Livanova Welcomes Nice Interventional Procedures Guidance on Sutureless Aortic Valve Replacement

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Announcement comes as Company completes enrollment in PERSIST-AVR Trial for Perceval sutureless aortic valve

LONDON--(BUSINESS WIRE)--Sep. 10, 2018-- LivaNova PLC (NASDAQ:LIVN), a market-leading medical technology company, welcomes the recently updated interventional procedures guidance for sutureless aortic valve replacement issued by the U.K. National Institute for Health and Care Excellence (NICE), which states that sutureless aortic valve replacement is an alternative to conventional surgical aortic valve replacement. The NICE guidance comes as LivaNova completes enrollment for a global aortic valve replacement clinical trial comparing the benefits of sutureless versus standard aortic valve replacement for aortic stenosis.

Based on its evaluation, NICE concludes that the sutureless aortic valve replacement procedure may be faster than the standard procedure, reducing cardiopulmonary and aortic cross-clamp times. Additionally, sufficient evidence was found to support the safety and efficacy of the sutureless procedure. The guidance was informed by a comprehensive assessment of literature and detailed review of evidence from various sources, including six systematic reviews and meta-analyses and two case series. The review also included patient feedback and considered outcomes such as quality of life, valve durability and clinical improvements.

Concurrently, LivaNova completed enrollment for the **Per**ceval®**S**utureless **I**mplant vs. **St**andard **A**ortic **V**alve **R**eplacement (PERSIST-AVR) study with more than 900 patients from 47 centers in 12 countries. While the original study protocol was for 1,234 patients, the introduction of an innovative adaptive design allowed for a reduced sample size and the ability to analyze data earlier. PERSIST-AVR, which began in April 2016, is the only worldwide, prospective, randomized, multi-center trial comparing the LivaNova Perceval sutureless aortic valve with standard sutured bioprostheses in patients with aortic valve disease.

The principal investigators for PERSIST-AVR are Professor Theodor Fischlein, M.D., Ph.D., Paracelsus Medical University Cardiovascular Center, Nuremberg, Germany, and Professor Roberto Lorusso, M.D., Ph.D., Cardio-Thoracic Surgery Department, Maastricht University Medical Centre, Maastricht, The Netherlands. “The speed of recruitment and global engagement is a solid statement for the adoption of Perceval around the world,” said Fischlein. Lorusso added, “This release of data will certainly support our daily experience of aortic valve replacement with Perceval.”

Since 2007, Perceval has been implanted in thousands of patients with aortic valve disease to help improve their lives.

“Our Perceval sutureless aortic valve is one of our important growth drivers and continues to offer surgeons and patients a proven alternative with unique benefits compared to traditional aortic valve replacement,” said Alistair Simpson, LivaNova General Manager of Cardiac Surgery. “The updated NICE guidance and completion of our PERSIST-AVR clinical trial enrollment are key milestones that will support an even greater adoption rate.”

For more information on the NICE guidance, visit https://www.nice.org.uk/guidance/ipg624.

About LivaNova

LivaNova PLC is a global medical technology company built on nearly five decades of experience and a relentless commitment to improve the lives of patients around the world. LivaNova’s advanced technologies and breakthrough treatments provide meaningful solutions for the benefit of patients, healthcare professionals and healthcare systems. Headquartered in London, LivaNova has a presence in more than 100 countries worldwide. The Company currently employs approximately 4,000 employees. LivaNova operates as two businesses: Cardiac Surgery and Neuromodulation, with operating headquarters in Mirandola (Italy) and Houston (U.S.), respectively.

For more information, please visit www.livanova.com.

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LivaNova PLC
Deanna Wilke, +1 (281) 727-2764
Director, Corporate Communications
corporate.communications@livanova.com