Helius Medical Technologies, Inc. Announces Participation of Neurology Center of New England in its Therapeutic Experience Program

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-- Fifth 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., Jan. 10, 2023 (GLOBE NEWSWIRE) -- Helius Medical Technologies, Inc. (Nasdaq:HSDT) ("Helius" or the "Company"), a neurotech company focused on neurological wellness, today announced the addition of Neurology Center of New England, P.C. ("NCNE") to its Therapeutic Experience Program (TEP). NCNE joins four 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). The initiative will be led by Dr. Salvatore Napoli, Medical Director of NCNE.

"Dr. Napoli and his team are important contributors to our PTAP program, and we are elated about their participation in the TEP study. NCNE is a highly reputable medical center known for its high-touch, integrated approach to treating MS and other neurological conditions. The center's unique approach to patient care will further enhance our understanding of the impact of PoNS therapy, as applied in real-world clinical settings, on therapeutic outcome," said Antonella Favit-Van Pelt, M.D., Ph.D., Helius' Chief Medical Officer.

"It's been well established that many people suffering the physical symptoms of MS are able to manage their disease progression with advanced pharmacological and non-pharmacological therapeutic interventions. PoNS therapy has shown the ability to improve gait and balance in patients with MS, and we are thrilled to include this important treatment in our broad spectrum of high-quality neurological care," stated Dr. Napoli.

About Neurology Center of New England

The Neurology Center of New England is a comprehensive neurological care center devoted to the diagnosis, care and management of patients with neurological diseases and syndromes. NCNE manages patients with conditions such as MS, migraine and other headache syndromes, Parkinson's disease, neuropathy, seizure disorders and epilepsy, dementia and memory disorders, numbness, and spasticity/dystonia.

About the Therapeutic Experience Program

The Therapeutic Experience Program 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 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 fourth quarter of 2022 and continue into 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 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 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 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. 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 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, 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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