Helius Medical Technologies, Inc. Receives UPC Numbers for its PoNS® System and Mouthpiece

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-- UPC numbers assigned by Wolters Kluwer Health, provider of trusted clinical technology --
-- PoNS system and mouthpiece will be included in pharmacy database utilized by 17 out 20 of the top-grossing pharmacy benefit managers (PBMs)
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-- PoNS expected to be one of few products with both pharmacy and device codes, providing dual paths for potential reimbursement --

NEWTOWN, Pa., Sept. 28, 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 ®”) system and mouthpiece have been assigned universal product code (“UPC”) numbers by Wolters Kluwer Health – Medi-Span® (“Medi-Span”). Medi-Span is the leading automated clinical screening solution– providing a data backbone and vital support to payers, pharmacy benefit managers (“PBMs”), wholesalers, and manufacturers.

The PoNS system has been assigned the Global Trade Item Number (“GTIN”) of 00864288000462, with a direct price of $25,700. The PoNS mouthpiece has been assigned the GTIN of 00864288000431, with a direct price of $7,900. These UPC numbers are now included in Wolters Kluwer Health’s pharmacy database, which a large number of health care companies are subscribed to including 17 out of 20 of the top-grossing PBMs. Consequently, this will allow Helius to pursue reimbursement through both the pharmacy and the Durable Medical Equipment (“DME”)/HCPCS pathways.

“Receiving UPC numbers for the PoNS system and mouthpiece is a gamechanger for Helius,” said Dane Andreeff, Helius’ President and Chief Executive Officer. "We will now be able to reference these UPC numbers as we negotiate reimbursement with third party payers, and prescriptions can be written with these UPC numbers. We believe that having these UPC numbers in place will facilitate and potentially expedite negotiations with third party payers on a faster timeline than the DME/HCPCS pathway. Additionally, once HCPCS codes are assigned by CMS and a payment amount has been determined for Medicare, PoNS will be one of the few products with both pharmacy and device codes, providing dual paths for potential reimbursement.”

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 (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-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.

About Wolters Kluwer Health – Medi-Span

Wolters Kluwer Health provides trusted clinical technology and evidence-based solutions that engage clinicians, patients, researchers, students, and the next generation of healthcare providers. Medi-Span is the leading embedded drug data and automated clinical screening solution, using technology to support clinicians with making better informed medication-related decisions. It is designed to alert clinicians and pharmacists making prescribing and dispensing decisions to information about avoidable medication errors, inappropriate dosing, and adverse events. It also provides the data backbone and vital support to healthcare businesses, like payers, PBMs, wholesalers, and manufacturers in to help expand services, streamline processes, and analyze data.

For more information visit www.wolterskluwer.com/en/solutions/medi-span.

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, the potential impact of UPC code assignment on the success of the commercialization of PoNS system, the availability of Medicare

reimbursement for the PoNS system, Helius' ability to negotiate reimbursement with third party payers, and the strategic plans of the Company and the effectiveness of those plans.

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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