



Helius Medical Technologies Announces DMEPOS Accreditation for PoNS

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-- Critical initial step toward US reimbursement --

NEWTOWN, Pa., June 20, 2023 (GLOBE NEWSWIRE) -- Helius Medical Technologies, Inc. (Nasdaq:HSDT) ("Helius" or the "Company"), a neurotech company focused on delivering a novel therapeutic neuromodulation approach for balance and gait deficits, today announced that its Portable Neuromodulation Stimulator (PoNS®) device has been awarded Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) accreditation by The Compliance Team (TCT), which is authorized by the Centers for Medicare & Medicaid Services (CMS) to accredit all DMEPOS products and services. The accreditation certifies that Helius has established processes that conform to TCT's Exemplary Provider® DMEPOS Quality Standards.

"We are thrilled that PoNS has been awarded DMEPOS accreditation. Not only does the certification underscore our commitment to quality and patient care, but it is also a crucial part of our U.S. reimbursement strategy. Organizations that wish to bill Medicare must have accreditation from an approved agency and it's become a standard with other funding sources as well," said Helius President and Chief Executive Officer Dane Andreeff.

"DMEPOS accreditation has particular relevance under the proposed Transitional Coverage for Emerging Technologies (TCET) legislation. If passed as currently proposed, companies with a breakthrough designation could be covered by Medicare for up to four years, allowing time to gather the necessary clinical data to prove the efficacy of their products. PoNS has breakthrough designations in both multiple sclerosis and stroke in the U.S. and this certification establishes that Helius is an Exemplary Provider® and our PoNS device has already met and exceeded CMS quality standards," concluded Andreeff.

TCT is a nationally recognized healthcare accreditation organization that provides comprehensive accreditation and certification services to healthcare providers in all fifty states. TCT's proprietary accreditation status is known as Exemplary Provider Accreditation® and its industry-leading accreditation model features healthcare's first comprehensive set of plain language, operations-driven quality standards with expert-led implementation guidance.

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.

PoNS is also authorized for sale in Canada for three 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; and (iii) for 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 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 Company's ability to obtain reimbursement for the PoNS device, and the potential for TCET to be approved.

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, disruptions in the banking system and financial markets, lingering impacts of the COVID-19 pandemic, the effect of macroeconomic conditions and the Company's ability to access capital markets, 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, availability of funds, manufacturing, labor shortage and supply chain risks, our ability to maintain and enforce our intellectual property rights, clinical trials and the clinical development process, the product development process, the regulatory submission review and approval process, our operating costs and use of cash, and our ability to achieve significant revenues, 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, 2022, 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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