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Bioness Medical Announces 510(k) Clearance for PoNS® (Portable Neuromodulation Stimulator) to Manage Patients Recovering from Stroke

- *First non-invasive, orally applied neuromodulation device FDA-cleared for stroke rehabilitation, expanding access for the more than 7 million Americans living with stroke-related gait disability*
- *Clearance expands PoNS indication beyond existing Multiple Sclerosis approval*

VALENCIA, Calif., June 29, 2026 - Bioness Medical, Inc. ("Bioness", or the "Company"), a global leader in functional electrical stimulation (FES) and advanced rehabilitation technologies, today announced that the Company's PoNS® (Portable Neuromodulation Stimulator) System has received FDA 510(k) clearance for the treatment of dynamic gait deficit due to chronic stroke symptoms. This clearance is supported by the Stroke Registrational Program (SRP), a three-study, 159-patient program at 10 centers of excellence in the U.S. and Canada, which demonstrated a sustained, statistically significant, and clinically meaningful improvement in dynamic gait deficit versus physical therapy (PT) alone, with a favorable safety profile, across all studies.

The PoNS System expands the Company's L300 Go and H200 Wireless FES technology platform to include a unique non-invasive neuromodulation of the central nervous system, delivered via the tongue, by leveraging stimulation of selective cranial nerve pathways to promote neuroplasticity and functional recovery.

"The evidence from the registrational program demonstrate the superiority of active PoNS Therapy® as compared to physical therapy alone, when applied in standard routine clinical settings for stroke rehabilitation," said Antonella Favit-Van Pelt, M.D., Ph.D., Bioness' Chief Medical Officer. "The totality of data in chronic stroke survivors with gait deficits confirms the broader evidence of PoNS therapeutic effect in improving walking disability by transitioning the outcome of physical therapy alone to a clinically meaningful effect with a 45.5% increased response rate to PoNS treatment as compared to PT alone."

About PoNS SRP
PoNS efficacy and safety was clinically established from three clinical trials across 10 sites and 159 enrolled chronic stroke survivors with gait deficit due to stroke. The studies were structured to assess the effectiveness and safety of the PoNS device in conjunction with routine physical rehabilitation therapy as compared to PT alone, over a 12-week treatment period. Participants were also followed for 12 weeks after completion of treatment to assess

durability of treatment effect. Primary efficacy endpoints for gait by the Functional Gait Assessment (FGA) and balance by Berg Balance Scale (BBS), as well as key secondary endpoints including risk of falling (determined by FGA <23) and durability of effect (established at <30% reduction of FGA improvement 12 weeks after completion of study treatment) were analyzed, across the two pivotal studies, using a propensity score design methodology adjusted for multiplicity control. Study success was achieved by demonstrating superiority, using the Hochberg method, for either primary endpoint, which, then, allowed for analysis of the key secondary endpoints with the same methodology.

SRP Study Results

Overall, the primary endpoint was met and statistically significant for gait deficit (FGA). The primary analysis of the pooled pivotal randomized controlled and single-arm studies demonstrated that treatment with active PoNS plus PT led to a statistically significant and clinically meaningful adjusted mean change in FGA of 5.37 points (95% CI: 4.23 to 6.52) at Week 12 as compared to a non clinically meaningful change of 3.31 points (95% CI 1.96 to 4.76) in the control group (sham PoNS plus PT) in the primary per-protocol dataset. The treatment group difference by propensity adjustment was 2.06 (95% CI 0.29 to 3.84) with a 2-sided p-value of 0.0233 that met the Hochberg requirement for multiplicity (< 0.025). 45% more subjects treated with active PoNS responded to treatment using a 6-point FGA increase threshold (56.1% vs 11.1%) and at least 30% more using a ≥4-point or ≥5-point improvement threshold (63.1% vs 33.3% and 58.5% vs 33.3%, respectively). Maintenance of active PoNS therapeutic effect achieved at Week 12 was also demonstrated, with a mean percentage reduction in FGA ranging between -4.71% and -4.97% and with 89.7% (95% CI 81.8% to 97.5%) of subjects meeting the durability performance goal. Improvement from baseline to Week 12 was also demonstrated for BBS in the active PoNS group although it did not reach between-group statistically significant separation. Similarly, risk of falling was resolved in 17.4% of subjects in the active PoNS group as compared to 8.9% in the control subjects, albeit not statistically significant. Treatment with PoNS was confirmed to be safe and well-tolerated with no incidence of treatment-related SAEs, across the SRP trials and existing RWE data, and adverse events (ranging between 0.0% and 14.8%) that were unrelated to the PoNS device.

"This FDA clearance is a major step forward for stroke rehabilitation and for the millions of patients suffering from stroke-related walking difficulties," said Todd Cushman, CEO of Bioness. "PoNS is a non-invasive, prescription-based therapy that uses the brain's natural ability to rewire itself to help patients walk better and regain their independence. Built for home use, PoNS is easy to use, accessible, and affordable — and with Medicare coverage, it gives healthcare providers a dependable treatment option to help their patients regain functional mobility."

For current multiple sclerosis (MS) users, the perception on PoNS effectiveness and the feedback on its therapeutic value has been consistently positive. Leveraging deep, well-

established relationships in the rehabilitation and neurology fields, our seamless conversations on the benefit of Bioness Medical technologies will continue.

About PoNS

PoNS® is a non-invasive, non-implantable, orally applied prescription medical device that delivers gentle neurostimulation through a mouthpiece placed on the tongue, used at home in conjunction with a physical rehabilitation exercise program. By stimulating branches of the trigeminal and facial cranial nerves, PoNS activates direct connections to the brainstem, promoting neuroplasticity mechanisms that facilitate the development of new neural networks to compensate for impaired corticospinal pathways, delivering reliable, durable improvements in walking function.

Multiple Sclerosis:

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 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.

Chronic Stroke:

The PoNS device is indicated for use as a treatment of dynamic gait deficit due to chronic symptoms from stroke 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.

About Bioness Medical

Bioness Medical is a leading provider of advanced rehabilitation technologies designed to restore mobility, function, and independence. Its portfolio spans functional electrical stimulation, robotic gait training, and neuromodulation, supporting clinicians and healthcare systems worldwide with evidence-based solutions.