Helius Medical Technologies, Inc. Announces Participation of Dr. Deborah Backus and Shepherd Center in its Therapeutic Experience Program

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-- Second 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., May 17, 2022 (GLOBE NEWSWIRE) -- Helius Medical Technologies, Inc. (Nasdaq:HSDT) ("Helius" or the "Company"), a neurotech company focused on neurological wellness, today announced the addition of Shepherd Center in Atlanta, Georgia to its Therapeutic Experience Program ("TEP"). This initiative will be led by Deborah Backus, PT, Ph.D., FACRM, Vice President of Research and Innovation and Director of Multiple Sclerosis Research at the Virginia C. Crawford Research Institute at Shepherd Center. Shepherd Center joins NYU Langone Health as the second Center 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).

"Our Therapeutic Experience Program enables clinicians to evaluate the effectiveness of PoNS therapy for MS patients with gait deficit in a real-world environment while providing important information about PoNS therapy to key opinion leaders in MS management," said Antonella Favit-Van Pelt, M.D., Ph.D., Helius' Chief Medical Officer. "The Virginia C. Crawford Research Institute at Shepherd Center is an important partner to TEP, and we are thrilled with Dr. Backus's contribution to our efforts of bringing innovative therapies to people with MS. Shepherd Center is one of the top ten rehabilitation hospitals in the United States with a world-renowned Multiple Sclerosis Institute and integrated research program, and we look forward to a long-standing collaboration."

"Shepherd Center is dedicated to improving the function, health, and quality of life in all people with MS, and we are excited to partner with Helius on this important study," said Dr. Deborah Backus. "People with MS often have decreased mobility, leading to more disability and less participation in daily life activities. We believe PoNS therapy can be an effective therapeutic option for our patients."

About Shepherd Center

Shepherd Center, located in Atlanta, Georgia, is a private, not-for-profit hospital specializing in medical treatment, research and rehabilitation for people with spinal cord injury, brain injury, multiple sclerosis, spine and chronic pain, and other neuromuscular conditions. Founded in 1975, Shepherd Center is ranked by U.S. News & World Report among the top 10 rehabilitation hospitals in the nation. In its more than four decades, Shepherd Center has grown from a six-bed rehabilitation unit to a world-renowned, 152-bed hospital that treats more than 740 inpatients, nearly 280 day program patients and more than 7,100 outpatients each year in more than 46,000 visits.

About the Therapeutic Experience Program

The Therapeutic Experience Program ("TEP") 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 will be conducted at ten to twelve Centers of Excellence across the United States, with an estimated four PoNS devices per site. Enrollment is expected to begin in the second quarter of 2022 and continue through late 2022. A total of forty to fifty subjects 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 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) 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 (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. 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, patient participation, the results and other details of the TEP study, and the Company’s collaboration with Shepherd Center.

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 and ability to raise capital, 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, 2021, its Quarterly Report on Form 10-Q for the quarter ended March 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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