Helius Medical Technologies, Inc. Announces Publication of its PoNS™ Registrational Clinical Trial (TBI-001) in TBI

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122 Subject, Multicenter, Double-Blind, Randomized, Clinical Trial Finds PoNS Treatment™ found Significant Improvement in Balance and Gait Deficits for Individuals Who Have Experienced a Mild-to-Moderate Traumatic Brain Injury

NEWTOWN, Pa., April 30, 2020 (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 registrational clinical trial, TBI-001, was published on April 29, 2020 in *Neuromodulation: Technology at the Neural Interface*. The TBI-001 trial found that PoNS Treatment™ provided significant improvement in balance in patients with a chronic balance deficit following a mild-to-moderate traumatic brain injury ("mmTBI").

This newly-published, 122 subject, multicenter, double-blind randomized clinical trial, found that the PoNS Treatment, which pairs translingual neurostimulation using the Portable Neuromodulation Stimulator (PoNS™) device with therapeutic activities, significantly improves balance and gait. Conducted by researchers at 7 clinical sites across the US and Canada, this trial, which was completed in 2017, is the second double-blind, randomized clinical trial to demonstrate the level of balance improvement PoNS Treatment provides to patients suffering from chronic balance deficit as a result of a mild-to-moderate traumatic brain injury. For more information on the TBI-001 trial and its results, see the published journal article.

"Whether traumatic brain injuries are mild, moderate or severe, the devastating effects can last a lifetime," said Philippe Deschamps, Chief Executive Officer of Helius Medical Technologies. "We are excited to announce the publication of this 122 subject, multicenter, double-blind, randomized, clinical trial in a peer-reviewed journal and believe that it provides important clinical support for the PoNS Treatment as new, novel, valuable treatment option for patients suffering from the effects of mmTBI."

The PoNS Treatment involves the use of the PoNS device in conjunction with therapeutic activities. The PoNS device sits on the surface of a patient's tongue and delivers mild, gentle electrical impulses to the surface of the tongue. These impulses excite the neural network flowing to the brain. This neural activity, combined with therapeutic activities, is believed to enable "neuroplasticity" which may restore lost function.

The TBI-001 trial evaluated subjects who had experienced a mild-to-moderate traumatic brain injury at least one year prior to receiving the PoNS Treatment and had reached a plateau in recovery (according to their healthcare providers) with physical therapy alone. Subjects used the PoNS device for 5 weeks in conjunction with therapeutic activities. At the end of the 5-week treatment program, patients demonstrated improved balance and gait. Researchers found that 67.2 percent of the pooled patient population who completed 5 weeks of PoNS Treatment experienced a clinically and statistically significant improvement in balance, as indicated in their mean SOT (Sensory Organizational Test) scores at 2 weeks and 5 weeks compared to baseline. Mean DGI (Dynamic Gait Index) scores were significantly increased from baseline at weeks 2 and 5.

Exploratory endpoints, such as the headache disability index, sleep quality index and quality of life measure index were also observed as part of the trial. While further analysis and research is needed, there was an indication of improvements in these exploratory endpoints. Demonstrated improvements in balance and gait, coupled with potential improvements in the exploratory endpoints, may allow treated individuals to experience improved quality of life.

Mr. Deschamps continued: "We are very encouraged by the results of the clinical trial. As a result of their improvements in balance and gait, many of our patients reported being able to perform independent self-care tasks, like dressing and showering, that were once beyond their reach prior to receiving PoNS Treatment."

Katherine Webb, a patient enrolled in the study described her experience during the study. "It had been 4 and a half years since my injury when I first started the study. For those 4 and a half years, I had not been able to put one foot in tandem in front of the other and walk with my feet in a row without tipping or falling over due to loss of balance. It was early February of 2017, and with the device in my mouth, I walked the line. The Physiotherapist FaceTimed my husband and daughter who were flooded with tears as they watched. As a result of my improved balance throughout the study I experienced many more firsts since my TBI, like washing my hair without having to balance against the shower walls for stability," said Katherine Webb.

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 a class II, non-implantable medical device authorized for sale in Canada. PoNS is intended as a short term treatment (14 weeks) of chronic balance deficit due to mild-to-moderate traumatic brain injury and is to be used in conjunction with physical therapy and indicated 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. The PoNS is an investigational medical device in the United States, the European Union, and Australia, and is currently under review for clearance by the AUS Therapeutic Goods Administration. PoNS Treatment is currently not commercially available in the United States, the European Union or Australia.

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, the success of the Company’s planned study, business and commercialization initiatives and objectives, the potential receipt of regulatory clearance of the PoNS device in the United States, the European Union and Australia and the Company’s revenue guidance.

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 uncertainties associated with clinical trial enrollments and the results of clinical trials, uncertainties associated with the clinical development process and FDA regulatory submission and approval process, including 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, and 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, 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.

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