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NEWS RELEASE

LivaNova Announces OSPREY Clinical Study Meets Primary Safety and Efficacy Endpoints

Top-line results compared to baseline at six months:
Median apnea-hypopnea index reduction of 66.2%
Median oxygen desaturation index reduction of 63.3%

London, November 11, 2024 — LivaNova PLC (Nasdaq: LIVN), a market-leading medical technology company, today announced that it met the primary endpoints for its OSPREY randomized controlled trial (RCT), Treating Obstructive Sleep Apnea Using Targeted Hypoglossal Nerve Stimulation. Together with its safety endpoints, the RCT achieved statistical significance of its primary endpoint responder rates[1,2] between the treatment arm and the sham arm for the LivaNova aura6000™ System. The aura6000 is an implantable hypoglossal neurostimulator intended to treat adult patients with moderate to severe obstructive sleep apnea (OSA).

In the OSPREY study, apnea-hypopnea index (AHI) and oxygen desaturation index (ODI) reductions are analyzed as part of the study's secondary endpoints. Comparing median values from baseline to six months with therapy (assessed at the seven-month follow-up visit), OSPREY subjects in the device stimulation group experienced significant reductions in these endpoints as follows:

- AHI reduced by 66.2% when the median at baseline of 34.3 is compared to the median of 11.6 at six months.
- ODI reduced by 63.3% when the median at baseline of 34.9 is compared to the median of 12.8 at six months.

Once the six-month results analysis is completed, LivaNova will submit the OSPREY clinical data to the U.S. Food and Drug Administration (FDA) as part of its premarket approval submission for the aura6000 System.

"The study results reinforce our belief that targeted hypoglossal nerve stimulation provides a compelling alternative for patients with obstructive sleep apnea. The significant reductions in AHI and ODI achieved after only six months of therapy gives us strong evidence of this technology's potential at 12 months and beyond," said Vladimir Makatsaria, Chief Executive Officer of LivaNova. "I would like to thank the patients and physicians who have participated in OSPREY to date. We look forward to evaluating the full results as patients complete 12 months of therapy."

Beyond the primary endpoints, the OSPREY trial will continue to collect long-term data. After all subjects have completed 12 months with therapy (assessed at the 13-month follow-up visit), LivaNova expects the data to be available in the first half of 2025.

"In addition to meeting the primary safety and efficacy outcomes, the reductions in AHI and ODI after only six months of therapy demonstrate a significant clinical impact for the patients," 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 University of California San Diego Health.

There were no serious adverse device-related or procedure-related events reported in OSPREY throughout the primary endpoint visits.

For more information on the aura6000 System and the treatment of OSA, visit the LivaNova website.

1 The primary efficacy endpoint measured the difference in apnea-hypopnea index (AHI) responder rates between active and no stimulation targeted hypoglossal nerve stimulation (THNS) therapy after seven months of follow-up with a predetermined p-value of $p<0.025$.

2 Per trial protocol, a responder is defined to have realized at least a 50% improvement from the baseline AHI, leading to an AHI value below 20.

About OSPREY

OSPREY is a prospective, multi-center, randomized controlled open-label trial demonstrating the safety and efficacy of the aura6000™ Hypoglossal Nerve Stimulator 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 and the aura6000™ System. 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.

LivaNova Investor Relations and Media Contacts

+1 281-895-2382
Briana Gotlin
VP, Investor Relations
InvestorRelations@livanova.com
Deanna Wilke
VP, Corporate Communications
Corporate.Communications@livanova.com

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