



## **Helius Medical Technologies to Start Its Registrational Clinical Trial**

Newtown PA – April 13, 2015 - Helius Medical Technologies, Inc. (CSE: HSM) (OTCQB: HSDT) (“Helius”) is pleased to announce that it recently met with the US Food and Drug Administration (“FDA” or the “Agency”) as part of the Agency’s pre-submission (pre-sub) process regarding Helius’s protocol for its double-blind, randomized, sham-controlled study of the safety and effectiveness of the Portable Neuromodulation Stimulator (PoNS™) 4.0 device for cranial nerve noninvasive neuromodulation (CN-NINM) training in subjects with a chronic balance deficit due to mild-to-moderate traumatic brain injury (TBI).

During the pre-sub meeting, FDA provided Helius with valuable feedback on its TBI study protocol, and thereafter informed Helius that it can proceed with the study. Additionally, the Agency determined the PoNS™ TBI study to be a nonsignificant risk device study

The multi-site TBI study will take place at Oregon Health and Science University Center for Regenerative Medicine (Portland, OR), Orlando Regional Medical Center (Orlando, FL), and The Montreal Neurofeedback Center (Montreal, QC). The primary endpoint of the trial is improvement in chronic balance deficit analyzed by the sensory organization test (SOT) at 5-weeks. Recruitment for the study is set to begin in a few weeks. In the coming weeks, individuals interested in the recruitment process should visit <http://heliusmedical.com/our-research/clinical-trials> to learn more.

### **About Helius Medical Technologies (HMT)**

Helius Medical Technologies is a medical technology holding company focused on neurological wellness. HMT seeks to use 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](http://www.heliusmedical.com).

### **About the PoNS™**

The Portable Neuromodulation Stimulator (PoNS) device is an investigational medical device being studied for the treatment of neurological symptoms caused by disease or trauma as part of a physical therapy program. The PoNS 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 Multiple Sclerosis (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.

**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.*

*All statements in this news release, other than statements of historical facts, are forward-looking statements. 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 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 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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