
LivaNova Announces First Patient Implanted in OSPREY Clinical Study for Patients Coping with Obstructive Sleep Apnea

Study to evaluate effectiveness of hypoglossal nerve stimulation

London, February 24, 2022 — LivaNova PLC (Nasdaq: LMN), a market-leading medical technology and innovation company, today announced the first patient implanted in the investigational device exemption (IDE) clinical study, “Treating **O**bstructive **S**leep **A**pnea using **T**argeted **H**ypoglossal **N**eurostimulation” ([OSPREY](#)). The randomized controlled trial (RCT) seeks to demonstrate the safety and effectiveness of the LivaNova aura6000™ System, an implantable hypoglossal neurostimulator intended to treat adult patients with moderate to severe obstructive sleep apnea (OSA). The first OSPREY patient was implanted by Dr. Mitchell Miller at BayCare’s Morton Plant Hospital in Clearwater, Florida.

“With this first patient and the launch of this randomized clinical trial, we are taking a major step toward finding new, effective treatments for the global population of OSA patients and adding to the clinical literature surrounding these therapies,” said Dr. Atul Malhotra, Professor of Medicine at University of California, San Diego and Principal Investigator for OSPREY. Dr. Malhotra is an internationally recognized expert in sleep apnea who has published more than 385 original manuscripts, plus more than 285 reviews/chapters, in leading journals and actively treats patients in pulmonary, critical care and sleep medicine. “The clinical study will determine if the apnea-hypopnea index responder rate of subjects stimulated via the device is statistically significantly higher than the rate of subjects without stimulation. Throughout the study, independent statisticians will conduct interim data analyses to determine predictive probability of success for OSPREY. With this being a randomized study rather than simply observational, we will get a clear sense that targeted hypoglossal neurostimulation therapy is the mechanism of improvement for the patients.”

The OSPREY study will take place at approximately 20 sites across the United States. It will ultimately enroll a maximum of 150 adult patients with moderate to severe OSA who do not achieve results from a traditional continuous positive airway pressure (CPAP) machine or have declined its use.

“Approximately one billion people worldwide live with OSA, but most are undiagnosed and untreated¹, which can seriously impact their health, increasing the rates of death, stroke, hypertension, motor vehicle accidents, heart failure, diabetes, depression and daytime sleepiness,²” said Damien McDonald, LivaNova Chief Executive Officer. “There is a great need to offer patients diagnosed with OSA new and less restrictive treatment options. The OSPREY study will be the first RCT to confirm

efficacy of hypoglossal nerve stimulation and now, with the first OSPREY patient implanted, we are another step closer to successfully bringing the innovative aura6000 System to market.”

The aura6000 System, which received CE mark in 2012, is designed to maintain muscle tone of the tongue and upper airway so that airway obstruction and resulting sleep apnea are significantly reduced or eliminated. It features a programmable, rechargeable and implantable pulse generator (IPG) that is implanted in a subcutaneous pocket near the patient’s clavicle during an outpatient surgery. The IPG generates mild stimulation that is delivered via a lead to the hypoglossal nerve, thereby stimulating the patient’s tongue during sleep and keeping the airway open. An innovative alternative to the traditional CPAP machine, the aura6000 System allows the patient to sleep without being connected to masks, hoses, facemasks or mouthpieces. For more information on the aura6000 System for the treatment of OSA, visit the [LivaNova website](#).

About LivaNova

LivaNova PLC is a global medical technology and innovation company built on nearly five decades of experience and a relentless commitment to provide hope for patients and their families through innovative medical technologies, delivering life-changing improvements for both the Head and Heart. Headquartered in London, LivaNova employs approximately 3,000 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.

About BayCare Health System

Morton Plant Hospital is part of BayCare, a leading not-for-profit health care system that connects individuals and families to a wide range of services at 15 hospitals and hundreds of other convenient locations throughout the Tampa Bay and central Florida regions. Inpatient and outpatient services include acute care, primary care, imaging, laboratory, behavioral health, home care, and wellness. Our mission is to improve the health of all we serve through community-owned, health care services that set the standard for high-quality, compassionate care. For more information, visit www.BayCare.org.

Safe Harbor Statement

This news release contains “forward-looking statements” concerning the Company’s goals, beliefs, expectations, strategies, objectives, plans and 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 clinical 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.

References

- 1 *Benjafield et al. Estimation of the global prevalence and burden of obstructive sleep apnea: a literature-based analysis Lancet Respir Med 2019; 7: 687-98.*
- 2 *Knauert et al. Clinical consequences and economic costs of untreated obstructive sleep apnea syndrome World Journal of Otorhinolaryngology-Head and Neck Surgery 2015; 1: 17-27.*

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