Helius Medical Technologies, Inc. Announces First Clinical Evidence of Positive Long-term Therapeutic Effects of PoNS Therapy® on Gait Deficit Improvement in Multiple Sclerosis from the PoNS® Therapeutic Experience Program Study

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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--

--Statistically significant findings in DGI (Dynamic Gait Index) during Phase 1 and Phase 2 among the 38 subjects who completed the treatment protocol showing a total mean improvement of 5.00 (4.1 to 5.9, p<0.001) at week 14--

NEWTOWN, Pa., Jan. 22, 2025 (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 results from the PoNS Therapeutic Experience Program, or PoNSTEP, study for people with multiple sclerosis (MS).

"The results from this study validate existing evidence of the efficacy of PoNS across clinical data and real-world utilization of the therapy by demonstrating durability of effect as further evidence of its long-term therapeutic benefits," stated Antonella Favit-Van Pelt, M.D., Ph.D., Helius' Chief Medical Officer. "The PoNSTEP study marks an important stepstone in further understanding the role of neuromodulation and, consequently, neuroplasticity in gait function rehabilitation. PoNS Therapy's neuromodulation effect on brain mechanisms of motor control is likely to enhance neuroplasticity and contribute to maintain PoNS therapeutic effect on gait deficit in people with MS."

The recently completed study, provides the first clinical evidence of a positive relationship between adherence to using the PoNS device with targeted physical exercise (PoNS Therapy) and improvement of gait deficit, along with establishing the long-term therapeutic effect of PoNS Therapy at six months post-treatment in people with MS. This observation is in line with maintenance of effect's evidence from other clinical trials in people with balance deficits due to traumatic brain injury.

The study involved 43 patients with gait deficit due to mild-to-moderate MS, who received 14 weeks of physical rehabilitation with PoNS Therapy. The therapy included 2 weeks in the clinic (Phase 1) and 12 weeks at home (Phase 2), followed by a 6-month post-treatment observation (Phase 3). Of the 41 patients who started, 38 completed the study, and 29 were evaluated at 6 months. Patients with a 30% or greater decline in functional improvement were eligible for an additional 12 weeks of therapy. The primary outcome measure was the DGI, with changes evaluated using statistical tests and correlation analyses to assess adherence and DGI improvements.

PoNSTEP Results

- There were statistically significant findings in DGI during Phase 1 and Phase 2 among the 38 subjects who completed the treatment protocol for a total mean improvement of 5.00 (4.1 to 5.9, p<0.001) at week 14.
- In Phase 2, average therapy adherence 71% and gait improvement was linearly associated with adherence (r=0.345; p=0.034), while, in Phase 1 adherence, was 89.5% and, consequently, not associated with improvement.
- In addition to mean 2.5 points improvement in DGI achieved in Phase 1, Phase 2, participants with ≥85% adherence improved mean 3.7 points [1.8 SD]; those with <85% adherence improved mean 2.0 points [1.8 SD], and the difference was statistically significant [p=.0.008].
- 28 of 41 (70.7%) participants who completed the 14-wk therapy were reassessed at 6-months and only 1 of 28 showed ≥ 30% decline in DGI (95% exact binomial CI: 0.09% to 18.4%).
- Mean decline (%) in DGI was -4.1 (95% CI -9.4% to 1.1%; range -35.7% to 25.0%) with the 95% CI's lower bound showing statistically reliable evidence that the true mean decline was no more than -9.4% (p=0.12).

"We are pleased to report the PoNSTEP study results corroborate the known evidence of PoNS Therapy's efficacy in improving gait deficit due to MS," stated Dane Andreeff, Helius' President and Chief Executive Officer. "Like many therapeutics, treatment compliance is key to achieving incremental and lasting therapeutic beneficial effects with PoNS Therapy. This important study provides convincing evidence of the role of neuroplasticity for a durable gait function improvement in MS. We thank all the investigators and patients involved in the study and we look forward to sharing the data to increase awareness on PoNS Therapy at upcoming scientific conferences."

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 endpoints are, among others, maintenance of improvement of gait and balance deficit over 6-m 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 (GE), 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 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 (“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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