

SonR™: Long Term Clinical Update Confirms Risk Reduction in Heart Failure Hospitalization

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RESPOND-CRT landmark trial confirms significant long term risk reduction in heart failure hospitalization with LivaNova's exclusive SonR sensor-based CRT optimization system

LONDON, Aug. 28, 2016 (GLOBE NEWSWIRE) -- LivaNova PLC (NASDAQ:LIVN) (LSE:LIVN) ("LivaNova" or the "Company"), a market-leading medical technology company, today announced long term results from the RESPOND-CRT clinical trial after an 18 month follow-up period. The results were presented by the principal investigator, Prof. Josep Brugada, at an oral Clinical Trial Update session during the annual European Society of Cardiology (ESC) meeting. The RESPOND-CRT trial was designed to investigate the clinical efficacy and safety of device-based optimization using LivaNova's proprietary SonR cardiac contractility sensor technology in patients with advanced heart failure.

Previously, on May 5, 2016, LivaNova announced the RESPOND-CRT one-year results at the annual Heart Rhythm Society (HRS) and subsequently published a [press release](#). The one-year data showed that the study met its primary safety and efficacy end points and demonstrated that SonR was associated with a 35% risk reduction in heart failure hospitalization.

Automatic optimization with SonR was compared to manual echocardiography guided optimization. The proprietary SonR optimization system allows for cardiac resynchronization therapy to be continuously adapted to the needs of each patient, thus delivering an individualized therapy.

Longer term results, after a complete 18 months patient follow-up, confirmed the significant risk reduction in heart failure hospitalization on the overall population enrolled in the study. Additionally, in subgroups of patients with atrial fibrillation and renal dysfunctions, a 48% and 41% risk reduction in cardiovascular death or hospitalization was observed with SonR, respectively.

"We are very pleased to observe the consistent long-term clinical benefits of the SonR optimization system," said Prof. Josep Brugada, MD, PhD, Cardiovascular Institute, Hospital Clínic, University of Barcelona, Spain. "Reduction of hospitalization is key for heart failure patients. The impressive improvements in cardiovascular clinical outcomes for patients with atrial fibrillation or renal dysfunction show that SonR can treat even better the sicker patients."

"The successful outcomes of the RESPOND-CRT study provides important data that we are pleased to share with the healthcare community," said Benoît Clinchamps, LivaNova, Vice President, General Manager CRM. "LivaNova is committed to developing and delivering safe and effective technology to better treat heart failure patients. The SonR sensor-based optimization system fully resonates with this commitment."

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 AV or VV optimization either with SonR or echocardiography. The primary analyses were performed at 12 months, secondary analysis were performed at 18 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 [P <0.0001 non-inferiority].

The design of the trial has been published in the American Heart Journal, 2014.¹

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.^{2,3,4}

The SonR tip 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 Platinum families. The new Platinum 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 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 our 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 LivaNova 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. Investors are cautioned that all such statements involve risks and uncertainties, including without limitation, the factors 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, and/or announced or published pursuant to the rules of, the United States Securities and Exchange Commission and/or the United Kingdom Financial Conduct Authority by LivaNova, together with the risk that our internal leadership and organizational realignment will not lead to intended improvements, efficiency or results. This list of factors is not exhaustive. LivaNova does not give any assurance (1) that LivaNova will achieve its expectations, or (2) concerning any result or the timing thereof.

All information in this press 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 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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