Helius Medical, Inc Receives U.S. Marketing Authorization for the PoNS™ Device

March 29, 2021 12:00 PM EDT

First and only tongue-delivered neuromodulation therapy provides new treatment option for U.S. patients living with gait deficit due to symptoms from multiple sclerosis

NEWTOWN, Pa., March 29, 2021 (GLOBE NEWSWIRE) -- Helius Medical Technologies, Inc. (Nasdaq:HSDT) (TSX:HSM) ("Helius" or the "Company"), a neurotech company focused on neurological wellness, today announced that its wholly owned subsidiary, Helius Medical, Inc, has received marketing authorization from the U.S. Food and Drug Administration ("FDA") for the Portable Neuromodulation Stimulator (PoNS™) device.

The PoNS device is indicated for use 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 .

"With the receipt of FDA marketing authorization, Helius is proud to announce that our PoNS device is now the first, and only, medical device cleared in the U.S. for this indication," said Dane Andreeff, Interim President and Chief Executive Officer of Helius. "This milestone represents the most important achievement of our organization since its inception, and I would like to thank our dedicated employees, our shareholders, and the people who participated in the research for making it possible. MS is a chronic, degenerative and often debilitating disease that is estimated to affect approximately 1 million patients in the U.S. Many of these patients experience problems with their gait, or walking, as a result of MS which can severely restrict their mobility and daily activities. Our aim in obtaining marketing authorization is to provide MS patients suffering from gait deficit with a non-drug, non-implantable treatment that has the potential to significantly improve their ability to walk, and potentially enhance their safety and quality of life as a result."

Mr. Andreeff continued: "For this vastly underserved population of MS patients with a clear medical need and few viable treatments, our innovative PoNS device and treatment represents a new therapeutic option with demonstrated results. Specifically, its safety and efficacy has been demonstrated in two clinical studies and a retrospective analysis of real-world data which were submitted to, and assessed by, the FDA as part of our request for marketing authorization. The receipt of FDA marketing authorization represents an important validation of both the strength and quality of this supporting data, and ultimately the safety and efficacy of our PoNS device."

Mr. Andreeff concluded: "Looking ahead, Helius remains committed to providing our PoNS Treatment to patients as efficiently and effectively as possible. We are focused on preparing to commercialize our PoNS Treatment in the U.S., which we expect to begin in the first quarter of 2022. As part of our pre-commercial activities, we will continue to work with the Centers for Medicaid and Medicare with the goal of obtaining reimbursement coverage under the Medicare Coverage of Innovative Technology, or MCIT, pathway for FDA cleared and designated breakthrough devices. Longer-term, we also intend to pursue additional indications for our PoNS device to expand access to our platform technology in order to help as many patients as possible."

About Helius Medical Technologies, Inc.

Helius Medical Technologies is a neurotech company focused on neurological wellness. The Company's purpose is to develop, license and acquire unique and non-invasive platform technologies that amplify the brain's ability to heal itself. 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 Treatment™

The Portable Neuromodulation Stimulator (PoNS™) is an innovative non-surgical medical device, inclusive of a controller and mouthpiece, which delivers mild electrical stimulation to the surface of the tongue to provide treatment of gait deficit and 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. The PoNS device is authorized for sale in Canada as a class II, non-implantable, medical device intended as a short term treatment (14 weeks) of gait deficit due to mild and moderate symptoms from MS, and chronic balance deficit due to mild-to-moderate traumatic brain injury (mmTBI) and is to be used in conjunction with physical therapy. The PoNS device is an investigational medical device in the European Union ("EU") and Australia ("AUS"). It is currently under premarket review by the AUS Therapeutic Goods Administration.

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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," "continue," "looking ahead," "look forward," "will," "committed to," "goal," "expect," "remain," "aim," "potential" and similar expressions. Such forward-looking statements include, among others, statements regarding the Company's future growth and operational progress, the next phase of the Company's market development activities, clinical and regulatory development plans for the PoNS device, the ability of the PoNS device to significantly improve MS patients' ability to walk, and as a result may enhance their safety and quality of life, expected time to commercialization and the Company's ability to obtain reimbursement coverage under the MCIT pathway and to secure marketing authorization for additional indications.

These statements involve substantial known and unknown risks and uncertainties. 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, the impact of the COVID-19 pandemic, 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, market awareness of the PoNS device, future clinical trials, manufacturing and supply chain risks, potential changes to the MCIT program resulting from the 60-day deferral of the program implementation, the product development process and FDA regulatory submission review and approval process, other development activities and ongoing government regulation, and other risks detailed from time to time in the filings made by the Company with securities regulators, including the risks and uncertainties described in the "Risk Factors" sections of the Company's Annual Report on Form 10-K for the year ended December 31, 2020 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.

The Toronto Stock Exchange has not reviewed and does not accept responsibility for the adequacy or accuracy of the content of this news release.