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NEWS RELEASE

CORE-VNS Study Further Validates Effectiveness of LivaNova's VNS Therapy on Severe Focal Seizures in Both Children and Adults with Drug-Resistant Epilepsy

Long-term, real-world evidence demonstrates early and lasting outcomes of adjunctive VNS Therapy on severe focal seizures

London, June 5, 2025 — LivaNova PLC (Nasdaq: LIVN), a market-leading medical technology company, today announced completion of the CORE-VNS study, evaluating comprehensive outcomes of real-world evidence for more than 800 people with epilepsy treated with VNS Therapy™ worldwide. With the clinical study report (CSR) now complete, the final 36-month data further validate the effectiveness of VNS Therapy for severe focal seizures in both children and adults with drug-resistant epilepsy (DRE) and demonstrate early and lasting outcomes of adjunctive VNS Therapy on severe focal seizures.

"It is critically important to conduct long-term, real-world studies like CORE-VNS, and it is pleasing to see these clinically meaningful and durable results demonstrating the effectiveness of VNS Therapy for people living with drug-resistant epilepsy," said Arjune Sen, Professor of Global Epilepsy at The University of Oxford and Consultant Neurologist at Oxford University Hospitals NHS Foundation Trust. Prof. Sen is also coordinating investigator for the CORE-VNS study.

The CORE-VNS 36-month data analysis reaffirms the effectiveness of VNS Therapy, in pediatric and adult patients, and expands upon LivaNova's presentation of interim 24-month data evaluating the effectiveness of VNS Therapy in children ages 4 to 18 years old with focal onset seizures at the American Epilepsy Society's annual conference in December 2024.[1] Within the full 36-month analysis, the greatest proportion of patients at all ages reported focal onset seizures with impaired awareness (FIA) to be their most disabling seizure type. CORE-VNS study data demonstrate the impact of VNS Therapy, including:

- In children 4 to 18 years old, FIA motor seizures, for example, reduced by a median of 87% at 36 months. Including adults, 34% of people with FIA motor seizures reported 100% seizure reduction (freedom from these seizures over the three months prior to their three-year study visit), with an overall median reduction of 80%.
- In children 4 to 18 years old, focal to bilateral tonic-clonic (FBTC) seizures reduced by a median of 100% at 36 months. Including adults, 49% of people with FBTC seizures reported 100% seizure reduction at the three-year study visit, with an overall median reduction of 95%.

- The effectiveness of VNS Therapy was noted as early as three months after implantation, followed by further substantial reduction noted in both FIA and FBTC seizures at the 12-, 24-, and 36-month study visits.
- Unlike many long-term follow-up studies on DRE, CORE-VNS had a high patient-retention rate throughout the three years of follow-up (82%).

“LivaNova is deeply committed to advancing epilepsy research and in every study of VNS Therapy to date, we continue to see that effectiveness can be achieved early and continue to improve month by month and visit by visit. This remained true over the course of three years in CORE-VNS,” said Kathryn Nichol, Ph.D., Vice President Global Medical Affairs, LivaNova. “Further, CORE-VNS confirms that VNS Therapy is effective for the most severe focal seizures in pediatric and adult patients. Not all seizures are created equal—this is why evaluating severe focal seizures that may have a larger impact on quality of life and outcomes in people with drug-resistant epilepsy is so important.”

CORE-VNS is the largest prospective study of VNS Therapy ever conducted worldwide. The full, 36-month CORE-VNS study results will be published later this year.

"The strong outcomes from the CORE-VNS study bolster our efforts to narrow the DRE treatment gap, increase access to care, and drive awareness of surgical therapies for this significantly under-addressed patient population,” said Stephanie Bolton, LivaNova President, Global Epilepsy.

About CORE-VNS

CORE-VNS is a real-world, long-term, open-label study focused on the outcomes of VNS Therapy™ in people diagnosed with drug-resistant epilepsy (DRE). Enrolling more than 800 people from 61 worldwide sites, the study is the most comprehensive assessment of the effectiveness of VNS Therapy to date and provides modern insights into the global use of VNS Therapy in the management and control of seizures.

Adverse events in the CORE-VNS study were typical of those reported in the product labeling and experienced following placement of a VNS Therapy device. The most commonly reported (>5%) adverse events overall included respiratory, thoracic, and mediastinal disorders (dysphonia, dyspnea, cough) and general disorders/administration site conditions. See important safety information at VNSTherapy.com/safety.

About VNS Therapy for Epilepsy

VNS Therapy™ is clinically proven safe and effective as an add-on treatment to reduce the frequency of seizures in adults and children as young as 4 years old with drug-resistant epilepsy and partial onset seizures. It is a unique treatment approach developed for people with drug-resistant epilepsy—a condition that affects approximately one in three people with epilepsy. Unlike some other surgical treatment options for people with drug-resistant epilepsy, VNS Therapy implantation involves an outpatient procedure and does not require penetration of the skull. Outside the United States, the VNS Therapy indications for use may vary. For more information, visit VNSTherapy.com.

References

1 *Wheless J, Zafar M, Motamedi G, et al. Focal Onset Seizure Response in Children 4-18 years of age at 24 months – Outcomes from the CORE-VNS Study. Presented at the American Epilepsy Society Annual Meeting, 07 December 2024*

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 CORE registry and VNS Therapy™ for epilepsy. 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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