Helius Medical Technologies, Inc. Announces Preliminary CMS Payment Determination of Reimbursement for Portable Neuromodulation Stimulator (PoNS®)

May 6, 2024 1:00 PM EDT

-- The Centers for Medicare & Medicaid Services (CMS) released its preliminary Medicare payment determinations for the PoNS Controller and Mouthpiece --

-- Public Meeting Scheduled for May 29, 2024 --

NEWTOWN, Pa., May 06, 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 proposed Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) fee schedule payment rates for the PoNS Controller and Mouthpiece to be discussed at the bi-annual Healthcare Common Procedure Coding System (HCPCS) Public Meeting, scheduled for May 29, 2024.

For the PoNS Mouthpiece (HCPCS code A4594), CMS based pricing on the cash pay price of $4,500, resulting in a total capped payment of $3,075.53. For the PoNS Controller (HCPCS Code A4593), CMS preliminarily set pricing by mapping reimbursement to existing code E0745, (Neuromuscular stimulator, electronic shock unit), resulting in a total capped fee of $1,206.53.

"CMS's preliminary determination of reimbursement for both the PoNS Controller and Mouthpiece is a significant win for Helius," stated Helius' President and Chief Executive Officer, Dane Andreeff. "We intend to present at the HCPCS Public Meeting on May 29, 2024 and expand on how PoNS differs, mechanistically and therapeutically, from any neuromuscular peripheral stimulation therapy. We will present arguments to support a higher reimbursement rate for the PoNS Controller using the gap filling methodology, along with advocating for reimbursing the PoNS Mouthpiece through the lump sum payment structure at a higher rate than the one established in the preliminary determination."

"Once the decision is finalized, the payment rates will be effective October 1, 2024. We believe Medicare price determination will allow us to expand reimbursement across third-party payers and give us a pathway to positive cash flow as we continue pursuing authorization for stroke in the U.S."

The preliminary payment determinations published by CMS for discussion at the Public Meeting are only proposed fee schedule rates. The Company cannot provide any assurance that these rates will be finalized and adopted in their current amounts, or at all.

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 the fees published by CMS for PoNS and the potential for reimbursement in October 2024.

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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