Helius Medical Technologies Announces Authorization from Health Canada to Market the PoNS™ Device for the Treatment of Gait Deficit Due to Mild and Moderate Multiple Sclerosis (MS)

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NEWTOWN, Pa., March 24, 2020 (GLOBE NEWSWIRE) -- Helius Medical Technologies, Inc. (NASDAQ:HSDT) (TSX:HSM) ("Helius" or the "Company"), today announced that its Canadian Class II license amendment application for the treatment of gait deficit in patients with mild and moderate symptoms from multiple sclerosis ("MS") has received marketing authorization from Health Canada. Helius' Portable Neuromodulation Stimulator (PoNS™) device is now authorized to be marketed for the 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, in addition to the short-term treatment (14 weeks) of chronic balance deficit due to mild-to-moderate traumatic brain injury and is to be used in conjunction with physical therapy.

"We are very pleased to receive regulatory clearance to market our PoNS Treatment to the approximately 93,500 patients in Canada who suffer from MS," said Philippe Deschamps, Chief Executive Officer of Helius. "Given the chronic and progressive nature of this potentially debilitating neurodegenerative disease, we feel that there is a strong clinical need for novel therapies such as our PoNS Treatment. We are proud to provide MS patients with a treatment option that has the potential to improve or restore their gait function, or in other words their ability to walk."

The PoNS treatment is available through authorized Treatment Centers throughout Canada. For a list of the authorized treatment centers in Canada please visit www.ponstreatment.ca.

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 product in development 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 authorized class II, non-implantable medical device authorized for sale in Canada. PoNS is intended as a short term treatment (14 weeks) of chronic balance deficit due to mild-to-moderate traumatic brain injury and is to be used in conjunction with physical therapy and indicated 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. The PoNS is an investigational medical device in the United States, the European Union, and Australia, and is currently under review for clearance by the AUS Therapeutic Goods Administration. PoNS Treatment is currently not commercially available in the United States, the European Union or Australia.

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," "look forward," "will" and similar expressions. Such forward-looking statements include, among others, statements regarding the Company's future clinical and regulatory development plans for the PoNS, the success of the Company's planned study, business and commercialization initiatives and objectives, the potential receipt of regulatory clearance of the PoNS device in the United States, the European Union and Australia and the Company's revenue guidance.

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 the uncertainties associated with clinical trial enrollments and the results of clinical trials, uncertainties associated with the clinical development process and FDA regulatory submission and approval process, including the Company's capital requirements to achieve its business objectives and other risks detailed from time to time in the filings made by the Company with securities regulators, and including the risks and uncertainties about the Company's business described in the "Risk Factors" sections of the Company's Annual Report on Form 10-K for the year ended December 31, 2019, 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.

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