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NEWS RELEASE

LivaNova Announces 12-month Data from OSPREY Clinical Study for Moderate to Severe Obstructive Sleep Apnea, Demonstrating Strong Response and Durability of Therapy

Top-line results at 12 months of treatment show meaningful improvement over time:
Overall responder rate of 65%
Overall reduction in median apnea-hypopnea index of 68%
Overall reduction in median oxygen desaturation index of 68%

London, May 7, 2025 — LivaNova PLC (Nasdaq: LIVN), a market-leading medical technology company, today announced 12-month, top-line data from its OSPREY randomized controlled trial (RCT), evaluating outcomes with the aura6000™ System for the treatment of moderate to severe obstructive sleep apnea (OSA). At 12 months of therapy, the treatment arm responder rate was 65% with responders defined as those who realized at least a 50% improvement from the baseline apnea-hypopnea index (AHI) and an AHI value below 20. The study features a differentiated neurostimulation modality called proximal hypoglossal nerve stimulation (p-HGNS), which utilizes six electrodes placed on the proximal trunk of the hypoglossal nerve, offering broad access to the muscles controlling the airway and providing customized titration.

In November 2024, the company announced that OSPREY met its primary and secondary endpoints following six months of therapy. Study patients in the treatment arm of OSPREY have since shown continued improvement. When comparing baseline median values to six and 12 months of therapy (assessed at the seven- and 13-month follow-up visits, respectively), OSPREY subjects showed significant reductions in AHI and oxygen desaturation index (ODI) over time:

- AHI reduced by 68% when the median at baseline of 34.3 is compared to the median of 11.0 at 12 months (versus the median of 11.6 at six months).
- ODI reduced by 68% when the median at baseline of 34.9 is compared to the median of 11.1 at 12 months (versus the median of 12.8 at six months).

Further, after 12 months of treatment, OSPREY subjects in the device stimulation group experienced clinically meaningful improvements in the Epworth Sleepiness Scale (ESS) and the Functional Outcomes of Sleep Questionnaire (FOSQ). ESS and FOSQ as compared to baseline are secondary outcome measures within the study. ESS is a patient questionnaire that assesses how likely the patient is to fall asleep during the day and FOSQ is a patient questionnaire that assesses the effects of fatigue on daily activities.

"OSPREY is the first major multi-center randomized, controlled pivotal trial of hypoglossal nerve stimulation. Patients in the device stimulation group experienced a rapid onset of therapy with continued improvement over time," 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. "Responder rates in the treatment group were strong throughout the first year with one in four patients responding on day one, 50% responding by month three, and 65% responding by the 12-month mark. In addition, patient-reported outcomes for daytime sleepiness and functional outcomes of sleep quality demonstrated meaningful improvement over the course of 12 months."

Dr. Malhotra will present the OSPREY six-month results and 12-month top-line data at the American Thoracic Society International Conference on Tuesday, May 20, at 9:51 a.m. PDT in San Francisco.

OSPREY baseline values of OSA severity and body mass index (BMI) were representative of the general OSA population. Relative to other large-scale trials of hypoglossal nerve stimulation (HGNS) in support of U.S. Food and Drug Administration (FDA) approval, OSPREY included patients with greater OSA severity and higher BMI. Plus, OSPREY was designed to include patients with complete concentric collapse (CCC). Based on a recently presented predictive algorithm[1], 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 at month 12 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[2].

"The OSPREY trial demonstrated rapid and sustained improvement for patients who received active proximal hypoglossal nerve stimulation, including those with severe obstructive sleep apnea, elevated body mass index, and high risk of complete concentric collapse," said Ahmet Tezel, Ph.D., Chief Innovation Officer of LivaNova. "The OSPREY 12-month results further validate the potential of this therapy as a treatment alternative for the large and growing OSA population. With the strength of our clinical data, expertise of our neuromodulation team, and strategic growth opportunity ahead, we are eager to bring this innovation to patients."

LivaNova recently completed its premarket approval submission to FDA for the aura6000 System based on meeting OSPREY's primary safety and efficacy endpoints following six months of treatment. LivaNova has also provided FDA with interim 12-month results from the OSPREY study and intends to share the full 12-month dataset with FDA during its review.

The aura6000 System is an investigational implantable proximal hypoglossal neurostimulator undergoing clinical evaluation for the treatment of adult patients with moderate to severe OSA. There were no serious adverse device-related or procedure-related events reported during OSPREY.

References

1 *The PREDICTOR algorithm was presented at the 2024 International Surgical Sleep Society Educational Update in Miami (https://surgicalsleepmeeting.org/educational-update-meeting/). The presentation occurred on Friday, Sept. 27, 2024, with the lecture being delivered by Jordan Weiner, MD (https://surgicalsleepmeeting.org/wp-content/uploads/2024/09/16253-ISSS-2024-EducationI-Agenda-22.pdf).*

2 *CYB-03127-R1*

About OSPREY

OSPREY is a prospective, multi-center, randomized controlled open-label trial evaluating the safety and efficacy of the aura6000™ System versus a no stimulation control in subjects with moderate to severe OSA who have failed or are unwilling to use positive airway pressure treatment. CAUTION—the aura6000 System is an investigational device. Limited by Federal (or United States) law to investigational use.

About LivaNova

LivaNova PLC is a global medical technology company built on nearly five decades of experience and a relentless commitment to provide hope for patients and their families through medical technologies, delivering life-changing solutions in select neurological and cardiac conditions. Headquartered in London, LivaNova employs approximately 2,900 employees and has a presence in more than 100 countries for the benefit of 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 presentations at upcoming conferences. 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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