



Helius Medical Technologies Announces Authorization from Health Canada to Market Portable Neuromodulation Stimulator (PoNS®) Device for the Treatment of Gait Deficit Due to Mild and Moderate Symptoms from Stroke

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-- PoNS already approved in Canada for treatment of chronic balance deficit due to mild-to-moderate traumatic brain injury (TBI) and gait deficit due to mild and moderate symptoms from Multiple Sclerosis (MS) --

NEWTOWN, Pa., March 09, 2023 (GLOBE NEWSWIRE) -- Helius Medical Technologies, Inc. (Nasdaq:HSDT) ("Helius"), a neurotech company focused on delivering a novel therapeutic neuromodulation approach for balance and gait deficits announced today that Health Canada has expanded the indication for PoNS to include use as a short term treatment (14 weeks) of gait deficit due to mild and moderate symptoms from stroke, to be used in conjunction with physical therapy. PoNS is already authorized in Canada for use as a short term treatment of chronic balance deficit due to mild to moderate TBI and gait deficit due to mild and moderate symptoms from MS.

"An estimated 878,000 Canadians are currently living with stroke, with more than 89,000 new strokes occurring each year. Walking impairment is a major source of post-stroke disability and we're thrilled that patients suffering gait deficit due to stroke can now have access to this important therapy," said Helius President and Chief Executive Officer Dane Andreeff. "PoNS has been commercially available in Canada since 2019 for MS and TBI, and it's gratifying to know Health Canada has found that PoNS Therapy can provide significant and clinically meaningful gait improvement also in stroke patients, suggesting that PoNS Therapy provides an effective therapeutic benefit regardless of the underlying condition."

PoNS Therapy applied in a real-world setting provides a significant and clinically meaningful improvement in gait or balance to patients with MS, TBI, and chronic stroke. "Patients suffering a gait deficit due to mild and moderate stroke symptoms face a clear medical need that is not fully met due to limitations of current treatment methods, including pharmacologic agents and rehabilitation activities alone," said Dr. Antonella Favit-Van Pelt, Helius' Chief Medical Officer.

A real-world evidence (RWE) database analysis showed that mild and moderate stroke patients using PoNS Therapy for their gait deficit experienced a significant amelioration of their gait averaging a 6.74-point improvement in the functional gait assessment (FGA) score over a 14-wk treatment period (95% CI: 4.85 to 8.63). Overall, 69.2% of patients experienced at least a 5-point FGA improvement, which is larger than the 4.2-point minimal detectable change usually seen in stroke patients.

"Improvement of gait ability represents an important milestone in the rehabilitation of stroke patients and translates into meaningful therapeutic outcomes, such as decreasing the risk of falling," said Dr. Favit-Van Pelt.

In the RWE study, before starting PoNS Therapy, the majority of patients were considered at risk of falling (as determined by an FGA<23 score at baseline). Routine rehabilitative physical therapy does not usually provide a meaningful shift in the risk of falling for stroke patients (~1-3%). After treatment with PoNS therapy, 28% of patients were no longer at fall risk at the end of the 14-week treatment period.

In Canada, patients with MS and mild to moderate TBI have experienced the benefit of being treated with PoNS Therapy.

"When we look at PoNS Therapy efficacy data on improving gait or balance deficits in the three indications allowed in Canada," continued Dr. Favit-Van Pelt, "it appears that PoNS employs a shared mechanism of action that is likely to modulate mechanisms of gait and balance control across these three medical conditions."

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 promote neuroplasticity, improving the lives of people dealing with neurologic diseases. The Company's first commercial product is the Portable Neuromodulation Stimulator (PoNS®) device. For more information about the PoNS® or Helius Medical Technologies, 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).

PoNS is also authorized for sale in Canada for two indications: (i) for use as a short-term treatment (14 weeks) of chronic balance deficit due to mild-to-moderate traumatic brain injury ("mTBI") and is to be used in conjunction with physical therapy; and (ii) 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.

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 market for stroke in Canada, and PoNS Therapy’s ability to modulate mechanisms of gait and balance control in stroke patients.

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, 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, manufacturing and supply chain risks, the product development process and 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, 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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