Helius Medical Technologies, Inc. Announces Reimbursement Payment Determination Updates from CMS for its Portable Neuromodulation Stimulator (PoNS®) Controller and Mouthpiece

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-- Reimbursement Determination for the PoNS Mouthpiece (HCPCS code A4594) *set at $2,963.30 on Lump Sum Payment to be challenged by Helius --*

-- National Reimbursement Payment Determination from CMS for its PoNS Controller Deferred to the Next Cycle --

NEWTOWN, Pa., Oct. 14, 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) posted final Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies fee schedule payment rates for the PoNS Mouthpiece (HCPCS code A4594) at $2,963.30 to be implemented January 1, 2025 and deferred final national determination of the payment rate for the PoNS Controller (HCPCS Code A4593) to the next payment cycle.

"We strongly disagree with CMS' methods, rationale, pricing and deferral for determining the payment rates for both the PoNS Mouthpiece and the PoNS Controller. Helius has spent millions of dollars in R&D to develop technology that the FDA designated a Breakthrough Device and cleared nearly four years ago. Further, the clinical and recent claims data supports fair pricing levels that would provide value for all stakeholders. This evidence will again soon be presented to CMS in efforts to establish appropriate pricing that would facilitate market access for the millions of MS patients who continue to suffer from gait deficit without the potential benefit of PoNS. We are hopeful that we will be able to finalize fair reimbursement for the PoNS Mouthpiece and Controller with CMS in the near future," commented Helius' President and Chief Executive Officer, Dane Andreeff. "We believe that increased patient access to our PoNS technology will support revenue growth and as we scale, we intend to establish a pathway to positive cash flow generation as we continue pursuing authorization for stroke in the U.S."

CMS has corrected the reimbursement for the PoNS Mouthpiece as an essential accessory for which payment is made on a lump sum basis, as opposed to the preliminary determination of making monthly rental payments. The methodology used for setting the price remained the gap filling approach.

"We are pleased with the progress in correctly classifying the mouthpiece as an accessory and with using the gap filling approach, but we disagree with the use of prior temporary introductory pricing, discontinued early this year, in determination of the starting point. The temporary introductory pricing was offered in an attempt to make PoNS accessible to patients on a cash pay basis while we pursued reimbursement. However, it does not reflect current market pricing as it is substantially below the contracted prices with the VA, DoD and GSA and paid by a major insurance carrier," continued Andreeff. "We will be approaching CMS prior to the CMS pricing taking effect on January 1, 2025 to request that they revisit the starting point for the gap filling process to more appropriately use the market pricing established through negotiation with the VA and an insurance carrier."

As also published on October 7, 2024, CMS elected to defer final determination of reimbursement for the PoNS Controller until the next payment cycle due to "more time needed to evaluate this complex issue." Subsequently, on October 8, 2024, CMS published the preliminary rate of reimbursement for the PoNS Controller at the capped total payment of $519.80, based on its view that the product is comparable to devices reported with HCPCS code E0730 (transcutaneous electrical nerve stimulation (TENS) device, four or more leads, for multiple nerve stimulation). This preliminary decision will be discussed at the HCPCS public meeting on November 8, 2024.

CMS previously made a preliminary determination that the PoNS Controller rate of reimbursement should be determined by reference to a different code, HCPCS code E0745, (Neuromuscular stimulator, electronic shock unit) in May 2024. Helius successfully rebutted this determination in the May 2024 public meeting and subsequent communications with CMS, resulting in CMS agreeing with the Company by not finalizing a payment rate based on HCPCS code E0745. Andreeff added "Now, under the new preliminary decision, CMS has pivoted to improperly find the PoNS Controller to be comparable to a TENS device."

"We will again present the differences between the PoNS Controller from other devices, this time the TENS devices, in the upcoming public meeting and communications with CMS. We remain hopeful that CMS will properly set pricing for the PoNS Controller using the gap filling methodology that works off the government contract and insurance pricing," concluded Andreeff.

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 development, commercialization and success of the Company’s PoNS and PoNS Treatment 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, 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, 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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