Helius Medical Technologies, Inc. Announces FDA Breakthrough Device Designation for the Treatment of Dynamic Gait and Balance Deficits Following a Stroke

August 17, 2021 12:00 PM EDT

NEWTOWN, Pa., Aug. 17, 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 it has received Breakthrough Designation from the U.S. Food and Drug Administration ("FDA") for its PoNS™ device with the proposed indication for use as a temporary treatment of dynamic gait and balance deficits due to symptoms from stroke, to be used as an adjunct to a supervised therapeutic exercise program in patients 22 years of age and over.

"We are very pleased to announce the receipt of Breakthrough Designation for our PoNS device to treat stroke-induced gait and balance deficits," said Helius CEO, Dane Andreeff. "Strokes are a large and growing cause of long-term disability in the United States. An estimated 7 million Americans are living with stroke-related complications, and more than 80% of stroke survivors are estimated to develop gait impairment.[1]"

Mr. Andreeff continued: "Obtaining Breakthrough Designation represents an important milestone in our path to providing this underserved patient population with a non-drug, non-implantable treatment option that has the potential to significantly improve their gait and balance, their ability to walk and perform daily tasks. We look forward to building on this achievement by utilizing the Breakthrough Devices Program to facilitate our pursuit of U.S. regulatory clearance for treatment of stroke-induced symptoms in close collaboration with the FDA."

The Breakthrough Devices Program is a voluntary program for certain medical devices and device-led combination products that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions.

The goal of the Breakthrough Devices Program is to provide patients and health care providers with timely access to these medical devices by speeding up their development, assessment, and review, while preserving the statutory standards for premarket approval, 510(k) clearance, and De Novo marketing authorization, consistent with the FDA's mission to protect and promote public health.

The Breakthrough Devices Program offers manufacturers such as Helius an opportunity to interact with the FDA's experts through several different program options to efficiently address topics as they arise during the premarket review phase, which can help manufacturers receive feedback from the FDA and identify areas of agreement in a timely way. Manufacturers can also expect prioritized review of their submission.

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 including 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 device, inclusive of a controller and mouthpiece, which delivers electrical stimulation to the surface of the tongue to provide treatment of gait deficit. 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. It 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™ is an investigational medical device in Australia ("AUS") and 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," "will," "goal," "aim to," "look forward" and similar expressions. Such forward-looking statements include, among others, statements regarding the Company's regulatory plans and pursuit of U.S. regulatory clearance for treatment of stroke-related symptoms.

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 future clinical trials and the clinical development process, the product development process and FDA regulatory submission review and approval process, other development activities, 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, 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, manufacturing and supply chain risks, potential changes to the MCIT program resulting from the 60-day deferral of the program implementation, 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, 2020, its Quarterly Report on Form 10-Q for the quarter ended June 30, 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.

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

[1] Carmen M. Cirstea. Gait Rehabilitation After Stroke, Should we re-evaluate our practice? Stroke 2020;51(10):2892-94.