SonR: 35% Risk Reduction in Heart Failure Hospitalization

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RESPOND-CRT LANDMARK TRIAL REVEALS A REDUCED RISK IN HEART FAILURE HOSPITALIZATION WITH LIVANOVA'S EXCLUSIVE SONR SENSOR-BASED CRT OPTIMIZATION SYSTEM

LONDON, May 05, 2016 (GLOBE NEWSWIRE) -- LivaNova, PLC (NASDAQ:LIVN) (LSE:LIVN), a market-leading medical technology and innovation company, today announced results from the RESPOND-CRT clinical trial, showing that a 35% risk reduction in heart failure hospitalization was associated with SonR.

The RESPOND-CRT trial was designed to investigate the clinical efficacy and safety of device-based optimization using the SonR cardiac contractility sensor in patients with advanced heart failure. The results, announced today by Prof. Josep Brugada at an oral late breaking presentation during the annual Heart Rhythm Society Meeting, showed that the study successfully met its primary and secondary end points.

The proprietary SonR optimization system allows for cardiac resynchronization therapy to be continuously adapted to the needs of each patient, thus delivering individualized therapy.

In the RESPOND-CRT trial, optimization with SonR was compared to optimization using echocardiography. Even though echo-guided optimization was considered best practice in terms of reducing the number of non-responders to CRT, it has never been widely adopted in routine practice because of the significant resource consumption it requires.

The overall positive response to CRT reached in the group of patients treated with SonR was 75%, a reduction of approximately 16% in non-responders versus the echo group. In addition to a global favorable effect on long-term heart failure hospitalization, optimization with SonR resulted in a significant improvement in clinical response for patients with a history of atrial fibrillation or renal dysfunction.

"In order to deliver the very best CRT treatment to our heart failure patients, there has been a real need for an optimization solution that is both automatic and efficient," said Prof. Josep Brugada, MD, PhD, Cardiovascular Institute, Hospital Clínic, University of Barcelona, Spain. "Today the results of the RESPOND-CRT trial have shown that SonR perfectly meets this need. The high rates of responders together with the beneficial improvements in clinical outcomes indicate a significant advancement in CRT therapy, one that will allow us to better treat a larger number of heart failure patients."

"SonR is a great example of LivaNova's commitment to developing innovative medical technology that really matters, and we would like to thank the participating centers and the several independent committees for their great support in this landmark study," said Stefano Di Lullo, LivaNova, President of the CRM Business Unit. "The RESPOND-CRT trial results offer our CRM business a unique growth opportunity while helping physicians treat patients with heart failure globally."[1]

About the RESPOND-CRT Trial

The RESPOND-CRT study is a prospective, multicenter, randomized, double-blind study designed to evaluate the safety and efficacy of the SonR system. The trial enrolled 1,039 patients at 125 sites in Europe, US and Australia who were implanted with a CRT-D device. Patients were randomized 2:1 to receive either AV or VV optimization with SonR or echocardiography. The primary analyses were performed at 12 months.

The RESPOND-CRT trial is an Investigation Device Exemption (IDE) study approved by the Food and Drug Administration (FDA).

The study met all of its primary safety and efficacy end points.

The SonRtip lead was proven to be safe, with only 1% of patients reporting lead dislodgement and 0.1% of patients reporting lead fracture.

Optimization with SonR was proven to be as effective as echo-guided optimization based on responder rates. Patients were defined as responders at 12 months based on a hierarchical set of criteria as follows: alive, free from heart failure events, with an improved NYHA functional class or quality of life. Responder rates were 75% in the SonR arm and 70.4% in the Echo arm with the P value [P <0.0001] of the non-inferiority test showing that SonR is as effective as AV and VV echo-guided CRT optimization.

The design of the trial has been published in the American Heart Journal, 2014.[2]

About SonR contractility sensor

The SonR sensor uses measurements of cardiac contractility in order to optimize cardiac resynchronization therapy. The SonR cardiac contractility sensor consists of a micro accelerometer embedded in the tip of the SonRtip atrial lead. The sensor continuously measures the vibrations generated by the myocardium during cardiac contractions which are correlated to cardiac contractility. [3,4,5]

The SonRtip lead is connected to a LivaNova CRT-D device featuring an algorithm which automatically adapts the atrioventricular (AV) and interventricular (VV) intervals based on cardiac contractility measurements. Optimization is performed on a weekly basis both at rest and during exercise. This allows for cardiac resynchronization therapy to be continuously adapted to the individual needs of each patient.

SonR technology is available exclusively in LivaNova CRT-D devices including the Paradym, Intensia and Platinium families. The new Platinium CRT-D SonR device was launched in Europe in November 2015.

References

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About LivaNova

LivaNova PLC 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 4,600 employees worldwide and is headquartered in London, U.K. With a presence in more than 100 countries, LivaNova operates as three business units: Cardiac Surgery, Cardiac Rhythm Management, and Neuromodulation, with operating headquarters in Clamart (France), Mirandola (Italy) and Houston (U.S.), respectively.

LivaNova is listed on NASDAQ and is admitted to the standard listing segment of the Official List of the UK's Financial Conduct Authority and to trading on the 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 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 the Company'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 press release are based on information presently available to LivaNova and assumptions that the Company believes to be reasonable, but are inherently uncertain. As a result, our 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 and involve known and unknown risks, uncertainties and other factors that are, in some cases, beyond the Company's control. Investors are cautioned that all such statements involve risks and uncertainties, including without limitation, statements concerning developing novel opportunities in neuromodulation, 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: (i) risks that the legacy businesses of Cyberonics, Inc. and Sorin S.p.A. (together, the "combined companies") 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; (ii) the inability of LivaNova to meet expectations regarding the timing, completion and accounting of tax treatments; (iii) risks relating to unanticipated costs of integration, including operating costs, customer loss or business disruption being greater than expected; (iv) our organizational and governance structure; (v) reductions in customer spending, a slowdown in customer payments and changes in customer demand for products and services; (vi) unanticipated changes relating to competitive factors in the industries in which LivaNova operates; (vii) the ability to hire and retain key personnel; (viii) the ability to attract new customers and retain existing customers in the manner anticipated; (ix) the reliance on and integration of information technology systems; (x) changes in legislation or governmental regulations affecting LivaNova; (xi) international, national or local economic, social or political conditions that could adversely affect LivaNova, its partners or its customers; (xii) conditions in the credit markets; (xiii) business and other financial risks inherent to the industries in which LivaNova operates; (xiv) risks associated with assumptions made in connection with critical accounting estimates and legal proceedings; (xv) LivaNova's international operations, which are subject to the risks of currency fluctuations and foreign exchange controls; (xvi) 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 Company's business, including those described in the "Risk Factors" section of Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, the Registration Statement on Form S-4 and other documents filed from time to time with the United States Securities and Exchange Commission by LivaNova. 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.

All information in this press release is as of the date of its release. The Company does not undertake or assume any obligation to update publicly any of the forward-looking statements in this press 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 press release.

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