Regulatory Approval

January 11, 2016 9:08 AM ET

LONDON, January 11, 2016 -- LivaNova PLC (NASDAQ:LIVN) (LSE:LIVN) (the "Company") announced that, on January 8, 2016, the Company received approval from the United States Food and Drug Administration ("FDA") for the Perceval Sutureless Heart Valve ("Perceval"). The approval is effective immediately, and the Company will begin commercial distribution of the device in the U.S. over the coming quarter.

Perceval is a surgical aortic valve with a unique self-anchoring frame that enables the surgeon to replace the diseased valve without suturing it into place. The valve's functional component is made of bovine pericardium and is mounted on a super-elastic alloy frame. Clinical results in patients implanted with Perceval have shown a significant reduction in surgical procedural time for both isolated and complex aortic valve replacement with aortic cross-clamp times typically reduced by at least 50%.

"We are excited to bring this important product to the U.S. market, which will provide real value to patients and physicians," said André-Michel Ballester, Chief Executive Officer. "The rapid acceptance of Perceval in Europe, an increasing number of positive publications on the product, and the solid preparation of our U.S. sales team, all provide a strong base for the achievement of our short and long term plans," concluded Mr. Ballester.

Perceval is indicated for the replacement of diseased, damaged, or malfunctioning native or prosthetic aortic valves. The sale and distribution of the Perceval heart valve is limited to prescription use by specially-trained practitioners, and the Company has developed a nationwide training and proctoring program to help ensure the safety and effectiveness of 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".

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

Investor Relations:
Vivid Sehgal
Chief Financial Officer
e-mail: investor.relations@livanova.com

Investor Relations and Media:
Greg Browne
Senior Vice President, Finance
Phone: +1 (281) 228-7262
Fax: +1 (281) 218-9332
e-mail: corporate.communications@livanova.com

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