NEWS RELEASE

Annals of Internal Medicine Publishes 12-Month Results from LivaNova's OSPREY Clinical Study for Obstructive Sleep Apnea

- *Study demonstrates proximal hypoglossal nerve stimulation (pHGNS) yielded clinically significant responses and sustained improvements over time*
- *First rigorous RCT study design in HGNS space supports pHGNS becoming a competitive option in the treatment landscape*

LONDON, APRIL 20, 2026 – LivaNova PLC (Nasdaq: LIVN), a market-leading medical technology company, today announced that the journal *Annals of Internal Medicine* has published an article chronicling the full 12-month data set for the Company's OSPREY randomized controlled trial (RCT). The researchers evaluated the safety and efficacy of proximal hypoglossal nerve stimulation (pHGNS), a differentiated neurostimulation modality, when delivered by LivaNova's aura6000™ System for the treatment of moderate to severe Obstructive Sleep Apnea (OSA). Overall, the authors concluded that pHGNS for OSA yielded clinically significant improvements versus the control at month (M) 7 with sustained improvements through M13 of OSPREY, corresponding with six and 12 months of therapy, respectively, providing unique RCT evidence for clinically relevant improvements in apnea-hypopnea index (AHI), sleep quality, and patient-reported outcomes (PROs). LivaNova previously announced 12-month, top-line data from the OSPREY trial in May 2025.

"Previous HGNS studies have largely been case series of highly selected OSA patients, leading to a deficiency in the evidence base," said Dr. Atul Malhotra, lead investigator for the study, who is also a professor of medicine at University of California San Diego School of Medicine and sleep medicine specialist at UC San Diego Health. "OSPREY was designed to overcome that challenge by including participants with diverse demographics, as well as a broad range of OSA severity to better represent patients who are commonly seen in clinical practice. We carefully assessed pre-specified objective endpoints and several subjective patient-reported outcomes, making our findings more comprehensive than prior studies in this area. For patients battling moderate to severe OSA, OSPREY's aggregate data clearly demonstrate improvement in both objective OSA severity and associated factors such as daytime sleepiness and other PROs."

In "Proximal Hypoglossal Nerve Stimulation for Obstructive Sleep Apnea, the OSPREY Study: A Randomized Controlled Trial,"[1] the study explored pHGNS as a potential alternative for adult patients with OSA who are intolerant of positive airway pressure (PAP) therapy. pHGNS utilizes six electrodes

placed on the proximal trunk of the hypoglossal nerve, offering broad access to the muscles controlling the airway and a wider set of titration options.

A total of 104 adults participated in OSPREY, with more diverse demographic profiles and greater OSA severity than in other pivotal HGNS trials, including higher body mass index (BMI) and no exclusion for complete concentric collapse (CCC). The no stimulation-controlled 2:1 randomized study, with therapy initiated at M1 (treatment) and M7 (control), was rigorously designed. Study outcome measures included the proportion of patients achieving at least a 50% improvement from the baseline AHI and an AHI of <20 events/hour (e/hr) at M7 (primary endpoint) following randomization, improvements in oxygen desaturation index (ODI) and PROs, and safety. An open-label extension was conducted following the M7 endpoint, with all participants receiving therapy until M13.

OSPREY patients in the treatment cohort demonstrated marked improvements in subjective measures, including clinician-rated assessments like the CGI-I (Clinical Global Impression–Improvement) scale and PROs such as the Epworth Sleepiness Scale (ESS), a patient questionnaire that assesses how likely the patient is to fall asleep during the day, and the Functional Outcomes of Sleep Questionnaire (FOSQ), which assesses the effects of fatigue on daily activities. The degree of subjective outcome improvements at M13 in the treatment group was clinically meaningful with pHGNS treatment, thus pHGNS led to major improvements in objective and subjective outcomes, the authors said, adding that "we also demonstrated acceptable safety without any serious adverse events related to pHGNS and no unanticipated device events."

OSPREY data also demonstrated:

- There were improvements in the proportion of subjects achieving ≥25% ODI reduction at M7: 69% (treatment) vs. 38% (control), yielding a reduction in median ODI from baseline (35 events per hour [e/hr]) to M7 (13 e/hr) with treatment.
- The median AHI in the pHGNS treatment group was 34.3 e/hr at baseline and 11.6 e/hr at M7; the difference in median (95% confidence interval) AHI between the treatment and control groups at M7 was −18.9 (−27.0, −10.6) e/hr. By M13, outcomes improved in both groups; median AHI in the pHGNS treatment group was 11.0 e/hr with treatment and 20.9 e/hr in the control group (now active).
- CGI-I response rate in the treatment group exceeded the control group at M7 (56% vs 9%) and increased to 59% at M13. The CGI-I scale is a seven-point clinician-rated tool used to assess a patient's overall change in illness severity over time.
- PROs included:
    - ESS scores demonstrating improvement in treatment group at M7 (median score 10.0 to 6.0) beyond the minimal clinically importance difference (MCID) of 2, but not in

control group (median score 9.0 to 9.0). By M13, both groups improved on therapy from baseline.

  - For the FOSQ, there was an improvement from baseline to M7 in the treatment group (median score 15.8 to 17.8) meeting the MCID of 2, but not in the control group (median score 16.0 to 16.3). By M13, both groups improved on therapy from baseline to median scores of 18.5 (treatment) and 18.3 (control, now active).

- Arousals from sleep significantly declined with pHGNS stimulation therapy. The treatment group at baseline had an arousal index of about 55/hr despite having a sleep efficiency of ≥85%, and at M13 arousals declined to 29/hr. Of note, respiratory arousals were essentially resolved while some non-respiratory arousals persisted.
- No serious procedure-related adverse events were reported. Most treatment-emergent adverse events (TEAEs) were mild or moderate in severity, and the most common events were headache, implant site pain, and difficulty swallowing.

"This is rigorous data for the category with the highest-quality evaluation of neurostimulation safety and effectiveness in OSA to date," said Ahmet Tezel, Ph.D., Chief Innovation Officer of LivaNova. "LivaNova's pHGNS technology is designed to provide more complete control of the tongue and airway, enabling the ability to treat a wide range of challenging patients compared to previous HGNS pivotal studies, including patients with higher AHI, higher BMI, and complete concentric collapse, and delivers durable, holistic clinical responses. The results over time are quite compelling."

OSPREY baseline values of OSA severity and BMI were representative of the general OSA population. Importantly, OSPREY did not exclude patients with CCC. Based on a recently presented predictive algorithm[2], it was determined that the OSPREY study enrolled patients at increased risk of CCC at a ratio aligned with the general OSA population seen in clinical practice. Response rates and AHI reductions with 12 months of pHGNS therapy for patients in OSPREY with predicted risk for CCC were consistent with the results for the full study population, demonstrating the robustness of the therapeutic response[3].

"OSA affects up to 1 billion people worldwide, yet the majority of patients remain undiagnosed and untreated," said Lucile Blaise, Global Head of Commercialization, OSA, at LivaNova. "With strong clinical results, a dedicated team, and a commitment to innovation, we are eager to make this treatment available to patients in need of an alternative therapy."

As reported in March, LivaNova received premarket approval (PMA) from the U.S. Food and Drug Administration (FDA) for the aura6000 System, an implantable proximal hypoglossal neurostimulator, after meeting OSPREY's primary safety and efficacy endpoints following six months of treatment. Building upon the FDA PMA approval, LivaNova is preparing its next-generation OSA device for a PMA

supplement application to the FDA. This device is being designed for compatibility with magnetic resonance imaging (MRI), remote and secure configuration management capabilities, and long-lasting, rechargeable battery technology (up to 15 years). Pending a successful conclusion of the FDA's review, the Company anticipates commercializing its OSA product independently in 2027.

References

1 *Atul Malhotra, MD; Alan R Schwartz, MD; Eric G Lovett, PhD; Nadine Juran, RN; Shaun A Nguyen, MD; Jose E Barrera, MD; Richard K Bogan, MD; Samuel A Mickelson, MD; Haresh Boghara, MD; Mitchell B Miller, MD; Ofer Jacobowitz, MD, PhD; on Behalf of the OSPREY Investigators. Annals of Internal Medicine. 2026 Apr 21.doi: 10.7326/ANNALS-25-04414. Online ahead of print.*

2 *The PREDICTOR algorithm was presented at the 2024 International Surgical Sleep Society Educational Update in Miami. The presentation occurred on Friday, Sept. 27, 2024, with the lecture being delivered by Jordan Weiner, MD (https://surgicalsleep.org/wp-content/uploads/2025/11/16253-ISSS-2024-Educationl-Agenda-22.pdf).*

3 *Data on file*

About LivaNova's OSPREY Study

OSPREY, a prospective, multi-center, randomized, controlled, open-label clinical trial, evaluated the safety and efficacy of the aura6000™ System compared to a no-stimulation control in adult subjects with moderate to severe obstructive sleep apnea (OSA) who failed, do not tolerate, or are ineligible for treatment with standard-of-care therapies, including positive airway pressure (PAP). Data from the OSPREY trial supported U.S. Food and Drug Administration (FDA) approval of the aura6000 System (PMA P250013).

About LivaNova

LivaNova PLC is a global medical technology company built on nearly five decades of experience and a vision to change the trajectory of lives for a new day. Through ingenious medical solutions in select neurological and cardiac conditions, LivaNova strives to ignite patient turnarounds. Headquartered in London, with approximately 3,300 employees and a presence in more than 100 countries, LivaNova serves patients, healthcare professionals, and healthcare systems worldwide. For more information, please visit www.livanova.com.

Safe Harbor Statement

This news release contains "forward-looking statements" concerning the Company's goals, beliefs, expectations, strategies, objectives, plans, underlying assumptions, and other statements that are not necessarily based on historical facts. These statements include, but are not limited to, statements regarding the OSPREY study, the aura6000™ System, and LivaNova's plans for commercialization of its next-generation OSA device. Actual events may differ materially from those indicated in our forward-

looking statements as a result of various factors, including those factors set forth in Item 1A of the Company's most recent Annual Report on Form 10-K, as supplemented by any risk factors contained in Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. LivaNova undertakes no obligation to update the information contained in this press release to reflect subsequently occurring events or circumstances.

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