



## Helius Medical Technologies, Inc. Receives PoNS® Market Authorization in Australia

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NEWTOWN, Pa., Nov. 04, 2021 (GLOBE NEWSWIRE) -- Helius Medical Technologies, Inc. (Nasdaq:HSDT) (Helius or the Company), a neurotech company focused on neurological wellness, today announced it received market authorization from the Australian Therapeutic Goods Administration (TGA) for the sale of PoNS as a Class IIa medical device. The Company's representative in Australia is working with the TGA to finalize the exact scope of the authorization, which is expected to cover the use of PoNS to improve balance and gait when used as an adjunct to a therapeutic exercise program.

"We are thrilled that we will be able to introduce this groundbreaking therapy for patients in Australia needing to improve their balance and gait," said Dane C. Andreeff, President and Chief Executive Officer of Helius. "This marks the third country in which PoNS is authorized and further validates the effectiveness of our innovative PoNS therapy. We will begin evaluating the pathway toward commercialization in Australia once the scope of the authorization is finalized."

### About Helius Medical Technologies, Inc.

Helius Medical Technologies is a leading neurotech company in the medical device field focused on neurologic deficits using non-implantable platform technologies that amplify the brain's ability to compensate and promotes neuroplasticity, aiming to improve the lives of people needing to improve their balance and gait. The Company's first commercial product is the Portable Neuromodulation Stimulator (PoNS®). For more information, visit [www.heliusmedical.com](http://www.heliusmedical.com).

### About the PoNS Device and PoNS Therapy

The Portable Neuromodulation Stimulator (PoNS) is an innovative non-surgical device, inclusive of a controller and mouthpiece, which delivers electrical stimulation to the surface of the tongue to improve balance and gait. The PoNS device is indicated for use in the United States as a short-term treatment of gait deficit due to mild-to-moderate symptoms from multiple sclerosis ("MS") and is to be used as an adjunct to a supervised therapeutic exercise program in patients 22 years of age and over by prescription only. It is authorized for sale in Canada for two indications: (i) PoNS is authorized for use as a short term treatment (14 weeks) of chronic balance deficit due to mild-to-moderate traumatic brain injury ("mTBI") and is to be used in conjunction with physical therapy; and (ii) PoNS is authorized for use 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.

### 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," "expect," "will," "goal," "aim to" and similar expressions. Such forward-looking statements include, among others, statements regarding finalizing the exact scope of approval in Australia and the Company's plans to begin evaluating the pathway toward commercialization in 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 uncertainties associated with the regulatory submission review and approval process, the clinical development process, the Company's capital requirements to achieve its business objectives, availability of funds, the impact of the COVID-19 pandemic, manufacturing, labor shortage and supply chain risks, the Company's ability to train physical therapists in the supervision of the use of the PoNS Treatment, the Company's ability to secure contracts with rehabilitation clinics, the Company's ability to build internal commercial infrastructure, build a commercial team and build relationships with Key Opinion Leaders, neurology experts and neurorehabilitation centers, market awareness of the PoNS device, future clinical trials, the product development process, other development activities, ongoing government regulation, and other risks detailed from time to time in the "Risk Factors" section of the Company's filings with the United States Securities and Exchange Commission and the Canadian securities regulators, which can be obtained from either at [www.sec.gov](http://www.sec.gov) or [www.sedar.com](http://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.

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