Helius Medical Technologies, Inc. Launches Therapeutic Experience Program; NYU Langone Health Is Initial Clinical Trial Site

November 8, 2021 1:00 PM EST

-- Multi-center, company-sponsored, open label observational interventional trial to evaluate impact of subjects' adherence to PoNS® therapy for gait improvement in Multiple Sclerosis --
-- Program to include 10-12 U.S. Centers of Excellence; enrollment to commence in Q4 2021 --

NEWTOWN, Pa., Nov. 08, 2021 (GLOBE NEWSWIRE) -- Helius Medical Technologies, Inc. (Nasdaq:HSDT) ("Helius" or the "Company"), a neurotech company focused on neurological wellness, today announced the launch of its Therapeutic Experience Program ("TEP") with NYU Langone Health as its first Center of Excellence. The TEP study is designed to assess adherence to Portable Neuromodulation Stimulator (PoNS) therapy in patients with multiple sclerosis ("MS").

"We are excited to partner with one of the nation's premier academic medical centers on this important program aiming to provide US clinicians with the opportunity to evaluate PoNS therapy for MS patients with gait deficit in a real-world environment," said Antonella Favit-Van Pelt, M.D., Ph.D., Helius' Chief Medical Officer. "Through NYU Langone Health and future Centers of Excellence, the TEP study will enable key opinion leaders in the management of MS to build their knowledge of PoNS therapy and advise the broader medical community."

"For people with mild to moderate symptoms of MS, gait deficit can greatly affect function, independence, and quality of life," said Leigh E. Charvet, PhD, NYU Langone Health. "So far, non-pharmacological interventions have had limitations, but Helius' clinical evidence has shown that PoNS can be an effective therapeutic option for our patients. We're thrilled to move forward and participate in the program as, for clinicians, the TEP study will answer a crucial scientific question: what impact does patient's adherence to PoNS therapy regimen have on a meaningful therapeutic outcome?"

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 late in the fourth quarter of 2021 and continue through mid-2022. 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 non-surgical device, inclusive of a controller and mouthpiece, which delivers electrical stimulation to the surface of the tongue to provide treatment of gait deficit. 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. It is authorized for sale in Canada for two indications: (i) PoNS is authorized 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) 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.

About NYU Langone Health

NYU Langone Health is a world-class, patient-centered, integrated academic medical center, known for its excellence in clinical care, research, and education. It comprises more than 200 locations throughout the New York area, including six inpatient locations, a children's hospital, three emergency rooms and a level 1 trauma center. Also part of NYU Langone Health is the Laura and Isaac Perlmutter Cancer Center, a National Cancer Institute designated comprehensive cancer center, and NYU Grossman School of Medicine, which since 1841 has trained thousands of physicians and scientists who have helped to shape the course of medical history. For more information, visit www.nyulangone.org.

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 of the TEP 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, 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 June 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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