

## LivaNova Achieves Clinical Milestone in Heart Failure Program

*300th patient randomized in ANTHEM-HFrEF pivotal study*

**London, April 19, 2021** – LivaNova PLC (NASDAQ:LIVN), a market-leading medical technology and innovation company, today announced it has randomized the 300th patient in the **Autonomic Regulation Therapy to Enhance Myocardial Function and Reduce Progression of Heart Failure With Reduced Ejection Fraction (ANTHEM-HFrEF) Pivotal Study**, which was approved by the U.S. Food and Drug Administration (FDA) under the Breakthrough Devices Program.

“Randomization of the first 300 patients represents an important milestone for the ANTHEM-HFrEF Pivotal Study,” said Bruce H. KenKnight, PhD and LivaNova Vice President of the Heart Failure Program. “After the first 300 randomized patients have completed their nine-month follow-up visits and a total of at least 400 patients have been randomized, independent statisticians will begin performing the first in a series of pre-specified interim analyses approved by the FDA. These data will be used to evaluate the use of Autonomic Regulation Therapy (ART) utilizing Vagus Nerve Stimulation (VNS) for the improvement of symptoms, function, morbidity and mortality in patients with heart failure and reduced ejection fraction (HFrEF).”

The LivaNova VITARIA® System has been designed to deliver ART using mild electrical stimulation of the right vagus nerve to increase parasympathetic activity, both centrally and peripherally, which is intended to improve regulation of cardiovascular function, performance and electrophysiological stability in patients with advanced heart failure. If approved for use by the FDA, this bioelectric form of neuromodulation will become the first-in-class device-based therapy for adjunctive treatment of chronic heart failure in the US.

“Many patients remain symptomatic despite guideline-directed medical therapy and, in most cases, symptoms are associated with dysfunction of the autonomic nervous system. This landmark trial being conducted in both the U.S. and Europe was specifically designed in collaboration with the FDA and medical experts to assess the impact of ART on important clinical outcomes, including heart failure symptoms, hospitalization for heart failure and cardiovascular death,” said Dr. Marvin A. Konstam, Chief Physician Executive of the CardioVascular Center at Tufts Medical Center, Professor of Medicine at Tufts University School of Medicine, Boston and Principal Investigator for the ANTHEM-HFrEF Pivotal Study.

To learn more about the ANTHEM HFrEF study, visit [clinicaltrials.org](https://clinicaltrials.org).

## 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 4,000 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](http://www.livanova.com).

## Safe Harbor Statement

This news release contains “forward-looking statements” concerning our 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 ART and our approach to treating heart failure by delivering ART using VNS Therapy. Actual results 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 our Annual Report on Form 10-K for the year ended December 31, 2020, as supplemented by any risk factors contained in our Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K. We undertake no obligation to update the information contained in this press release to reflect subsequently occurring events or circumstances.

## LivaNova Investor Relations and Media Contacts

**Melissa Farina**, +1 (281) 228-7262  
VP, Investor Relations  
[InvestorRelations@livanova.com](mailto:InvestorRelations@livanova.com)

**Deanna Wilke**, +1 (281) 727-2764  
VP, Corporate Communications  
[Corporate.Communications@livanova.com](mailto:Corporate.Communications@livanova.com)

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