Helius Medical Technologies, Inc. Announces Strong Enrollment of its Stroke Pivotal Study Exceeding Initial Target

January 21, 2025 12:00 PM EST

--128 enrolled participants, as of December 31, 2024, exceeds initial target of 90 participants--

--150 maximum participant enrollment projected by end of January--

--The stroke registrational program is intended to demonstrate the safety and effectiveness of the novel Portable Neuromodulation Stimulator (PoNS®) for improving balance and gait deficits in stroke survivors--

--On track for FDA submission for stroke authorization in the second quarter of 2025--

NEWTOWN, Pa., Jan. 21, 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 it has completed and far exceeded the initial target enrollment for its stroke registrational program. With 128 participants randomized to-date the program is on track to reach the maximum enrollment target of 150 participants by the end of January 2025.

"Gait and balance deficits are the most frequently occurring disability in stroke patients and represent the largest market opportunity for PoNS Therapy®," said Dane Andreeff, Helius Medical President and Chief Executive Officer. "We are excited for the opportunity to make PoNS available to the over 7 million patients in the U.S. living with disability from stroke as we remain on target to achieve FDA authorization for stroke in 2025."

In 2021, the U.S. Food and Drug Administration granted Breakthrough Designation for PoNS in stroke. Helius has designed and implemented the stroke registrational program to establish the effects of cranial-nerve non-invasive neuromodulation ("CN-NINM"), delivered using PoNS Therapy, on gait and balance in chronic stroke survivors to support an FDA submission to expand the PoNS device indication to this patient population. The registrational studies also aim at establishing PoNS efficacy on decreasing risk of falling and maintaining the therapeutic effect post-treatment.

"Completing enrollment of our registrational program's studies is a significant step toward providing stroke patients with a new therapeutic tool to improve their mobility. We have shown PoNS is effective in treating gait deficits for MS patients and we are excited to reinforce similar therapeutic benefits to address a dire medical need in this patient population," said Antonella Favit-Van Pelt, M.D., Ph.D., Helius Chief Medical Officer. "Our ability to enroll this study in a timely manner highlights providers' interest in PoNS Therapy and demonstrates patients' demand for impactful rehabilitation therapies. With maximum target enrollment expected by the end of the month, we are tracking to our goal to submit for stroke authorization in the second quarter of 2025."

In March 2023, the FDA endorsed the stroke registrational program which originally included two initial studies. The first was an investigator-initiated randomized placebo-controlled trial (MUSC-RCT) in approximately 60 subjects, led by Dr. Steven Kautz at the Medical University of South Carolina (MUSC) and Dr. Mark Bowden at Brooks Rehabilitation. The second study was a company-sponsored open-label study (HMI-OLS), in approximately 30 subjects. In May 2024, Helius added a third company-sponsored randomized placebo-controlled trial (HMI-RCT) across five sites in Canada and the U.S. All three studies shared the same design and endpoints, including primary outcomes on gait and balance improvement, as well as key secondary endpoints with Type 1 error of reduced risk of falling and maintenance of effect at 12 weeks post-treatment.

Enrollment of the stroke registrational studies started at MUSC for the MUSC-RCT in August 2023 and, at Brooks Rehabilitation, in August 2024. In June 2024, Helius started enrollment of the HMI-OLS at five U.S. Centers of Excellence for Neurorehabilitation including Shepherd Center, MGH-IHP, REHABOLOGYM, Brooks Rehabilitation and New England Neurological Center. Enrollment continued, with the HMI-RCT, in July 2024 at Neuro-Concept Rehabilitation Center, Neuphysio, Synaptic Health, Bergin Motion in Canada and REHABOLOGYM in the U.S.

"By December 31, 2024, we have reached our goal and exceeded our previously communicated target enrollment of 90 subjects, by randomizing 128 participants across the three registrational programs' studies and we expect to reach our full enrollment of 150 participants in the next couple of weeks. Achieving and exceeding enrollment rate of approximately 5 participants per site per month in such a short timeframe, significantly outperforming the enrollment benchmark for stroke-related medical device studies, is a monumental achievement for Helius," Dr. Favit-Van Pelt continued. "We are grateful to all our investigators for their extraordinary contribution and dedication to make PoNS Therapy available to stroke patients."

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 while 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 the timing and results of the stroke registrational program, the ability to make PoNS available to over 7 million patients, the ability to reach maximum target enrollment expected by the end of the month, and the timing or success of submitting and receiving stroke authorization. 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.

Investor Relations Contact
Philip Trip Taylor
Gilmartin Group
investorrelations@heliusmedical.com