Positive PoNSTEP Study Results Presented at Consortium of Multiple Sclerosis Centers Annual Meeting

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-PoNS Therapeutic Experience Program (PoNSTEP) study demonstrates durable long-term beneficial effects of PoNS Therapy® on gait deficit improvement in people with Multiple Sclerosis-

-Presentation of full PoNSTEP study results expanded upon top line data previously reported-

NEWTOWN, Pa., June 12, 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, today announced that Deborah Backus, PT, Ph.D., FACRM- Vice President of Research and Innovation at Atlanta's Shepard Center presented the positive results from the PoNS Therapeutic Experience Program, or PoNSTEP, study for people with multiple sclerosis (MS) at the 2025 Consortium of Multiple Sclerosis Centers (CMSC) Annual Meeting on May 29 in Pheonix, Arizona.

Dr. Backus' presentation highlighted the importance of treatment adherence as a key requirement for achieving a clinically meaningful improvement in gait disability over 14 weeks of therapy and its sustained therapeutic effect well into 6 months after the end of treatment. The study results confirm controlled and real-world clinical evidence of PoNS Therapy's long-term benefits already reported in people with balance deficit due to traumatic brain injury (TBI).

"The results from this study were received with great interest as they provide the first clinical trial evidence of the long-term therapeutic benefits of PoNS Therapy for functional rehabilitation in the MS population," stated Antonella Favit-Van Pelt, M.D., Ph.D., Helius' Chief Medical Officer. "We were excited to engage with both US healthcare professionals and Canadian MS specialists and offer additional insights on the body of clinical and mechanistic evidence of PoNS Therapy's effect in MS. We are encouraged by the growing recognition of the importance of PoNS' direct effect on the central nervous system and its targeted mechanism of action as well as how it correlates with a lasting and sustained effect on gait rehabilitation, especially when comparing PoNS Therapy to other interventions limited to peripheral neuromuscular or transcutaneous stimulation."

CMSC attendees were encouraged at Helius' recent successes in obtaining initial reimbursement from federal and private payers and appreciated the Company's relentless effort to engage with health insurance providers, viewing it as a much-needed endeavor to expand access to PoNS Therapy to all people with MS.

"We are excited by the positive conversations had at CMSC regarding both the therapeutic impact of the data presented and the recent announcement of reimbursement from the VA and out of network commercial payers for PoNS," stated Dane Andreeff, Helius' President and Chief Executive Officer. "We anticipate that the increase in reimbursement coverage will significantly lower the barrier to prescribe PoNS and allow for greater access to this important therapy."

About PoNS Therapeutic Experience Program (PoNSTEP)

The PoNS Therapeutic Experience Program ("PoNSTEP") 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, the availability of commercial reimbursement 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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