Helius Medical Technologies, Inc. Announces Publication of Peer-Reviewed Study: Translingual Neural Stimulation with the Portable Neuromodulation Stimulator (PoNS™) Induces Structural Changes Leading to Functional Recovery in Patients with Mild-to-Moderate Traumatic Brain Injury

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NEWTOWN, Pa., Sept. 08, 2020 (GLOBE NEWSWIRE) -- Helius Medical Technologies, Inc. (NASDAQ:HSDT) (TSX:HSM) ("Helius" or the "Company"), a neurotech company focused on neurological wellness, today announced the publication of an important, peer-reviewed study titled *Translingual Neural Stimulation with the Portable Neuromodulation Stimulator (PoNS™) Induces Structural Changes Leading to Functional Recovery in Patients with Mild-to-Moderate Traumatic Brain Injury*. The study was published in the peer reviewed journal EMJ Radiology. 2020;1[1]:64-71.

Traumatic brain injury ("TBI") of varying severity can result in balance and movement disorders, for which the benefits of treatment with physical therapy has limits. In this study, a 9 patient subset of the original 43 patients published in "Translingual Neurostimulation for the Treatment of Chronic Symptoms Due to Mild-to-Moderate Traumatic Brain Injury" with balance issues received translingual neural stimulation ("TLNS") with the PoNS device, in concert with physical therapy, and the effects on grey matter volume ("GMV") in the brain were evaluated. TBI-related balance and movement impairments were also assessed with the Sensory Organization Test ("SOT") and Dynamic Gait Index ("DGI"), which are validated and objective means of scoring such deficits.

When comparing pre- and post-intervention results, the most prominent GMV changes were increases within the cerebellum and temporal regions, which are involved in automatic processing of gait, balance, motor control and visual-motion relationships. Decreases of GMV in the frontal and occipital lobes (which are involved in conscious/effortful processing of gait, balance, motor control, and vision) positively correlated to increases in SOT/DGI scores. These results suggest that TLNS with the PoNS device could induce brain plasticity changes leading to positive changes in functional assessments. Overall, these data indicate that TLNS delivered in conjunction with physical therapy may offer an integrative way to treat balance disorders after a mild-to-moderate TBI.

"The University of Wisconsin, Madison, participated in a multicenter clinical trial of the PoNS to address balance issues after traumatic brain injury and saw the regimen improve subjects' outcomes," said study investigator Dr. Vivek Prabhakaran. "The data published in this article shows that commensurate with clinical improvement experienced by these subjects after the PoNS regime, there were changes in the brain documented with MRI. This suggests that the PoNS regime induces brain plasticity changes, which may be relevant for clinical recovery. We should continue to document these changes in future studies and are keen to see this treatment deployed to help a massive unmet clinical need."

"I am thrilled that the body of scientific evidence showing the potential beneficial effects of our PoNS technology continues to grow," added Dane Andreeff, Interim Chief Executive Officer of Helius. "It is particularly exciting when we can observe, as in this work, the brain changing positively following PoNS Treatment."

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 commercial product 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 authorized for sale in Canada as a class II, non-implantable, medical device intended as a short term treatment (14 weeks) of gait deficit due to mild and moderate symptoms from multiple sclerosis (MS), and chronic balance deficit due to mild-to-moderate traumatic brain injury (mmTBI) and is to be used in conjunction with physical therapy. The PoNS™ is an investigational medical device in the United States, the European Union ("EU"), and Australia ("AUS"). The device is currently under review for de novo classification and clearance by the FDA for use in gait deficits in MS. It is also under premarket review by the AUS Therapeutic Goods Administration. PoNS™ is currently not commercially available in the United States, the European Union or Australia.

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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," "continue," "look forward," "will" and similar expressions. Such forward-looking statements include, among others, statements regarding the Company's future clinical and regulatory development plans for the PoNS device and the potential regulatory clearance of the PoNS device, the success of the Company's PoNS device in treating balance disorders, the success of the Company's future trials, its business and commercialization initiatives and objectives, and the potential receipt of regulatory clearance of the PoNS device in the United States, the European Union and Australia.

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 the impact of the COVID-19 pandemic, uncertainties associated with clinical trial enrollments and the results of clinical trials, uncertainties associated with the clinical development process and regulatory submission and approval process, uncertainties associated with 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, including the risks and uncertainties about the Company's business described in the "Risk Factors" sections of the Company's Annual Report on Form 10-K for the year ended December 31, 2019, Quarterly Report on Form 10-Q for the quarter ended June 30, 2020 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.

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