



Helius Medical Technologies, Inc. Announces Launch of Patient Therapy Access Program for PoNS®

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New program seeks to expand access to patients suffering from multiple sclerosis (MS)

NEWTOWN, Pa., June 01, 2022 (GLOBE NEWSWIRE) -- Helius Medical Technologies, Inc. (Nasdaq:HSDT) ("Helius" or the "Company"), a neurotech company focused on neurological wellness, today announced the launch of its Patient Therapy Access Program ("PTAP"), which will provide qualifying patients access to on-label Portable Neuromodulation Stimulator ("PoNS") Therapy at a significantly reduced price. PoNS is indicated in the U.S. for use as a short-term treatment of gait deficit in adults with mild-to-moderate symptoms from multiple sclerosis ("MS") and is available by prescription only.

"In April, we announced that the first patients in the United States had purchased the PoNS device on a cash pay basis and begun treatment. We are also offering an opportunity for MS patients to be treated with PoNS Therapy™ through our previously announced Therapeutic Experience Program ("TEP"), gathering important clinical evidence in a real-world environment while we pursue reimbursement from third-party payers and CMS. Our goal is to bring treatment to as many qualifying patients as possible and we are proud to introduce our Patient Therapy Access Program for potential first-time users," stated Dane Andreeff, President and Chief Executive Officer of Helius.

"With the proper prescription and a letter of medical necessity, people struggling with MS in the U.S. will be able to access PoNS Therapy at a greatly reduced price. We believe this program will accelerate the adoption of PoNS Therapy and help to establish PoNS as the standard of care for MS patients with gait deficit. PTAP participants will also be invited to join Helius's upcoming registry program, which is designed to collect important health economic information to establish the value of PoNS on key therapeutic outcomes and will complement the data gleaned through TEP," concluded Mr. Andreeff.

The PTAP is currently available and expected to run through December 31, 2022.

About Helius Medical Technologies, Inc.

Helius Medical Technologies is a leading neurotech company in the medical device field focused on neurologic deficits using non-implantable platform technologies that amplify the brain's ability to compensate and promotes neuroplasticity, aiming to improve the lives of people dealing with neurologic diseases. The Company's first commercial product is the Portable Neuromodulation Stimulator (PoNS). For more information, visit www.heliusmedical.com.

About the PoNS Device and PoNS Therapy

The Portable Neuromodulation Stimulator (PoNS) is an innovative non-surgical medical device, inclusive of a controller and mouthpiece, which delivers electrical stimulation to the surface of the tongue to improve balance and gait. The PoNS device 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. Helius is advancing PoNS post-approval research in MS through a recently launched Therapeutic Experience Program (TEP) designed to partner with neurologists and neurorehabilitation therapists at 10-12 US centers of excellence, who express an interest in becoming "early adopters" of PoNS therapy.

PoNS is also authorized for sale in Canada for two indications: (i) for use as a short-term treatment (14 weeks) of chronic balance deficit due to mild-to-moderate traumatic brain injury ("mTBI") and is to be used in conjunction with physical therapy; and (ii) 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.

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 expected scope and duration of PTAP, and patients' ability to qualify for PTAP.

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, and ability to raise capital, the impact of the COVID-19 pandemic, 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, future clinical trials and the clinical development process, manufacturing and supply chain risks, the product development process and 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, 2021, 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.

Investor Relations Contact

Lisa M. Wilson, In-Site Communications, Inc.

T: 212-452-2793

E: lwilson@insitecony.com