. Expands Stroke Clinical Program with Participation of Shepherd Center

April 24, 2024 1:05 PM EDT

- Helius Medical and Shepherd Center partner on a study that aims at rehabilitating walking mobility in people recovering from stroke --
- Shepherd Center, a top neurorehabilitation hospital, is the third site in Helius' U.S. registrational program for Portable Neuromodulation Stimulator (PoNS®) in stroke --
- The single-arm study will evaluate PoNS in treating gait and balance deficits in chronic stroke survivors --
- Regulatory submission seeking marketing authorization for stroke expected in 2025--

NEWTOWN, Pa., April 24, 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 its clinical development program for the broadening of the labeling of its marketed PoNS device to include patients recovering from stroke with the participation of Shepherd Center, under the direction of Michael Yochelson, M.D., MBA, FAAN, FAAPMR, Chief Medical Officer. Participating to the Company-sponsored single-arm study, Shepherd Center joins Brooks Rehabilitation as a third clinical site to the overall registrational program. As one of the nation's top neurorehabilitation hospitals, Shepherd Center is known for its innovation, patient outcomes exceeding the national average, and expertise in providing world-class clinical care for people experiencing the most complex conditions, including stroke, spinal cord and brain injuries, multi-trauma, traumatic amputations, multiple sclerosis, and pain.

The study aims to evaluate the potential benefit of PoNS Therapy® in treating gait and balance deficits in chronic stroke survivors. Shepherd Center has been an impactful participant in the PoNS Therapeutic Experience Program ("PoNSTEP"), a Company-sponsored outcome research clinical trial designed to evaluate the impact of subjects' adherence to PoNS Therapy in people with multiple sclerosis ("MS"), a trial led by Deborah Backus, PT, Ph.D., FACRM, Vice President of Research and Innovation.

"Shepherd Center has been a valuable partner to Helius for almost two years. We are delighted Dr. Yochelson has agreed to contribute to the implementation of our stroke registrational program and undertake the study at Shepherd Center," said Antonella Favitt-Van Pelt, M.D., Ph.D., Helius' Chief Medical Officer. "Shepherd Center's earlier involvement with the MS program is a testament to the strength of our clinical program. Dr. Backus and her research team have made an impactful contribution to further demonstrating PoNS Therapy's ability to induce significant and clinically meaningful improvements in gait rehabilitation in MS patients. Clinical evidence with PoNS Therapy has led to a new indication for treatment of gait deficits in stroke patients in Canada as well as highlighted the importance of this therapy in reducing the risk of falling in stroke survivors with gait and/or balance deficits. This study, as part of the broader registrational program, is an important step toward potentially obtaining authorization for treatment of gait deficits in stroke patients in the U.S."

"Innovation is at the core of what we do, and strategic collaboration is critical to advancing rehabilitation medicine and discovering better, more effective ways to deliver care," said Dr. Backus. "From my experience with the therapy, PoNS has the potential to improve the lives of patients suffering from MS, and we believe it can have a meaningful therapeutic effect on chronic stroke survivors as well. I'm excited to bring this innovative treatment to Shepherd Center, where we take a patient-centric approach designed to promote the highest level of functioning possible."

With recruitment starting in May 2024, Dr. Yochelson anticipates enrolling approximately 8-10 participants into the trial by the end of the year.

### About Shepherd Center

Shepherd Center provides world-class clinical care, research, and family support for people experiencing the most complex conditions, including spinal cord and brain injuries, multi-trauma, traumatic amputations, stroke, multiple sclerosis, and pain. An elite center recognized as both Spinal Cord Injury and Traumatic Brain Injury Model Systems; Shepherd Center is ranked by U.S. News as one of the nation's top hospitals for rehabilitation. Shepherd Center treats thousands of patients annually with unmatched expertise and unwavering compassion to help them begin again. For more information visit [www.shepherd.org](http://www.shepherd.org).

### About Helius Medical Technologies, Inc.

Helius Medical Technologies is a leading neurotech company in the medical device field focused on neurologic deficits using an orally applied technology platform designed to amplify 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 about the PoNS® or Helius Medical Technologies, visit [www.heliusmedical.com](http://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 is 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 deficits 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](http://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, availability of funds, the Company’s ability to find additional sources of funding, manufacturing, labor shortage and supply chain risks, including risks related to manufacturing delays, the Company’s ability to obtain national Medicare insurance coverage and to obtain a reimbursement code, the Company’s ability to continue to build internal commercial infrastructure, secure state distribution licenses, market awareness of the PoNS device, future clinical trials and the clinical development process, the product development process and the 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, 2023, 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](http://www.sec.gov) or [www.sedar.com](http://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.

### **Investor Relations Contact**

Lisa M. Wilson, In-Site Communications, Inc.

T: 212-452-2793

E: [lwilson@insitecony.com](mailto:lwilson@insitecony.com)