Helius Medical Technologies, Inc. Provides Update on FDA's Review of its Request for De Novo Classification and 510(k) Clearance of the PoNS™ Device

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NEWTOWN, Pa., Jan. 25, 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 it has received a request for an additional information ("AI") letter from the U.S. Food and Drug Administration (the "FDA") related to the Company's request for De Novo classification and 510(k) clearance of the Portable Neuromodulation Stimulator (PoNS™) device

During the substantive review phase of a request for De Novo classification and 510(k) clearance, FDA may request additional information in order to obtain information necessary for the agency to continue or complete its review and, in such instances, places its review on hold until the requested information is submitted.

"We have enjoyed a good relationship with FDA in the development and review of our file. We believe we have the data and information to address FDA's questions and we look forward to submitting our response to enable FDA to resume its review process as expeditiously as possible," said Philippe Deschamps, Helius' Chief Executive Officer. "We will continue to work towards securing clearance of PoNS."

Mr. Deschamps continued: "The PoNS device is a novel technology and our pursuit of a clearance is focused on providing a solution for patients suffering from chronic balance deficit due to mild-to-moderate traumatic brain injury, a condition that impacts more than two million people in the United States. We understand and appreciate the thorough and detailed approach the FDA has taken to learn about our novel technology. We look forward to receiving clearance in the United States for our non-invasive treatment of chronic balance deficit due to mild-to-moderate traumatic brain injury."

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 United States, for which we have requested De Novo classification and 510(k) clearance from the FDA for the treatment of chronic balance deficit due to mild-to-moderate traumatic brain injury when combined with targeted physical therapy. PoNS is a licensed class II medical device in Canada. PoNS is currently not commercially available in the United States or the European Union.

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 plans to submit information to the FDA in response to the AI letter, the Company's ability to satisfactorily address the questions expressed in the AI letter, the resumption of the FDA's review of the Company's submission and the potential receipt of regulatory clearance of the PoNS device.

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 the FDA regulatory submission and approval process, including the possibility that the information that the Company submits to the FDA may be insufficient to address the questions raised in the AI letter and the possibility that the FDA may require additional clinical data in order to support clearance of the PoNS device, 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, 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, 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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