Helius Medical Technologies, Inc. Provides Updates on Efforts to Achieve Fair Market Access for its Portable Neuromodulation Stimulator (PoNS®) Device

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Management to host business update call today at 9:00am ET

NEWTOWN, Pa., Nov. 18, 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 provided updates on its efforts to achieve fair market access for its Portable Neuromodulation Stimulator (PoNS) device and announced plans to host a business update call today at 9:00am ET.

"We disagree with the proposed pricing for the PoNS Mouthpiece and are disappointed CMS has once again mapped the Controller pricing to a code for fundamentally different technology," said Dane Andreeff, Helius' President and Chief Executive Officer. "In the face of this challenge our team's response has been impressive as we continue to pursue fair market access for Medicare's Multiple Sclerosis (MS) patients with balance and gait deficit. At the November 8th HCPCS Level 2 Public meeting we again refuted CMS' methodology and presented compelling evidence in support of fair pricing for the PoNS device. Our diligent response and extensive evidence, outlined here today, has been successfully understood by the VA and a private payor. We are hopeful CMS can reach the same conclusions, and we will continue to support their reassessment."

Recent Reimbursement Updates

- CMS issued pricing determinations for both the PoNS Controller and Mouthpiece that the Company believes reflect incomplete information and erroneous assessments of the technology, which currently preclude market access to PoNS device prescriptions for Medicare's (MS) patients with balance and gait deficits
    - Mouthpiece pricing to take effect January 1, 2025 does not reflect recent market pricing in the gap-filling analysis. Helius has requested a meeting with CMS to occur prior to the effective date in an attempt to correct the pricing
    - Proposed Controller pricing incorrectly maps to a TENS device code as PoNS does not involve peripheral stimulation, and acts through neural plasticity and therefore is not grounded on the gate control theory of pain
    - Timing for the pricing determination and reimbursement implementation of the Controller on April 1st, three months after the Mouthpiece, an accessory required for use of the device. Helius plans to request the Controller pricing to be set in tandem with the Mouthpiece on January 1st
- Enduring a third review cycle for PoNS Controller pricing and the uncertain timeline has delayed access to PoNS Therapy® for qualified MS patients and delayed Helius' commercial launch
- Process has impacted the Company's market value and impeded its ability to access public markets to finance its operations thus leading to the pursuit of strategic alternatives

Business Update Call

Helius management plans to host a conference call to discuss recent business updates and its efforts to achieve fair market access for the PoNS device at 9:00am ET today, November 18, 2024. Interested parties may access the live and recorded webcast here or on the "Events" page under "News & Events" on the Helius investor relations website.

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 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-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 (“mmTBI”) 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 future CMS determinations, the Company’s future communications with CMS and the results of such communications, the potential for the Company to meet with CMS prior to the January 1 effectiveness date of the PoNS Mouthpiece pricing, the Company’s strategic alternative exploration process, and the development, commercialization and success of the Company’s PoNS and PoNS Treatment.

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, availability of funds, the Company’s ability to find additional sources of funding, manufacturing, labor shortage and supply chain risks, including risks related to manufacturing delays, the Company’s ability to obtain national Medicare insurance coverage and to obtain a reimbursement code, the Company’s ability to continue to build internal commercial infrastructure, secure state distribution licenses, market awareness of the PoNS device, future clinical trials and the clinical development process, the product development process and the 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, 2023, its Form 10-Q for the quarter ended September 30, 2024, 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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