

## **LivaNova PLC Announces FDA Approval of Stented Heart Valve CROWN PRT™ for Aortic Valve Disease**

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### **LivaNova Demonstrates Commitment to Advancing Cardiac Surgery Through Broad Portfolio of Aortic Valve Replacement Solutions**

LONDON, Feb. 01, 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, today announced it has been granted approval from the United States Food and Drug Administration (FDA) for its [innovative stented aortic bioprosthesis CROWN PRT](#) for the treatment of aortic valve disease. This is the second valve to be approved in the U.S. this year and is expected to be launched in the coming months. LivaNova’s Perceval valve, the sutureless biological valve on the market for aortic valve replacement procedures, was approved on January 8, 2016.

The CROWN PRT is the latest advancement in stented aortic bioprosthesis technology and features a surgeon-friendly design, optimizing hemodynamics and the patented Phospholipid Reduction Treatment (PRT), which was designed to enhance valve durability. As a high-performing, durable valve, CROWN PRT is an ideal aortic valve replacement option for older patients.

“CROWN PRT is a modern bioprosthesis enabling a simple, safe, reliable and reproducible cardiac surgery procedure for patients in need of an aortic valve replacement,” said Prof. Rainald Seitelberger, M.D., Salzburg University Clinic in Austria. “Data have shown that phospholipids play an important role in the calcification process of bioprosthesis, and LivaNova’s CROWN PRT has proven to decrease phospholipid content in the tissue<sup>1</sup> leading to superior valve longevity. CROWN PRT’s durability, along with its ease of use during procedures and ability to provide excellent hemodynamic performance, makes it an ideal valve for current and future aortic valve replacements.”

CROWN PRT enables intuitive intraoperative handling through enhanced ease of implant with visible markers and improved radiographic visualization through dedicated X-ray markers. The stented aortic heart valve replacement is strategically designed to provide physicians with greater surgical versatility and provides patients a long-lasting valve replacement.

“LivaNova is excited to launch CROWN PRT with its outstanding hemodynamic performance and durability, and we look forward to its adoption in the dynamic and evolving market of cardiac surgery,” said Michel Darnaud, President, LivaNova Cardiac Surgery Business Unit. “With nearly 50 years of experience in heart valve design and innovation, LivaNova is proud to be the only cardiac surgery company offering the most comprehensive spectrum of heart valves available in the U.S., including sutureless, stented and stentless valves. The introduction of our state-of-the-art aortic valve technologies, CROWN PRT and Perceval valve, reflects LivaNova’s commitment to providing cardiac surgery treatments that optimize a surgeon’s ability to deliver the best care possible to their patients.”

To learn more about LivaNova and its broad range of cardiac surgery solutions, including the Perceval and CROWN PRT, please visit: [www.livanova.com](http://www.livanova.com).

References: <sup>1</sup> Based on 60-day animal model. Data on file.

#### **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](http://www.livanova.com), or contact:

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