LivaNova PLC Announces the First Patient Enrolled in the PERSIST-AVR Trial

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New International Study Evaluates Perceval, the First Truly Biological Sutureless Valve, for Patients Requiring Aortic Valve Replacement Surgery

LONDON, April 04, 2016 (GLOBE NEWSWIRE) -- LivaNova, PLC (NASDAQ:LIVN) (LSE:LIVN) (the "Company"), a global medical technology company, announced today the first implant of the Perceval sutureless valve in the ***PERSIST-AVR*** (**Per**ceval **S**utureless **I**mplant Vs **St**andard **A**ortic **V**alve **R**eplacement) trial at CHU Brabois, University of Lorraine, Nancy, France. Engineered to restore the natural valve performance, Perceval is a sutureless heart valve for patients who require replacement of their aortic valve.

PERSIST-AVR is the first worldwide, prospective, randomized, multi-center trial, comparing Perceval sutureless aortic valve with standard sutured bioprostheses in patients with aortic valve disease. The study will enroll over 1,200 patients with severe symptomatic aortic stenosis or steno-insufficiency in patients who are candidates for surgical replacement of their native aortic valve. The primary endpoint of the trial is non-inferiority of Major Adverse Cardiac Cerebrovascular Events (MACCE) at one year according to VARC-2 criteria.[1]

"The clinical experience with the Perceval valve has been positive on multiple fronts as measured by reduced cross-clamp time, great hemodynamic performance, low structural valve deterioration and freedom from reoperation up to five-year follow-up.[2] PERSIST-AVR is designed to confirm these results compared to standard sutured stented valves. Moreover, the trial will demonstrate how the use of Perceval in aortic valve surgery is linked with significant cost savings, driven primarily by reduced procedural costs and reduced hospital stay," said Professor Thierry Folliguet, M.D., Ph.D., who enrolled the first patient in PERSIST-AVR. Prof. Folliguet is part of the Steering Committee of the study and one of the early implanters of Perceval.

Conducted worldwide, the study is planned to have a two-year enrollment period and a yearly follow-up for a five-year period. The primary endpoint is expected to be available in 2019.

"We know that PERSIST-AVR is a landmark clinical trial, being the first randomized study in 30 years in the field of valvular surgery. Its initiation is a great endeavor in the cardiac surgery communities. More than 60 centers around the world will be recruited pointing out the strong interest generated by Perceval. We look forward to obtaining promising data for the use of Perceval in the daily aortic valve replacement setting," said Professor Theodor Fischlein, M.D., Ph.D., Paracelsus Medical University Cardiovascular Center, Nuremberg, Germany, and Dr. Roberto Lorusso, M.D., Ph.D., Cardio-Thoracic Surgery Department, Maastricht University Medical Centre (MUMC+), Maastricht, The Netherlands, both principal investigators of the study.

"As the first trial of its kind, the PERSIST-AVR study is a significant milestone for LivaNova, the healthcare community and patients worldwide," said Michel Darnaud, President, Cardiac Surgery B.U., LivaNova, PLC. "We are proud to support this important trial. We anticipate its results could significantly impact daily practice and establish the Perceval sutureless valve as the prosthesis of choice for future heart valve surgeries."

To date, the Perceval sutureless valve has been implanted in more than 15,000 patients in over 310 hospitals worldwide. More than 115 publications testify the good clinical results obtained with the device. The Perceval valve is approved for use in Europe, US and other international markets including Canada and Australia.

References

[1] Kappetein, A. P., Head S. J., Genereux P., et al. "Updated Standardized Endpoint Definitions for Transcatheter Aortic Valve Implantation: The Valve Academic Research Consortium-2 Consensus Document." *J Thorac Cardiovasc Surg* 145,

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[2] 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 Cardiothorac Surg. 2016 Jan;49(1):234-41

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

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