



## Helius Medical Technologies, Inc. Presents Poster at the 2022 Consortium of Multiple Sclerosis Centers (“CMSC”) Annual Meetin

June 6, 2022 12:00 PM EDT

-- Study finds significant improvement in gait deficit in multiple sclerosis patients using translingual neurostimulation (“PoNS Therapy<sup>®</sup>”) combined with a therapeutic exercise program --

-- Poster was one of ten rehabilitation research presentations nominated for the Labe C. Scheinberg Award recognizing the platform or poster, in each therapeutic category, that has the greatest impact in advancing the care of people with MS --

NEWTOWN, Pa., June 06, 2022 (GLOBE NEWSWIRE) -- Helius Medical Technologies, Inc. (Nasdaq:HSDT) (“Helius” or the “Company”), a neurotech company focused on neurological wellness, today announced that a poster detailing the benefits of the Company’s Portable Neuromodulation Stimulator (“PoNS”) Therapy combined with a therapeutic exercise program was presented at the 2022 Consortium of Multiple Sclerosis Centers (“CMSC”) Annual Meeting held June 1-4, 2022, in National Harbor, Maryland.

“The CMSC Annual Meeting is a wonderful opportunity to engage with thought leaders and researchers in the MS space. We are delighted to share the benefits of our innovative PoNS device and to be part of the community that is working to bring cutting edge interventions to improve gait deficits in patients with MS. It is especially gratifying that our poster was selected out of 150 to receive a prestigious award nomination,” stated Antonella Favit-VanPelt, MD, PhD, Chief Medical Officer of Helius.

“Importantly, this latest dataset provides key real-world evidence of our therapy’s clinical benefits, which can be seen at two weeks from beginning rehabilitation treatment with PoNS. We look forward to continuing to gather real-world evidence through our Therapeutic Experience Program (“TEP”), a multi-center, company-sponsored, open label observational interventional trial to evaluate the impact of subjects’ adherence to PoNS therapy for gait improvement in MS, as well as through patients’ voluntary participation to our upcoming registry program as part of the recently announced Patient Therapy Access Program,” concluded Dr. Favit-VanPelt.

### Study Conclusions

- In this analysis of a real-world dataset of patients with MS with generally long duration of disease, translingual neurostimulation (PoNS Therapy) combined with a therapeutic exercise program significantly improved gait deficit at Week 2, the earliest evaluated time point, and at every subsequent time point.
- Gait deficit was assessed by the Functional Gait Assessment (“FGA”) scale. Mean improvements in FGA total scores based on observed data were highly statistically significant at all follow-up time points (paired t-test  $P < 0.0001$ ). Mean improvement in FGA at Week 14 of PoNS therapy was 4.75 (95% CI: 3.66 to 5.84), and the median improvement was 5 points with 58.3% of patients showing an improvement of  $\geq 4$  points, noticeably greater than the minimum detectable change (“MDC”) for older adults, stroke patients, and persons with other neurological disease.
- Analysis of real-world data pooled with the two randomized clinical trials (“RCTs”) demonstrated, consistent with the RCT data, that PoNS Therapy is safe and effective in improving gait deficit in individuals with mild and moderate symptoms from MS. Mean improvement in the Dynamic Gait Index (DGI) assessment from baseline to Week 14 was 4.58 (95% CI: 3.62 to 5.54) for the pooled RWE and RCT analysis including all possible data at all weeks. Over 55% of patients treated with active PoNS therapy experienced  $\geq 4$  point-improvement from baseline in the DGI score.

### Poster Details

Title: [Translingual Neurostimulation by Portable Neuromodulation Stimulator System as a New Rehabilitation Therapy for Improving Gait in People With Multiple Sclerosis](#)

**Authors:** Antonella Favit-VanPelt, MD, PhD<sup>1</sup>; Kim Skinner, PT, DPT<sup>1</sup>; Greg Maislin, PhD<sup>2</sup>; Nicole Strachan, BHK, MSc. P.Kin<sup>1</sup>; and Lola Abhulimen, MBA<sup>1</sup>

**ID:** REH08

<sup>1</sup>Helius Medical Technologies, Newtown, PA.

<sup>2</sup>Biomedical Statistical Consulting, Wynnewood, PA.

### **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 dealing with neurologic diseases. 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 medical 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. Helius is advancing PoNS post-approval research in MS through a recently launched Therapeutic Experience Program (TEP) designed to partner with neurologists and neurorehabilitation therapists at 10-12 US centers of excellence, who express an interest in becoming "early adopters" of PoNS therapy.

PoNS is also authorized for sale in Canada for two indications: (i) 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) 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. PoNS is also authorized for sale in Australia for short term use by healthcare professionals as an adjunct to a therapeutic exercise program to improve balance and gait.

### **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," "expect," "continue," "will," "goal," "aim" and similar expressions. Such forward-looking statements include, among others, the scope and success of TEP, and rate of adoption of PoNS Therapy.

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 Company's capital requirements to achieve its business objectives, and ability to raise capital, the impact of the COVID-19 pandemic, the Company's ability to train physical therapists in the supervision of the use of the PoNS Therapy, the Company's ability to secure contracts with rehabilitation clinics, the Company's ability to obtain national Medicare coverage and to obtain a reimbursement code so that the PoNS device is covered by Medicare and Medicaid, the Company's ability to build internal commercial infrastructure, secure state distribution licenses, 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 and the clinical development process, manufacturing and supply chain risks, the product development process and FDA regulatory submission review and approval process, other development activities, ongoing government regulation, and other risks detailed from time to time in the "Risk Factors" section of the Company's Annual Report on Form 10-K for the year ended December 31, 2021, 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](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.

### **Investor Relations Contact**

Lisa M. Wilson, In-Site Communications, Inc.  
T: 212-452-2793