



Helius Medical Technologies, Inc. Announces Participation of Montefiore Medical Center in its PoNS® Therapeutic Experience Program

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Sixth Center of Excellence added in multi-center, company-sponsored, open label observational interventional trial to evaluate the impact of subjects' adherence to PoNS Therapy™ for gait improvement in Multiple Sclerosis

NEWTOWN, Pa., Aug. 07, 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 addition of the Montefiore Medical Center ("Montefiore") to its PoNS Therapeutic Experience Program ("PoNSTEP"). Montefiore joins five other Centers of Excellence in this company-sponsored open-label observational trial designed to evaluate the impact of subjects' adherence to Portable Neuromodulation Stimulator ("PoNS®") therapy in patients with multiple sclerosis ("MS"). Montefiore's participation in the study will be held at the Burke Rehabilitation Center and led by Dr. Christopher Langston, medical director of The Madlyn Borelli Multiple Sclerosis Center at Montefiore Nyack Hospital.

"Dr. Langston is a renowned clinical researcher of current and advanced topics in MS management and patient-centered care. His interest in PoNS Therapy has led him to be one of the first PoNS prescribers and his growing experience with this therapy, along with a long-standing commitment to improving MS patients' condition, makes him a remarkable contributor to the PoNSTEP study," said Antonella Favit-Van Pelt, M.D., Ph.D., Helius' Chief Medical Officer.

"The MS patients we treat are often in the prime of their lives. At Montefiore, we believe it's important to understand all MS treatments available in order to guide our patients in choosing their best path. We strive to help them navigate their illness by exposing them to innovative therapies as well as giving them the opportunity to participate in advanced clinical trials. I've been an early adopter of PoNS Therapy to help my patients improve their gait and I'm excited to join the study," stated Dr. Langston.

About Montefiore Medical Center

As the academic medical center and University hospital for Albert Einstein College of Medicine, Montefiore Medical Center is nationally recognized for clinical excellence—breaking new ground in research, training the next generation of healthcare leaders, and delivering science-driven, patient-centered care.

Montefiore is ranked among the top hospitals nationally and regionally by U.S. News & World Report. For more than 100 years Montefiore has been innovating new treatments, new procedures and new approaches to patient care, producing stellar outcomes and raising the bar for medical centers in the region and around the world. Montefiore continues to advance the practice of medicine and set the standard for excellence.

The mission of Montefiore is to heal, to teach, to discover and to advance the health of the communities it serves. From its beginning in 1884, as a facility for the care of patients with tuberculosis and other chronic illnesses, to the new millennium, Montefiore has been at the forefront of patient care, research and education and steadfast commitment to its community.

About The Madlyn Borelli Multiple Sclerosis Center

The Madlyn Borelli Multiple Sclerosis Center at Montefiore Nyack Hospital provides comprehensive care for people with MS. Affiliated with Montefiore Einstein, the center offers a full array of diagnostic and treatment services under the direction of Medical Director Christopher Langston, MD, a fellowship-trained neurologist.

With access to the latest advances in MS care, The Madlyn Borelli Multiple Sclerosis Center offers FLAIR (Fluid-Attenuated Inversion Recovery) imaging technology for improved diagnosis. In addition to diagnosis and treatment, the center provides rehabilitation services, including physical and occupational therapy as well as support and educational programs for patients and their families.

The Madlyn Borelli Multiple Sclerosis Center is a designated Comprehensive Center for MS Care through the National Multiple Sclerosis Society's Partners in MS Care program.

About the Burke Rehabilitation Center

Burke Rehabilitation is a not-for-profit healthcare organization devoted solely to acute physical rehabilitation. Its main campus is located in White Plains, NY. Founded in 1915 through an endowment from philanthropist John Masterson Burke, it has been a member of the Montefiore Health System since 2016. Burke operates the only hospital in Westchester County dedicated solely to adult and adolescent rehabilitation medicine. Burke also offers therapeutic care in locations throughout Westchester County, the Hudson Valley and the Bronx for those who have experienced injuries, surgery, or chronic conditions, from the simple to the very complex. For additional information, please visit burke.org.

About the PoNS Therapeutic Experience Program

The PoNS Therapeutic Experience Program ("PoNSTEP") is a Helius-sponsored, open label observational, interventional multi-center outcome research trial designed to assess adherence to on-label PoNS therapy for improvement in gait deficits for patients with multiple sclerosis (MS) in a real-world clinical setting. The study will rate subjects' adherence to PoNS therapy, which combines the PoNS device with physical therapy, to better understand the relationship between adherence to the treatment regimen and therapeutic functional outcome. The primary endpoint of the study is maintenance of gait improvement from the end of supervised therapy (Phase 1) to the end of unsupervised therapy (Phase 2) in relation to the subject's adherence to PoNS therapy. The secondary endpoint is improvement of gait and balance deficit over time and clinical global impression of change.

The study is currently undertaken at six sites and aims to recruit up to seven or eight Centers of Excellence across the United States, with the potential of enrolling five to ten subjects per site. Enrollment began in the fourth quarter of 2022 and will continue throughout 2023. A total of fifty to sixty patients with MS are expected to take part in the program.

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 mild electrical stimulation to the surface of the tongue and it's used, primarily at home, with physical rehabilitation exercise, 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 ("mTBI") 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 expected enrollment, patient participation and other details related to and outcomes of the PoNSTEP study and the ability of key opinion leaders in the management of MS to build their knowledge of PoNS® therapy and advise the broader medical community.

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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