LivaNova Receives U.S. Food and Drug Administration Premarket Approval for aura6000 System to treat Moderate to Severe Obstructive Sleep Apnea

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– First and only hypoglossal nerve stimulation therapy approved in the U.S. without complete concentric collapse contraindication or warning language

– Next-generation, MRI-compatible device expected to launch in the first half of 2027, pending FDA supplement review

LONDON--(BUSINESS WIRE)--Mar. 19, 2026-- LivaNova PLC (Nasdaq: LIVN), a market-leading medical technology company, today announced the U.S. Food and Drug Administration (FDA) granted premarket approval (PMA) for the aura6000™ System for the treatment of adult patients with moderate to severe Obstructive Sleep Apnea (OSA). The System utilizes proximal hypoglossal nerve stimulation (p-HGNS), a differentiated neurostimulation modality, to treat OSA in patients with an apnea-hypopnea index (AHI) between 15 and 65 and who have failed, do not tolerate, or are ineligible for first-line therapies, such as positive airway pressure (PAP).

“FDA approval of the aura6000 marks a transformative moment for LivaNova and represents a major step forward for patients struggling with inadequately treated OSA,” said Ahmet Tezel, Ph.D., Chief Innovation Officer for LivaNova. “Our p-HGNS therapy underwent a rigorous evaluation for safety and efficacy in the OSPREY randomized controlled trial and delivered clinically significant responses and sustained improvements over time. Now, with FDA approval secured, we are advancing the device toward an even more sophisticated, next-generation system for patients and, ultimately, commercialization.”

Building upon the FDA PMA approval, LivaNova is continuing to prepare 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).

The FDA PMA approval is supported by data from OSPREY, LivaNova’s prospective, multi-center, randomized controlled trial (RCT). As previously announced in November 2024, OSPREY met its primary endpoints following six months of p-HGNS therapy, with study data demonstrating clinically significant reductions in AHI and oxygen desaturation index (ODI), in addition to several patient-reported outcomes relevant to sleep disturbance. The no stimulation-controlled 2:1 RCT, with therapy initiated at month (M) 1 (treatment) and M7 (control), was rigorously designed. At 12 months of p-HGNS therapy, as announced in May 2025, the treatment arm responder rate was 65%, with responders defined as those who realized at least a 50% improvement from the baseline AHI and an AHI value below 20. The treatment group continued to demonstrate clinically meaningful and durable improvements from M7 to M13:

- 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 p-HGNS 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 p-HGNS treatment group was 11.0 e/hr with treatment and 20.9 e/hr in the control group (now active).

OSPREY baseline values of OSA severity and body mass index (BMI) were representative of the general OSA population. Importantly, OSPREY did not exclude 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 with 12 months of p-HGNS 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[2].

“We are proud to bring the option of p-HGNS to more patients, as the first and only HGNS device FDA-approved without a contraindication or warning related to CCC and no requirement for a pre-implantation DISE (drug-induced sleep endoscopy),” Tezel said.

LivaNova’s p-HGNS therapy is an alternative for adult patients with moderate to severe OSA who refuse or are intolerant of PAP therapy or other first-line therapies. Utilizing six electrodes placed on the proximal trunk of the hypoglossal nerve, p-HGNS therapy offers broad access to the muscles controlling the airway and a wider set of customizable titration options to significantly reduce or eliminate airway obstruction and sleep apnea – also referred to as the PolySync™ algorithm.

“FDA approval of the aura6000 System validates our innovative solution that will soon provide a much-needed alternative for OSA patients who are unsuccessful with PAP and are seeking effective therapy, regardless of complete concentric collapse,” said Lucile Blaise, LivaNova’s Global Head of Commercialization for OSA. “The system has also been validated with a pivotal study in more severe patients than any other approved HGNS therapy, and we look forward to bringing our next-generation technology to market next year.”

References

1. *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).

2. *Data on file.*

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.

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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 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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