Helius to Spotlight Study Confirming Improved Long-Term Outcomes from Adherence to PoNS Therapy® at CMSC Annual Meeting

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Shepherd Center's Dr. Deborah Backus to Showcase Final Results of PoNSTEP Study, Providing New Insight into Maximizing Impact of Neuromodulation to Improve Gait in People with MS

NEWTOWN, Pa., May 20, 2025 (GLOBE NEWSWIRE) -- Helius Medical Technologies, Inc. (NASDAQ: HSDT), a neurotech company focused on delivering a novel therapeutic neuromodulation approach for balance and gait deficits, announced it will highlight the results of a new study confirming the therapeutic regimen and sustained efficacy of its Portable Neuromodulation Stimulator (PoNS®) device for people with multiple sclerosis (MS) at the 2025 Consortium of Multiple Sclerosis Centers (CMSC) Annual Meeting. The event runs from May 28-31 at the Phoenix Convention Center in Phoenix.

Deborah Backus, PT, Ph.D., FACRM – Vice President of Research and Innovation at Atlanta's Shepherd Center, one of six sites that conducted the PoNS Therapeutic Experience Program (PoNSTEP) study – will present the full study results for the first time at a platform presentation session on Thursday, May 29, from 3:20-3:40 p.m. Attendees can learn more about PoNSTEP from Helius Chief Medical Officer Antonella Favit-Van Pelt, M.D., Ph.D., who will meet attendees at booth 600 to answer questions and discuss the study outcomes in more detail.

"Those of us familiar with PoNS have seen how it enables some people with MS to walk better. But PoNSTEP data provide the first clinical evidence that there's a statistically significant relationship between adherence to PoNS Therapy and the degree of improvement – and that the improvement can be sustained," Dr. Backus said. "These results affirm the potential of PoNS Therapy to drive real, measurable gain in better mobility for people with MS. For a population that has long faced limited treatment options for gait deficits, this represents an important step forward."

PoNSTEP was a three-phase, real-world therapeutic experience study designed to assess the impact of adherence on gait deficit and long-term outcomes. Participants began with two weeks of supervised in-clinic therapy, followed by 12 weeks of combined clinic and at-home use, and concluded with a six-month follow-up period to evaluate the durability of their improvements.

PoNSTEP's key finding is that stronger adherence to PoNS Therapyä, which combines non-invasive cranial nerve translingual neuro-stimulation (TLNS) with specific physical exercises, results in better therapeutic outcomes. The most-adherent participants maintained superior gait improvement from the end of the study's supervised therapy phase through its unsupervised therapy phase, achieving a gain of over 6 points in their Dynamic Gait Index (DGI) scores – a key clinical measurement of walking function and balance – over the first 14 weeks of the trial. PoNSTEP data also show gait improvement levels are durable, sustained at 6 months post-treatment.

Highly adherent patients—using the device for at least 85% of the recommended 100–120 minutes per day during Phase 2—improved their Dynamic Gait Index (DGI) scores by more than 6 points. Those with moderate adherence (around 70%) showed a smaller, yet meaningful, improvement of 5 points total. These results demonstrate a linear relationship between adherence and gait improvement outcomes. In addition, more than 95% of participants who were evaluated 6 months later maintained their level of improvement.

"PoNSTEP is the latest in a series of important milestones for PoNS and I'm delighted to join Dr. Backus in sharing PoNSTEP full study results with the broader MS community," said Dr. Favit-Van Pelt.

The study provides further evidence of the power of neuromodulation and neuroplasticity in rehabilitating the neural network and confirms the benefit of 14 weeks of PoNS therapy as a meaningful therapeutic option for people with MS and gait deficit. Access to PoNS therapy is provided by insurance through the U.S. Department of Veterans Affairs and U.S. Department of Defense, with several commercial healthcare providers already starting to reimburse the device out of network.

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 the durability of the 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 endpoints are, among others, maintenance of improvement of gait and balance deficit over a 6-month timeframe and clinical global impression of change.

The study was performed 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.

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 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 (“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 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.

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.

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 future presentation and uses of the PoNSTEP study results 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 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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