



Helius Medical Technologies to Spotlight Expanded Authorizations for its PoNS Device at 2023 American Academy of Neurology Annual Meeting, Booth 1685

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MS, Stroke and mmTBI Cover Broader Set of Indications Across North American Markets

NEWTOWN, Pa., April 17, 2023 (GLOBE NEWSWIRE) -- Helius Medical Technologies (NASDAQ: HSDT) today announced it will exhibit at the American Academy of Neurology (AAN) Annual Meeting for the first time since its Portable Neuromodulation Stimulator (PoNS) device became commercially available in both the United States and Canada.

Helius's presence at the conference comes at a time when PoNS is seeking additional indications for neurological conditions that lead to gait and/or balance impairment. The U.S. Food and Drug Administration authorized PoNS to be used for therapeutic management of gait deficit due to [multiple sclerosis \(MS\)](#), as well as a Breakthrough Devices Designation in stroke. Health Canada authorized PoNS for short-term treatment of balance and gait deficit due to MS, [mild-to-moderate traumatic brain injury \(mmTBI\)](#) and, in the past month, [stroke](#).

Visitors to the 75th AAN Annual Meeting – held April 22-27, 2023, at the Boston Convention and Exhibition Center – have the opportunity to interact with Helius's medical team members, and learn more about PoNS mechanisms of action and therapeutic benefits in these indications by stopping at booth 1685.

"This is the right time to exhibit at the AAN conference," said Helius President and Chief Executive Officer Dane Andreeff. "Not only is the PoNS label expanding to a number of gait- and/or balance-related neurological indications, but we're experiencing real momentum, with a promising number of patients who are undergoing or have been through PoNS Therapy, as well as a growing pool of trained physical therapists, who are valued partners in treating patients with PoNS. We're excited to present new real-world evidence and share new patient testimonies about PoNS Therapy."

The PoNS device works by delivering electrical impulses through nerve fibers on the tongue, stimulating the flow of neural impulses to brain structures that control gait and balance. This cascade of activity results in a neuromodulatory effect that, when used regularly and consistently with physical therapy, essentially "rewires" parts of the brain, helping patients with specific neurological conditions improve their balance and/or ability to walk.

The growing list of indications results from PoNS's clinical and real-world efficacy and safety evidence. Specifically, real-world data on stroke, MS and mmTBI patients with gait or balance deficits consistently showed average gait improvements above 55% in Functional Gait Assessment (FGA) and Dynamic Gait Index (DGI) scores – two important measurements of walking ability. In addition:

- In a clinical trial focused on people with MS, 100% of participants experienced at least a 4-point improvement in their DGI scores after PoNS Therapy.¹ In a real-world clinical setting, 58.3% of patients saw a jump of at least 4 points in their FGA scores.²
- Real-world evidence from Canada showed that 69.2% of stroke patients treated with PoNS saw at least a 5-point increase in their FGA scores.³
- Data from Canada also show that at the end of the 14-week PoNS Therapy treatment period, 28% of stroke patients were no longer at risk of falling³, a result of particular significance since routine rehabilitative physical therapy does not usually provide a meaningful shift in the risk of falling for stroke patients (~1-3%).⁴
- After 14 weeks of PoNS Therapy, 74% of individuals with mmTBI experienced significant improvement in their balance.⁵ At a post-treatment follow-up after 12 weeks, PoNS Therapy users with mmTBI also saw significant improvements in balance.⁶

"This broadening set of authorizations really sheds light on the therapeutic potential of PoNS Therapy, and strengthens our confidence that it can significantly mitigate the impact of common, life-altering neurological conditions on gait and/or balance," Andreeff said. "We invite all AAN members to stop by booth 1685 and learn more about what PoNS Therapy can achieve."

1. Tyler ME, Kaczmarek KA, Rust KL, Subbotin AM, Skinner KL, Danilov YP. Non-invasive modularization to improve gait in chronic multiple sclerosis: a randomized-double blind controlled pilot trial. *Journal of NeuroEngineering and Rehabilitation*. 2014;11(1):1-10.
2. Helius Medical, Inc Portable Neuromodulation Stimulator (PoNS) Real World Evidence Study,

August 2, 2020

3. Helius Medical Inc. Portable Neuromodulation Stimulator (PoNSTM) in Stroke Real World Evidence Study for Canada: A Statistical Analysis Report. 2023, Jan 26.
4. Denissen S, Staring W, Kunkel D, Pickering RM, Lennon S, Geurts AC, Weerdesteyn V, Verheyden GS. Interventions for preventing falls in people after stroke. Cochrane Database Syst Rev. 2019 Oct 1;10(10):CD008728. doi: 10.1002/14651858.CD008728.pub3. PMID: 31573069; PMCID: PMC6770464.
5. Helius Medical Technologies. Data on File. 2019 Post Hoc Analysis – Long Term Treatment Trial – Responder rate – Pharma Data Associates
6. Tyler M, Skinner K, Prabhakaran V, Kaczmarek K, Danilov Y. Translingual neurostimulation for the treatment of chronic symptoms due to mild-to-moderate traumatic brain injury. Arch Rehabil Res Clin Transl 2019;1:100026

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 promote neuroplasticity, improving the lives of people dealing with neurologic diseases. The Company's first commercial product is the Portable Neuromodulation Stimulator (PoNS®) device. For more information about the PoNS® or Helius Medical Technologies, visit www.heliusmedical.com.

About the PoNS Device and PoNS Therapy

The Portable Neuromodulation Stimulator (PoNS) device 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. For more information about Helius' PoNS® device and PoNS® therapy, visit www.ponstherapy.com.

About the American Academy of Neurology

Founded in 1948, the AAN now represents more than 40,000 members and is dedicated to promoting the highest quality patient-centered care and enhancing member career satisfaction.

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