LivaNova

Health innovation that matters

NEWS RELEASE

LivaNova Announces a Positive Predictive Outcome of Trial Success in its OSPREY Clinical Study for Moderate to Severe Obstructive Sleep Apnea

London, March 20, 2024 — LivaNova PLC (Nasdaq: LIVN), a market-leading medical technology company, today announced its OSPREY clinical study, Treating Obstructive Sleep Apnea Using Targeted Hypoglossal Nerve Stimulation, has achieved a positive predictive outcome and will conclude enrollment earlier than anticipated. This means there is a greater than 97.5% probability that the OSPREY trial will successfully meet its primary endpoint. OSPREY is a prospective, multi-center, randomized controlled open-label trial demonstrating the safety and effectiveness of the aura6000™ Hypoglossal Nerve Stimulator System versus a no stimulation control in subjects with moderate to severe obstructive sleep apnea (OSA) who have failed or are unwilling to use positive airway pressure treatment. LivaNova notified the U.S. Food and Drug Administration (FDA) and its partner trial sites of this significant milestone for the OSPREY study.

"A planned interim analysis, per the approved protocol, was conducted for the first 90 patients enrolled in OSPREY. We are now able to estimate a high chance of success for achieving the primary endpoint in this unique randomized controlled trial without further patient enrollment," said Dr. Atul Malhotra, Professor of Medicine at University of California, San Diego and Principal Investigator for OSPREY. "While this milestone shows we are on a positive trajectory, long-term follow-up visits will continue for each patient through the primary endpoint and beyond."

The OSPREY study's primary efficacy endpoint is the demonstration that the apnea-hypopnea index (AHI) responder rate of subjects with device stimulation activated is statistically significantly higher than the rate of subjects without stimulation after seven months of follow-up. For OSPREY, response is defined as at least a 50% improvement from the baseline AHI, leading to an AHI value below 20. After the full cohort completes the seven-month follow-up visit and the results are compiled, LivaNova will submit OSPREY's final clinical module to the FDA.

"We are pleased to have achieved this positive milestone for the OSPREY study," said Vladimir Makatsaria, Chief Executive Officer of LivaNova. "In accordance with the study protocol, once the last patient implanted completes their final follow-up visit, we will conduct the final analysis for the study. Until then, we will continue to actively work with the clinical sites to manage the study patients."

The OSPREY study also assesses the safety of the aura6000 System and measures patient quality of life through indicators such as daytime sleepiness. For more information on the therapy and the treatment of OSA, visit the LivaNova website.

About Obstructive Sleep Apnea

OSA affects almost one billion people worldwide, of which 75% are undiagnosed. If left untreated, OSA can have serious implications, including increased cardiovascular disease, stroke, metabolic disease, excessive daytime sleepiness and a higher risk for traffic accidents.

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 improvements for both the Head and Heart. 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 progress relating to the OSPREY study and the aura6000 system. Actual events may differ materially from those indicated in 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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