LivaNova Launches International Pivotal Study Evaluating Use of Autonomic Regulation Therapy for Heart Failure

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LONDON--(BUSINESS WIRE)--Sep. 18, 2018-- LivaNova PLC (NASDAQ:LIVN), a market-leading medical technology company, today announced the first successful implantation of the VITARIA® System in a patient enrolled in the **A**uto**n**omic Regulation **Th**erapy to **E**nhance **M**yocardial Function and Reduce Progression of **H**eart **F**ailure With **R**educed **E**jection **F**raction (ANTHEM-HFrEF) Pivotal Study. The study is an international, multi-center, randomized trial to evaluate the VITARIA System for the treatment of advanced heart failure. The first implant in the pivotal study was completed at UnityPoint Health – St. Luke's Hospital in Cedar Rapids, Iowa, by Dr. Jared Kray.

"Patients with advanced heart failure continue to need additional and complementary therapy options, since drug treatment alone has slowed but not stopped heart failure progression," said Dr. Ron M. Oren, Heart Failure Cardiologist and Lead Investigator for the Study at the Heart and Vascular Institute in Cedar Rapids, Iowa. "We are pleased to participate in this important study to critically evaluate the safety and efficacy of Autonomic Regulation Therapy delivered by the VITARIA System."

The LivaNova VITARIA System delivers Autonomic Regulation Therapy (ART) using Vagus Nerve Stimulation (VNS) in patients who continue to experience symptoms of heart failure despite receiving guideline-directed medical therapy. The VITARIA System received CE Mark approval in 2015 and received Expedited Access Pathway designation as a breakthrough technology from the U.S. Food and Drug Administration in 2017. The therapy may be the first implantable active neurostimulation system for the treatment of advanced heart failure, if the study demonstrates statistically and clinically meaningful improvements in pre-specified endpoints related to heart failure symptom improvement, hospitalization and survival.

"LivaNova is dedicated to changing lives through the development and introduction of novel technologies, which address large unmet needs in the global medical community. Autonomic Regulation Therapy is based on our market-leading experience derived from VNS Therapy®, which is used to treat other disorders," said Edward Andrle, LivaNova General Manager of Neuromodulation. "The ANTHEM-HFrEF Pivotal Study brings us closer to offering the VITARIA System to a large segment of the more than 20 million people currently battling heart failure around the world."

"Autonomic Regulation Therapy holds promise for patients with advanced heart failure, and we are pleased that this landmark study is underway," said Dr. Marvin Konstam, Principal Investigator for the ANTHEM-HFrEF Pivotal Study and Chief Physician of the CardioVascular Center at Tufts Medical Center in Boston, Mass.

For more information about the VITARIA System and the treatment of heart failure with ART, visit www.ARTforHeartFailure.com.

About LivaNova

LivaNova PLC is a global medical technology company built on nearly five decades of experience and a relentless commitment to improve the lives of patients around the world. LivaNova's advanced technologies and breakthrough treatments provide meaningful solutions for the benefit of patients, healthcare professionals and healthcare systems. Headquartered in London, LivaNova has a presence in more than 100 countries worldwide. The Company currently employs approximately 4,000 employees. LivaNova operates as two businesses: Cardiac Surgery and Neuromodulation, with operating headquarters in Mirandola (Italy) and Houston (U.S.), respectively.

For more information, please visit www.livanova.com.

Safe Harbor Statement

This news release contains forward-looking statements within the meaning of Section 27A of the United States Securities Act of 1933, as amended, and Section 21E of the United States Securities Exchange Act of 1934, as amended. Forward-looking statements are not historical facts but are based on certain assumptions of management and describe LivaNova's future plans, strategies and expectations. Forward-looking statements can generally be identified by the use of forward-looking terminology, including, but not limited to, "may," "could," "seek," "guidance," "predict," "potential," "likely," "believe," "will," "expect," "anticipate," "estimate," "plan," "intend," "forecast," or variations of these terms and similar expressions, or the negative of these terms or similar expressions. Forward-looking statements contained in this news release are based on information presently available to LivaNova and assumptions that LivaNova believes to be reasonable, but are inherently uncertain. As a result, LivaNova's actual results, performance or achievements may differ materially from those expressed or implied by these forward-looking statements, which are not guarantees of future performance or actions that may be taken by LivaNova and involve known and unknown risks, uncertainties and other factors that are, in some cases, beyond LivaNova's control. You should carefully consider the risks and uncertainties that affect LivaNova, including those described in the "Risk Factors" section of LivaNova's Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other documents filed from time to time with the United States Securities and Exchange Commission.

All information in this news release is as of the date of its release. LivaNova does not undertake or assume any obligation to update publicly any of the forward-looking statements in this news release to reflect actual results, new information or future events, changes in assumptions or changes in other factors affecting forward-looking statements, except to the extent required by applicable law. If we update one or more forward-looking statements, no inference should be drawn that we will make additional updates with respect to those or other forward-looking statements. We caution you not to place undue reliance on any forward-looking statements, which are made only as of the date of this news release.

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