



Helius Medical Technologies Announces Positive Clinical Trial Results from its Multiple Sclerosis Pilot Study

(Newtown PA) – November 2, 2015 - Helius Medical Technologies, Inc. (CSE: HSM; OTCQB: HSDT) (“Helius”, or the “Company”), a medical technology company focused on the treatment of neurological symptoms caused by disease or trauma, announced today that the Multiple Sclerosis (“MS”) pilot study evaluating its investigational Portable Neuromodulation Stimulator (“PoNS™”) device, met all of its study objectives. A total of 14 subjects (7-active and 7-sham control) received treatment with the non-invasive brain stimulation technology and concomitant physiotherapy. The independent trial took place at the Montreal Neurological Institute and Hospital and Concordia University’s PERFORM Center. The study objectives were to explore the potential beneficial effects of PoNS™ stimulation, as previously reported, and to provide data to be used for the design of future studies to support requests for marketing authorization. The study included the first use of Functional MRI (“fMRI”) to measure the effect of PoNS™ while performing tasks with, and without, stimulation.

Study result highlights:

- fMRI measured the effect of PoNS™ neurostimulation while performing working memory and mental imagery tasks. Results suggest that the PoNS™ device may be facilitating neural plasticity.
- fMRI results were significantly different between the Active Group (who manifested brain function comparable to healthy subjects following treatment) and the control group. ($p < 0.02$).
- The PoNS™ stimulation group showed a statistically significant improvement ($p < .001$ in balance as measured by the Sensory Organization Test (SOT) scores, which were compared at baseline and week 14. The change in the control group did not reach the same level of statistical significance ($p > .05$).
- There was a good safety profile for the PoNS™ device reported in the study.

Factors to improve recruitment, screening, randomization and execution were identified and will be considered in the design of future MS studies. The results included a power analysis suggesting a sample size of 128 subjects (64 active, 64-sham) would be suitable for a definitive MS study.

“We are delighted with the findings that are consistent with prior studies. The fMRI data show that the PoNS™ may be changing the way the brain functions,” said Helius’ Chief Medical Officer, Dr. Jonathan Sackier. “Measuring brain activity and the changes taking place through fMRI is designed to determine in an objective way if, in fact, there are indications of neuroplastic change in the brain.”

“This is an exciting and promising development for our company, patients and the healthcare community. Addressing symptoms caused by MS has been a challenge for the medical community and we are excited to pursue PoNS™ as a potential therapeutic tool”, said Helius’

CEO, Philippe Deschamps. “We reached all the objectives of this study and are optimistic as we continue to advance the PoNS™ device through clinical trials.”

“The researchers from the Montreal Neurological Institute and Hospital are pleased with the execution of this study and are excited by the results as they point to a new frontier in research in brain injury rehabilitation. We are happy to be on the forefront of research that may bring this technology to patients in need,” said Dr. Gabriel Leonard, Principal Investigator for the study. Dr. Yves Lapierre and Dr. Alain Ptito from the Montreal Neurological Institute and Hospital joined Dr. Leonard as investigators in the study.

Helius would like to thank the study investigators Doctors Leonard, Ptito, and Lapierre, as well as study staff, subjects and founding scientists. The investigators and sponsor intend to submit study results for publication.

About the PoNS™

The PoNS™ device is a non-invasive means for delivering neurostimulation through the tongue. The PoNS™ therapy is currently being studied in the United States for the treatment of balance disorder for subjects with mild to moderate Traumatic Brain Injury (“mTBI”), and in Canada for the treatment of gait and balance disorder for subjects with MS.

The PoNS™ device is believed to be the first non-invasive means for delivering neurostimulation through the tongue. Researchers believe that use of the tongue as a gateway to the brain may be one of the most natural, non-invasive and direct ways to stimulate the brain. The tongue is anatomically unique, being richly innervated by thousands of nerve fibers and interconnected to the brainstem by two major cranial nerves.

About Helius Medical Technologies (HMT)

Helius Medical Technologies is a medical technology company focused on neurological wellness. HMT seeks to develop, license and acquire unique and non-invasive platform technologies that amplify the brain’s ability to heal itself. HMT intends to file for U.S. Food and Drug Administration clearance for the PoNS™ device. For more information, please visit www.heliusmedical.com. The contents of this website are not, and should not be deemed to be, incorporated by reference herein.

About the Montreal Neurological Institute

The Montreal Neurological Institute and Hospital – (“The Neuro”) is a world-leading destination for brain research and advanced patient care. Since its founding in 1934 by renowned neurosurgeon Dr. Wilder Penfield, The Neuro has grown to be the largest specialized neuroscience research and clinical centers in Canada, and one of the largest in the world. The seamless integration of research, patient care, and training of the world’s top minds make The Neuro uniquely positioned to have a significant impact on the understanding and treatment of nervous system disorders. The Montreal Neurological Institute is a McGill University research and teaching institute. The Montreal Neurological Hospital is part of the Neuroscience Mission of the McGill University Health Centre.

About PERFORM Centre

PERFORM is a research centre, based in the Montreal community, with a distinct Concordia approach to healthy lifestyle management. It represents a significant and forward-thinking

investment by the Quebec and Canadian governments as well as Concordia University in addressing the broader determinants of health.

Cautionary Disclaimer Statement:

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

This news release contains forward-looking statements and interpretations of clinical data relating to the commercialization of the PoNS™ technology, the advancement of the PoNS™ device through further clinical trials, and other statements that are not historical facts. Forward-looking statements are often identified by terms such as “will”, “may”, “should”, “anticipate”, “expects” and similar expressions. All statements other than statements of historical fact, included in this release are forward-looking statements that involve risks and uncertainties. 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 failure to satisfy the conditions of the Canadian Securities Exchange and other risks detailed from time to time in the filings made by the Company with securities regulations.

The reader is cautioned that assumptions used in the preparation of any forward-looking information 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 information. 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. The forward-looking statements contained in this news release are made as of the date of this news release and the Company will update or revise publicly any of the included forward-looking statements as expressly required by applicable law.

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