Helius Medical Technologies, Inc. Secures HCPCS Codes for Portable Neuromodulation Stimulator (PoNS®) Mouthpiece and Controller

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-- Significant step toward reimbursement for the only medical device approved in the U.S. for treatment of gait deficit due to multiple sclerosis ("MS") --

-- Proceeds from recent stock issuances through the Company's At-The-Market ("ATM") program extends cash runway into the third quarter 2024 --

NEWTOWN, Pa., March 04, 2024 (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 the Centers for Medicare & Medicaid Services ("CMS") has assigned Healthcare Common Procedure Coding System ("HCPCS") Level II codes A4593, "Neuromodulation stimulator system, adjunct to rehabilitation therapy regime" to describe the PoNS controller and A4594, "Neuromodulation stimulator system, adjunct to rehabilitation therapy regime, mouthpiece each" to describe the PoNS mouthpiece. The new HCPCS codes will be effective April 1, 2024.

"PoNS Therapy ® is life-changing for people who suffer gait impairment due to MS and we're pleased that CMS understood the benefits of this innovative treatment by establishing HCPCS codes for both the PoNS mouthpiece and controller. This marks a critical reimbursement and access milestone and provides Helius the ability to begin negotiating reimbursement with third-party payers using these unique HCPCS codes. We believe there is a reasonable likelihood that at the public meetings this summer CMS will determine a reimbursement amount for each of the PoNS controller and mouthpiece to take effect on October 1, 2024," stated Helius' President and Chief Executive Officer, Dane Andreeff.

"As we pursue widespread reimbursement for PoNS Therapy, we have continued to manage our cash burn. With the recently announced $1.5 million of net proceeds from the sale of shares of our common stock under our ATM program at an average share price of $9.17 per share, our cash runway has been extended into the third quarter of this year. Once we establish reimbursement for PoNS, we believe we will be able to expand reimbursement across third-party payers and have a pathway to positive cash flow as we continue to pursue authorization for stroke in the U.S.," concluded Andreeff.

PoNS is indicated for use in the United States as a short-term treatment of gait deficit due to mild-to-moderate symptoms from MS and is to be used as an adjunct to a supervised therapeutic exercise program. The Company is also seeking marketing authorization under PoNS's breakthrough designation for stroke in the United States, where over five million stroke survivors are affected by walking and balance disability. In Canada, PoNS is authorized to treat balance impairment due to MS, stroke and mild-to-moderate traumatic brain injury.

About Helius Medical Technologies, Inc.

Helius Medical Technologies is a leading neurotech company in the medical device field focused on neurologic deficits using orally applied technology platform that amplifies the brain's ability to engage physiologic compensatory mechanisms and promote neuroplasticity, improving the lives of people dealing with neurologic diseases. The Company's first commercial product is the Portable Neuromodulation Stimulator. For more information visit www.heliusmedical.com.

About the PoNS Device and PoNS Therapy

The Portable Neuromodulation Stimulator (PoNS) is an innovative, non-implantable, orally applied therapy that delivers neurostimulation through a mouthpiece connected to a controller and it's used, primarily at home, with physical rehabilitation exercise, to improve balance and gait. The PoNS device, which delivers mild electrical impulses to the tongue, 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 has shown effectiveness in treating gait or balance and a significant reduction in the risk of falling in stroke patients in Canada, where it received authorization for sale in three indications: (i) for use as a short-term treatment (14 weeks) of gait deficit due to mild and moderate symptoms from stroke and is to be used in conjunction with physical therapy; (ii) for use 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 (iii) 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 Company's plans to provide CMS additional information to support reimbursement economics ahead of the public meetings expected early this summer and the expectation that CMS will then determine a reimbursement amount for each of the PoNS controller and mouthpiece to be effective October 1, 2024, the success of the Company's developmental, regulatory and commercialization efforts, the impact of HCPCS codes on the Company's commercialization efforts, the sufficiency of the Company's future cash position, future decisions and approvals from applicable regulatory entities in the U.S. and Canada, and the uses and effectiveness of PoNS and PoNS Therapy.

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, the effect of macroeconomic conditions and the Company's ability to access capital markets, the Company's ability to continue to train physical therapists in the supervision of the use of the PoNS Treatment, the Company's ability to secure additional 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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