Helius Medical Technologies, Inc. Introduces Device in U.S. To Help Multiple Sclerosis Patients Improve Walking Ability

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-- Breakthrough technology for MS patients helps patients with gait deficit

-- Portable Neuromodulation Stimulator (PoNS®) is an innovative non-surgical medical device that includes a controller and a mouthpiece

-- Available directly to patients by prescription, used in conjunction with physical therapy

NEWTOWN, Pa., April 26, 2022 (GLOBE NEWSWIRE) -- Helius Medical Technologies, Inc. (Nasdaq: HSDT) ("Helius" or the "Company"), a neurotech company focused on neurological wellness, today announced availability in the market of its breakthrough technology with the potential to help patients in the United States with Multiple Sclerosis (MS) who struggle to walk. Gait deficit is a leading cause of mobility, disability and quality of life issues for the 70 percent (1.) of the one million patients with MS in the U.S. (2.)

The technology, known as Portable Neuromodulation Stimulator (PoNS®), is now available in the U.S. to help MS patients with gait deficit improve walking ability. PoNS is available commercially by prescription, for the first time, to patients in the U.S. aged 22 and over. Helius, which has offered PoNS in Canada since 2019, received marketing authorization last year from the U.S. Food and Drug Administration (FDA) for the use of PoNS for short-term treatment of gait deficit due to mild-to-moderate symptoms of MS. Helius also received a second FDA Breakthrough Designation for PoNS for the treatment of dynamic gait and balance deficits resulting from a stroke and is moving forward with the registrational program to develop PoNS Therapy™ for marketing authorization with an indication in stroke.

"We believe that we are unlocking the full potential of neuromodulation and neuroplasticity to help MS patients walk more steadily and safely," said Antonella Favit-Van Pelt, MD, PhD, Helius's Chief Medical Officer. MS is a progressively disabling condition with the first symptoms appearing in people between ages 20 and 40. "Approximately 40 percent of individuals with MS will need walking assistance within 15 years of the onset of the disease. (3.) PoNS therapy provides a unique opportunity for these patients to improve gait functionality and mobility" said Dr. Favit-Van Pelt.

Multiple sclerosis is a disease that impacts the brain and spinal cord that make up the central nervous system and controls everything we do. Difficulty in walking — also known as problems with gait — is among the most common mobility limitations in MS. Most gait problems can be helped to some extent by physical therapy, stretching exercises, the use of appropriate assistive devices and, in some cases, medications for spasticity, fatigue, and walking speed, according to the National Multiple Sclerosis Society.

PoNS is a portable, non-implantable device that delivers mild electrical stimulation to the dorsal surface of the patient's tongue. The device consists of a controller and a mouthpiece that contains gold-plated electrodes. The controller goes around the neck. The mouthpiece rests on the front of the tongue with the electrodes facing the tongue. When the device is on, the electrodes send mild electrical impulses to the tongue. These impulses stimulate two cranial nerves that have direct connections into the brain through the brainstem. When combining the PoNS device with physical activity, "PoNS Therapy", provides a neuromodulatory effect and sets off a cascade of activity in the brain that result in consolidated neuroplastic changes and therapeutic functional outcomes, improving gait deficit in MS patients.

Additionally, the therapist can connect the controller to a computer and view PoNS usage data via a software developed specifically for the PoNS device. The usage data allows the therapist to obtain important information on the individual's adherence to their therapy regimen.

Helius is advancing PoNS post-approval research in MS through a recently launched Therapeutic Experience Program (TEP) designed to partner with neurologists and neurorehabilitation therapists at 10 to 12 U.S. centers of excellence, who express an interest in becoming "early adopters" of PoNS Therapy, building their knowledge of PoNS Therapy to advise the broader medical community. Last year, New York University-Langone Health became the first of the Centers of Excellence to announce a TEP partnership. Helius also launched a collaboration with Dr. Steve Kautz, PhD, Chair, Department of Health Sciences and Research, College of Health Professions, at the Medical University of South Carolina, in an Investigator Initiated Trial to evaluate the effects of PoNS therapy on the recovery of gait and postural stability in chronic stroke survivors.

About Helius Medical Technologies, Inc.

Helius Medical Technologies is a leading neurotech company in the medical device field focused on neurologic deficits using non-implantable platform technologies that amplify the brain's ability to compensate and promotes neuroplasticity, aiming to improve the lives of people dealing with neurologic diseases. The Company's first commercial product is the Portable Neuromodulation Stimulator (PoNS). For more information, visit www.heliusmedical.com.

About the PoNS Device and PoNS Therapy

The Portable Neuromodulation Stimulator (PoNS) is an innovative non-surgical medical device, inclusive of a controller and mouthpiece, which delivers electrical stimulation to the surface of the tongue to improve balance and gait. The PoNS device 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. Helius is advancing PoNS post-approval research in MS through a recently launched Therapeutic Experience Program (TEP) designed to partner with neurologists and neurorehabilitation therapists at 10-12 US centers of excellence, who express an interest in becoming "early adopters" of PoNS therapy.

PoNS is also authorized for sale in Canada for two indications: (i) PoNS is authorized 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 (ii) PoNS is authorized 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 ponstreatment.com

Cautionary Disclaimer Statement

This press release does not and shall not constitute an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of these securities in any state or other jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or other jurisdiction. Any offer, if at all, will be made only by means of a prospectus, including a prospectus supplement, forming a part of the effective registration 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,” “continue,” “expect,” “will,” “goal,” “aim to” and similar expressions. Such forward-looking statements include, among others, statements regarding the Company’s future growth and operational progress, including commercial activities for the PoNS device, our revenue from sales of our products, progress of commercialization of the PoNS device in the U.S., expectations for the Therapeutic Experience Program, expectations for the clinical trial in stroke, clinical development plans, product development activities, plans for U.S. Food and Drug Administration, or FDA, filings and their subsequent approvals and our future expenses and cash flow.

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 ability to find additional sources of funding, the impact of the COVID-19 pandemic, manufacturing, labor shortage and supply chain risks, the Company’s ability to train physical therapists in the supervision of the use of the PoNS treatment, the Company’s ability to secure contracts with rehabilitation clinics, the Company’s ability to obtain national Medicare coverage and to obtain a reimbursement code so that the PoNS device is covered by Medicare and Medicaid, the Company’s ability to build internal commercial infrastructure, secure state distribution licenses, build a commercial team and build relationships with Key Opinion Leaders, neurology experts and neurorehabilitation centers, market awareness of the PoNS device, future clinical trials and the clinical development process, the product development process and FDA regulatory submission review and approval process, other development activities, ongoing government regulation and other factors, 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, 2021 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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