Helius Medical Technologies, Inc. Announces Fourth Partnership to Implement Clinical Experience Programs with PoNS™ Treatment in the United States

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NEWTOWN, Pa., Jan. 03, 2019 (GLOBE NEWSWIRE) -- Helius Medical Technologies, Inc. (NASDAQ:HSDT) (TSX:HSM) ("Helius" or the "Company"), a neurotech company focused on neurological wellness, today announced that its wholly owned subsidiary, NeuroHabilitation Corporation, has partnered with Kessler Institute for Rehabilitation and Kessler Foundation, New Jersey-based leaders in rehabilitation care and research, to implement its fourth Clinical Experience Program (CEP) for its Portable Neuromodulation Stimulator (PoNS™). PoNS is a licensed class II medical device in Canada and an investigational medical device in the U.S. and in the EU. PoNS is currently under review for US market clearance by the Food & Drug Administration (FDA) and EU clearance by the EU Notified Body.

Clinical Experience Programs are sponsored by Helius and implemented in partnership with leading, investigational, neurorehabilitation centers, including academic and research institutions, hospital systems and high-volume independent neurorehabilitation centers. CEPs enable the Company to continue to investigate in the clinical setting PoNS Treatment in patients with chronic balance deficit due to mild-to moderate-traumatic brain injury (mTBI).

The co-principal investigators of the clinical trial are Neil N. Jasey Jr., MD, director of Brain Injury Rehabilitation, and Irene Ward, PT, DPT, NCS, Brain Injury Clinical Research Coordinator, at Kessler Institute. Karen Nolan, PhD, senior research scientist at Kessler Foundation, is the co-investigator.

"We are proud to be part of this important and innovative program that brings new hope for persons with brain injury" said Dr. Jasey. "By combining cranial nerve stimulation with physical and cognitive therapies, this first of its kind tongue-delivered neuromodulation treatment offers a unique approach to restoring lost neurological function and improving quality of life."

"We are excited to announce our partnership with Kessler to implement the fourth Clinical Experience Program for our PoNS Treatment," said Philippe Deschamps, Helius' Chief Executive Officer. "Helius is focused on implementing our Clinical Experience Programs, as we await FDA 510(k) clearance for our PoNS device, in order to gain additional real-world experience in the use of PoNS Treatment in a clinical setting and generate clinical evidence, while also learning from key opinion leaders and leading investigational neurorehabilitation centers."

Mr. Deschamps continued: "We expect to begin patient recruitment and enrollment at the Kessler CEP during the first quarter of 2019, following site activation and training. We are pleased to have met our goal of having all of our CEP sites established in the United States by the end of 2018."

About Helius Medical Technologies, Inc.

Helius Medical Technologies is a neurotech company focused on neurological wellness. The Company's purpose is to develop, license and acquire unique and non-invasive platform technologies that amplify the brain's ability to heal itself. The Company's first product in development is the Portable Neuromodulation Stimulator (PoNS). For more information, visit www.heliusmedical.com.

About Kessler Foundation

Kessler Foundation, a major nonprofit organization in the field of disability, is a global leader in rehabilitation research that improves cognition, mobility and long-term outcomes, including employment, for people with neurological disabilities caused by diseases and injuries of the brain and spinal cord. Kessler Foundation leads the nation in funding innovative programs that expand opportunities for employment for people with disabilities. Learn more by visiting http://www.KesslerFoundation.org.

About Kessler Institute for Rehabilitation, Inc.

Kessler Institute for Rehabilitation (www.kessler-rehab.com) is one of only seven federally-designated Model Systems for the treatment and research of both traumatic brain and spinal cord injuries, a distinction shared with Kessler Foundation, and also leads the field in the care of individuals with stroke, neurologic diseases, limb loss, orthopedic trauma, cancer and cardiac conditions. Top-ranked by U.S. News & World Report for 26 consecutive years, Kessler has four hospital campuses in West Orange, Saddle Brook, Chester and Marlton, N.J., and more than 95 outpatient Kessler Rehabilitation Center locations throughout the state. For more information, visit www.kessler-rehab.com.

About the PoNS Device and PoNS Treatment

The Portable Neuromodulation Stimulator (PoNS) is an investigational, non-invasive, medical device in the US and the EU, it is currently under review by US Food & Drug Administration for US clearance and by the EU Notified Body for EU clearance, for the treatment of chronic balance deficit due to mild-to-moderate traumatic brain injury (mTBI) when combined with targeted physical therapy. PoNS is a licensed class II medical device in Canada. PoNS is currently not commercially available in the US or the EU.

PoNS Treatment is the first and only tongue-delivered neuromodulation that combines stimulation of cranial nerves with physical and cognitive therapy to restore lost neurological function. The Company's trials investigating the PoNS in mild to moderate traumatic brain injury are more fully discussed in the Company's disclosure materials, including its Annual Report on Form 10-K and other filings with the United States Securities and Exchange Commission.

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. Such forward-looking statements include, among others, statements regarding the potential regulatory approval and commercial launch of the PoNS Treatment.

Forward-looking statements are often identified by terms such as “believe”, “will”, “may”, “should”, “anticipate”, “expects”, “estimate”, “intend” and similar expressions.

There can be no assurance that such statements will prove to be accurate and actual results and future events could differ materially from those anticipated in such statements. Important factors that could cause actual results to differ materially from the Company’s expectations include the uncertainties associated with the FDA regulatory submission and approval process, including the possibility that the FDA may not find the Company’s regulatory submission sufficient to support clearance, the process of negotiating with rehabilitation centers to implement CEPs, the uncertainty of the health outcomes data to be generated by the CEPs, uncertainties associated with commercial contracting process and commercial launch, the Company’s capital requirements to achieve its business objectives and other risks detailed from time to time in the filings made by the Company with securities regulators.

The reader is cautioned that assumptions used in the preparation of any forward-looking statements may prove to be incorrect. Events or circumstances may cause actual results to differ materially from those predicted, as a result of numerous known and unknown risks, uncertainties, and other factors, many of which are beyond the control of the Company. The reader is cautioned not to place undue reliance on any forward-looking statement. Such information, although considered reasonable by management at the time of preparation, may prove to be incorrect and actual results may differ materially from those anticipated. Forward-looking statements contained in this news release are expressly qualified by this cautionary statement. Risks and uncertainties about the Company’s business are more fully discussed in the Company’s disclosure materials, including its Annual Report on Form 10-K for the year ended December 31, 2017, its Quarterly Report on Form 10-Q for the quarter ended September 30, 2018 and its other filings with the United States Securities and Exchange Commission and the Canadian securities regulators and which can be obtained from either at www.sec.gov or www.sedar.com.

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.

The Toronto Stock Exchange has not reviewed and does not accept responsibility for the adequacy or accuracy of the content of this news release.

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