

LivaNova, PLC Announces the First U.S. Implants of Perceval, the Only Sutureless Valve for Aortic Valve Replacement Surgery

March 8, 2016 9:00 AM ET

LONDON, March 08, 2016 (GLOBE NEWSWIRE) -- LivaNova, PLC (NASDAQ:LIVN) (LSE:LIVN) (the "Company"), a global medical technology company and a leader in the treatment of cardiovascular diseases, announced the first U.S. implantation of the Perceval valve, the sutureless biological aortic replacement valve.

Performed last week, two valves were implanted by Douglas Johnston, M.D., and Eric Roselli, M.D., Staff Cardiac Surgeons in the Miller Family Heart & Vascular Institute at Cleveland Clinic, in Cleveland, Ohio.

"The availability of a sutureless valve optimizes surgical options to treat aortic valve disease, including minimally invasive approaches. A collapsible device increases the surgeon's visibility of critical structures during the procedure, enhancing safety. This enables a quicker procedure, and the potential to further improve patient outcomes," said Dr. Eric Roselli*, Director of the Aorta Center, Cleveland Clinic Department of Thoracic and Cardiovascular Surgery.

*Dr. Roselli receives honoraria from LivaNova for providing educational programs.

Perceval helps reduce the complexity of aortic valve replacement (AVR) by enhancing the speed and efficiency of the procedure while providing optimized hemodynamic performance. The Perceval valve is designed for any patient requiring an AVR procedure, including high-risk and complex patients. With the absence of a rigid sewing ring and its super-elastic stent, Perceval optimizes the effective orifice area resulting in excellent hemodynamics.ⁱ

When compared to traditional surgical valves, the Perceval valve procedures lead to shorter Intensive Care Unit stays, ventilation time reduction and less blood transfusionⁱⁱ providing benefits to a broad range of patients, including high-risk and complex cases. Overall, Perceval has been shown to lower overall procedural cost compared to traditional sutured valves.ⁱⁱⁱ

"The first U.S. implant of Perceval is a significant milestone for LivaNova, but more importantly, is evidence of the rising innovation in cardiac surgery," said Michel Darnaud, President, Cardiac Surgery Business Unit, LivaNova. "With a commitment to provide advanced therapeutic solutions to surgeons worldwide, we look forward to Perceval's rapid adoption among the U.S. cardiac surgery community."

To date, the Perceval sutureless valve has been implanted in more than 15,000 patients in over 310 Hospitals worldwide. More than 115 publications demonstrate the excellent clinical results obtained with the device.

About LivaNova

LivaNova PLC, headquartered in London, UK, is a global medical technology company formed by the merger of Sorin S.p.A, a leader in the treatment of cardiovascular diseases, and Cyberonics Inc., a medical device company with core expertise in neuromodulation. LivaNova transforms medical innovation into meaningful solutions for the benefit of patients, healthcare professionals, and healthcare systems. The company employs approximately 4,500 employees worldwide. With a presence in more than 100 countries, LivaNova operates as three business units: Cardiac Rhythm Management, Cardiac Surgery, and Neuromodulation, with operating headquarters in Clamart (France), Mirandola (Italy) and Houston (U.S.A.), respectively.

LivaNova is listed on NASDAQ and listed on the Official List of the UK's Financial Conduct Authority and traded on London Stock Exchange (LSE) under the ticker symbol "LIVN".

Safe harbor statement

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933,

as amended and Section 21E of the Securities Exchange Act of 1934, as amended. These statements can be identified by the use of forward-looking terminology, including "may," "believe," "will," "expect," "anticipate," "estimate," "plan," "intend," "forecast," or other similar words. Statements contained in this press release are based on information presently available to LivaNova and assumptions that the parties believe to be reasonable. LivaNova is not assuming any duty to update this information if those facts change or if the assumptions are no longer believed to be reasonable. Investors are cautioned that all such statements involve risks and uncertainties, including without limitation, statements concerning developing novel opportunities in heart failure, sleep apnea and percutaneous mitral valve, creating new innovative solutions that benefit patients, healthcare professionals, and healthcare systems, and building significant shareholder value. Important factors that may cause actual results to differ include, but are not limited to: risks that the new businesses will not be integrated successfully or that the combined companies will not realize estimated cost savings, value of certain tax assets, synergies and growth, or that such benefits may take longer to realize than expected; the inability of LivaNova to meet expectations regarding the timing, completion and accounting and tax treatments; risks relating to unanticipated costs of integration, including operating costs, customer loss or business disruption being greater than expected; reductions in customer spending, a slowdown in customer payments and changes in customer demand for products and services; unanticipated changes relating to competitive factors in the industries in which the company operates; the ability to hire and retain key personnel; the ability to attract new customers and retain existing customers in the manner anticipated; reliance on and integration of information technology systems; changes in legislation or governmental regulations affecting the company; international, national or local economic, social or political conditions that could adversely affect the company or its customers; conditions in the credit markets; risks to the industries in which LivaNova operates that are described in the "Risk Factors" section of the Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and other documents filed from time to time with the SEC by Cyberonics, Inc. and LivaNova and the analogous section in annual reports and other documents filed from time to time by Sorin S.p.A. with the Italian financial market regulator (CONSOB); risks associated with assumptions made in connection with critical accounting estimates and legal proceedings; LivaNova's international operations, which are subject to the risks of currency fluctuations and foreign exchange controls; and the potential of international unrest, economic downturn or effects of currencies, tax assessments, tax adjustments, anticipated tax rates, raw material costs or availability, benefit or retirement plan costs, or other regulatory compliance costs. The foregoing list of factors is not exhaustive. You should carefully consider the foregoing factors and the other risks and uncertainties that affect the parties' businesses, including those described in Cyberonics' Annual Report on Form 10-K, as amended from time to time, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other documents filed from time to time with the SEC by Cyberonics and LivaNova and those described in Sorin's annual reports, registration documents and other documents filed from time to time with CONSOB by Sorin. LivaNova does not give any assurance (1) that LivaNova will achieve its expectations, or (2) concerning any result or the timing thereof, in each case, with respect to any regulatory action, administrative proceedings, government investigations, litigation, warning letters, consent decree, cost reductions, business strategies, earnings or revenue trends or future financial results.

For more information, please visit www.livanova.com, or contact:

Investor Relations and Media:

Karen King

Vice President, Investor Relations & Corporate Communications

Phone: +1 (281) 228-7441

Fax: +1 (281) 853-2537

e-mail: corporate.communications@livanova.com

References

¹ Shrestha M, Fischlein T, Meuris B, et al. European multicentre experience with the sutureless Perceval valve: clinical and haemodynamic outcomes up to 5 years in over 700 patients[†]. *Eur J Cardiothoracic Surg.* 2016 Jan;49(1):234-41.

ii Santarpino G, Pfeiffer S, Concistré G, et al. The Perceval S aortic valve has the potential of shortening surgical time: does it also result in improved outcome? *Ann Thorac Surg.* 2013;96:77-81.

iii Pollari F, Santarpino G, Dell'Aquila AM, et al. Better short-term outcome by using sutureless valves: a propensity-matched score analysis. *Ann Thorac Surg.* 2014;98:611-6.



LivaNova Plc