Helius Medical Technologies, Inc. Announces Positive Preliminary Results of the PoNSTEP Study

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-- Achieves primary endpoint showing a linear relationship between adherence to PoNS Therapy® in Phase 2 and improvement in DGI scores from Phase 1 to end of treatment at week 14 --

-- Confirms the therapeutic benefits of PoNS Therapy for gait deficit improvement in people with MS --

NEWTOWN, Pa., Sept. 30, 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 positive preliminary results from its Therapeutic Experience Program open-label observational study (PoNSTEP) which evaluates the impact of subjects' adherence to the Portable Neuromodulation Stimulator (PoNS®) Therapy program that treat gait deficit due to multiple sclerosis ("MS"). The study treatment phase is complete, and the ongoing post-treatment follow-up phase will be completed by the end of the year, with full results expected to be released in early 2025.

"As physicians, we often face challenges with patients embracing the importance of fully complying with their rehabilitation program" said Antonella Favit-Van Pelt, M.D., Ph.D., Helius' Chief Medical Officer, "The PoNSTEP study provides compelling evidence on how, with any self-directed at home physical therapy activity, adherence can significantly determine how much functional improvement any patient can achieve". We are encouraged to see the meaningful gait deficit improvements in patients who were consistently compliant with their therapy regimen."

Preliminary PoNSTEP Results

The primary endpoint of the study is aimed at demonstrating improvement in DGI from end of the 2-week supervised in-clinic treatment phase (Phase 1) to end of the 12-week at-home, unsupervised treatment phase (Phase 2), relative to subjects' adherence to PoNS device utilization in their weekly PoNS therapy program (PoNS Therapy). Forty-three subjects with gait deficit due to symptoms from multiple sclerosis were enrolled with 41 participants starting the study treatment and 38 participants completing the 14-week study treatment period who are currently undergoing post treatment follow-up (Phase 3).

PoNSTEP met the primary endpoint, showing statistically significant mean improvement in DGI during Phase 2 and a linear relationship between PoNS Therapy adherence and improvement in DGI scores from end of Phase 1 to end of treatment at week 14:

- In Phase 1, the average therapy adherence was almost 90% with a mean improvement of 2.5 points in DGI scores from baseline to the end of week 2 without, however, a clear correlation between adherence and DGI improvement (N=41, r=-0.03; p=0.83).
- In Phase 2, the average therapy adherence was 67% with a mean incremental improvement, at week 14, of an additional 2.8 points in DGI scores from the improvement achieved at the end of Phase 1 (paired t-test p<0.0001). In contrast to Phase 1, improvement in Phase 2 DGI was significantly moderated by PoNS adherence (N=38, r=0.345; p=0.034).

Over the course of the 14-week treatment (Phase 1 and Phase 2), the average therapy adherence met or exceeded 70% of the recommended, on label, PoNS Therapy utilization and led to a mean improvement of 5.0 points (p<0.0001) in DGI from baseline to the end of the 14-week treatment period moderated by adherence (r=0.34; p<0.0001). Among 23 participants who met or exceeded 70% therapy adherence, more than 65% experienced a cumulative mean DGI improvement of at least 5 points and approximately 74% gained at least 4-point improvement from baseline to end of treatment.

"This data is expected to confirm the importance of the at-home rehabilitation part of PoNS Therapy, following the supervised in-clinic treatment, in achieving optimal gait deficit improvement results," said Dr. Salvatore Napoli, MD, Medical Director, Neurology Center of New England. "We are also encouraged to see the high compliance rates across patients which is likely supported by the user friendly and straight forward application of PoNS Therapy."

The preliminary descriptive analysis of the active treatment data from Phase 1 and Phase 2 demonstrates that, overall, 66% of participants gained a clinically meaningful improvement of at least 4 points in the DGI assessment over the course of the therapy. In addition, 71% of participants gained at least a 2-point improvement in DGI in the first 2 weeks of in-clinic treatment (Phase 1) and 68 % had an incremental DGI improvement of at least 2 points over the course of the remaining 12 weeks of at-home therapy. In line with the clinical evidence from PoNS clinical studies and real-world utilization data, 50% of participants who used PoNS Therapy for the recommended 100-120 min/day, equivalent to 85% and 100% therapy adherence respectively, achieved over a 6-point improvement in DGI from baseline over 14 weeks of treatment.

Dr. Favit-Van Pelt added, "The study's preliminary results provide material confirmatory evidence of the therapeutic benefits of PoNS Therapy for gait deficit improvement in people with MS and strengthen the body of clinical evidence pointing to the importance of utilizing the therapy at the recommended dose regularly and consistently. The study preliminary results also highlight the importance of consolidating neuromodulation-mediated neural changes and the critical role of PoNS mechanism of neuroplasticity in functional rehabilitation of gait and balance."

About PoNS Therapeutic Experience Program (PoNSTEP)

The Therapeutic Experience Program ("TEP") is a Helius-sponsored, open label observational, interventional multi-center outcome research study 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 aims to understand better the relationship between adherence to on label (100-120 minute per day) PoNS Therapy, which combines the PoNS device with physical therapy, and the therapeutic outcome on gait deficit improvement over 14 weeks of study treatment, as measured by changes in the Dynamic Gait Index (DGI) scores. PoNS Therapy is applied in a supervised clinical setting for the first two weeks (Phase 1) and, independently, at home for the remaining 12 weeks (Phase 2). The study also includes a six month no-treatment follow-up phase aimed at establishing durability of therapeutic effect (Phase 3).

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 ongoing at six Centers of Excellence across the United States, including Neurology Center of New England in Foxboro (MA), the Shepherd Center in Atlanta (GA), Montefiore Medical Center ("Montefiore") in NY (NY), Oregon Health & Science University ("OHSU") in Portland (OR), MGH Institute of Health Professions in Boston (MA), NYU Langone Health in NY (NY), and recruited 43 MS participants with gait deficit. PoNSTEP will be completed by the end of 2024 and the Company expects to announce the full results early in 2025.

About Helius Medical Technologies, Inc.

Helius Medical Technologies is a leading neurotech company in the medical device field focused on neurologic deficits using 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 market authorization for 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 ("mmTBI") 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 marketing 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.

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.

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 timing of the release of data from the full PoNSTEP study and the results of the full study.

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 to obtain a reimbursement code, 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.

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