



Helius Medical Technologies, Inc. Completes Site Participation Enrollment for its U.S. Registrational Program in Stroke

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-- Inclusion of the top neurorehabilitation centers REHABOLOGYM, Neurology Center of New England, and MGH Institute of Health Professions completes site participation enrollment for the U.S. registrational program in stroke --

-- In Canada, an additional study on the use of Portable Neuromodulation Stimulator (PoNS®) Therapy to treat stroke has started to support Canadian reimbursement and U.S. approval for stroke --

NEWTOWN, Pa., June 17, 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 completion of site participation enrollment for its stroke registrational program in the U.S. with the addition of REHABOLOGYM, Neurology Center of New England (NCNE), and MGH Institute of Health Professions (MGH-IHP). The stroke registrational program, which also includes Brooks Rehabilitation and Shepherd Center, is designed to establish the effects of cranial-nerve non-invasive neuromodulation ("CN-NINM"), delivered using PoNS Therapy®, on gait and dynamic balance in chronic stroke survivors.

Under the direction of Avrielle Rykman Peltz, M.A., OTR/L and Dr. Jay Lombard, D.O., REHABOLOGYM has already enrolled six subjects and expects to reach at least ten patients by early July. NCNE and MGH-IHP joined the study in May and June, respectively, and both sites will begin enrollment in July. Brooks Rehabilitation started enrollment in April with three participants to date while Shepherd Center enrolled two participants in May and expects to add two more by the end of June. Helius anticipates enrolling at least thirty patients into the open label study, across all sites, by the end of the third quarter.

"PoNS Therapy has demonstrated the ability to generate neuroplasticity, essentially rewiring parts of the brain to significantly and meaningfully improve gait and balance in chronic stroke survivors. With the addition of REHABOLOGYM, NCNE, and MGH-IHP, we now have five of the top neurorehabilitation centers in the U.S. participating in our stroke registrational program, which will significantly bolster our FDA submission when we submit for regulatory approval in 2025," said Dr. Antonella Favit-Van Pelt, Helius' Chief Medical Officer.

"Having spearheaded several research studies on stroke funded by premier public and private medical establishments, Dr. Lombard and I see great potential for PoNS to assist with stroke recovery and are thrilled to partner with Helius on this groundbreaking, multi-center research trial. REHABOLOGYM's goal is to accelerate the advancement of cutting-edge technologies, especially when they can pair with therapeutic interventions to deliver long-lasting improvements for people affected by neurological conditions and injuries. PoNS Therapy perfectly aligns with our mission, and we believe that together we can help bring new, validated therapies to the neurologically impaired," said Avrielle Rykman Peltz, M.A., OTR/L, Co-Founder & Chief Operating Officer of REHABOLOGYM.

"Leading research suggests that the brain has significant plasticity, with the ability to establish new pathways after various types of brain injuries including stroke. With the only portable and readily accessible therapy that has the potential to generate neuroplasticity, Helius is leading the way in applying technological breakthroughs at the bedside," stated Dr. Jay Lombard, D.O., co-investigator at REHABOLOGYM.

The registrational program was established in part based on real-world evidence from Canada, where PoNS is already authorized for treatment of stroke. To support national reimbursement in Canada, Helius has begun an additional study on the use of PoNS Therapy to treat stroke, with the goal of enrolling 60 subjects by the end of 2024 at three centers of excellence for stroke rehabilitation. The study led by Dr. Murielle Grangeon, PhD, Adm., Founder and General Manager, at Neuro-Concept Rehabilitation Center, with the participation of Neuphysio and Synaptic Health, has already received approval by the Institutional Review Boards (IRB). The sites will begin patient enrollment by the end of the month and the results from this study will be part of the data package submission to obtain FDA authorization for stroke in the United States.

About REHABOLOGYM

REHABOLOGYM is a neuro-robotic rehabilitation center utilizing state of the art technologies and comprehensive methodologies for neurological occupational therapy (OT), physical therapy (PT), speech therapy (ST/SLP) and certified personal training (CPT). For more information visit www.rehabologym.com.

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 Multiple Sclerosis, migraine and other headache syndromes, Parkinson's disease, neuropathy, seizure disorders and epilepsy, dementia and memory disorders, numbness, and spasticity/dystonia. For more information visit www.myneurodr.com.

About MGH Institute of Health Professions

The MGH Institute of Health Professions is a private university focused on the health sciences and located in Boston, Massachusetts. It was founded by Massachusetts General Hospital in 1977 and is accredited by the New England Commission of Higher Education. For more information visit www.mghihp.edu.

About Neuro-Concept Rehabilitation Center

The Neuro-Concept center for neurological rehabilitation and adapted physical conditioning integrates into clinical practice the latest technologies and the advanced expertise of therapists to meet the needs of pediatric, adult and geriatric neurological clients. Based on evidence and neuroplasticity

concept, Neuro-Concept has been applying best practices in the rehabilitation of individuals living with a neurological condition. By offering intensive rehabilitation programs to improve recovery and functional independence in daily life, Neuro-Concept is dedicated to putting patient need first. For more information visit www.neuro-concept.ca.

About Neuphysio

Neuphysio is a private rehabilitation company that provides physiotherapy services to persons in London, ON and surrounding areas. Neuphysio offers clinic, in-home and community-based therapy to persons living with injury or disease. With a focus on neurological rehabilitation, vestibular rehabilitation and gait and balance training, the staff at Neuphysio offer world class service and quality of care. Client centered goals are functionally based and aimed at improving mobility, stability and quality of life. For more information visit www.neuphysio.com.

About Synaptic Health

Synaptic provides a comprehensive range of neurorehabilitation services designed to optimize recovery and enhance quality of life. From physiotherapy and occupational therapy to employing cutting-edge rehabilitation methods and technology, Synaptic's team strives to deliver the highest standard of therapy and is committed to delivering personalized rehab services tailored to the meet the unique needs of each individual. Synaptic extends support to individuals of all ages facing neurological injuries, conditions, and symptoms, regardless of their stage of recovery or whether they have received a formal diagnosis. For more information visit www.synaptichealth.ca.

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 that amplifies 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.

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's 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 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.

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 stroke registrational program and the additional Canadian stroke study, including the timing of enrollment, future regulatory submissions by the Company as well as future decisions and approvals from applicable regulatory entities in the U.S. and Canada, 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 negotiate reimbursement with other third-party payers, 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 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.

Investor Relations Contact

Lisa M. Wilson, In-Site Communications, Inc.
T: 212-452-2793
E: lwilson@insitecony.com