Helius Medical Technologies, Inc. Announces Third Collaboration 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, entered into an agreement in December 2018 to collaborate with Oregon Health & Science University (OHSU) in Portland, Oregon for launch of its third 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 U.S. market clearance by the Food & Drug Administration (FDA) and EU market 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 principal investigator of the clinical trial is Kenton Gregory, M.D., director of the Center for Regenerative Medicine, at Oregon Health & Science University.

"Helius is excited to announce this important collaboration with Oregon Health & Science University and we're pleased by the progress that we made with respect to the development of our Clinical Experience Programs – an important activity that we are pursuing in advance of U.S. regulatory clearance," said Philippe Deschamps, Helius' Chief Executive Officer. "We look forward to learning from this leading neurorehabilitation center and its team as we work together to gain more real-world experience in the clinical setting and generate evidence demonstrating the health outcomes that can be achieved with our innovative PoNS Treatment."

Mr. Deschamps continued: "We expect to begin patient recruitment and enrollment at the OHSU Center for Regenerative Medicine in the first quarter of 2019, following site activation and training."

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 the PoNS Device and PoNS Treatment

The Portable Neuromodulation Stimulator (PoNS) is an investigational, non-invasive, medical device in the U.S. and in the EU. It is currently under review by U.S. Food & Drug Administration for U.S. clearance and by the 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 U.S. 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.

Investor Relations Contact:

Westwicke Partners on behalf of Helius Medical Technologies, Inc.
Mike Piccinino, CFA
443-213-0500
info@heliusmedical.com