LivaNova

Health innovation that matters

NEWS RELEASE

New Data on LivaNova Perceval Sutureless Aortic Valve Show Consistent Outcomes, Lower Procedure Times Compared to Sutured Valves

PERSIST-AVR study results presented at American Association for Thoracic Surgery Annual Meeting

London, May 28, 2020 – LivaNova PLC (NASDAQ:LIVN), a market-leading medical technology and innovation company, presented the first data from the Perceval® Sutureless Implant Versus Standard-Aortic Valve Replacement (PERSIST-AVR) clinical study at the 100th Annual Meeting of the American Association of Thoracic Surgery (AATS). The study demonstrated that the Company's sutureless surgical aortic valve, Perceval, is a reliable and essential technology to treat aortic valve disease.

Prof. Theodor Fischlein, Director of the Department of Cardiac Surgery at Paracelsus Medical University (PMU) Cardiovascular Center, Nuremberg Clinic, presented the new data. Commenting on the findings, Prof. Fischlein said, "The PERSIST-AVR trial showed that in patients with severe symptomatic aortic valve stenosis who were undergoing open-heart aortic valve replacement, a sutureless valve was noninferior to stented valves with respect to Major Adverse Cerebral and Cardiovascular Events (MACCE) at one year. These findings represent that Perceval should be considered as an important addition to any comprehensive valve program."

PERSIST-AVR is the first prospective, randomized, multi-center international trial comparing Perceval outcomes with those of standard sutured valves. The study comes after more than 300 peer-reviewed publications providing clinical results obtained with Perceval. From March 2016 to September 2018, 910 patients in 12 countries were enrolled in PERSIST-AVR. These patients had severe symptomatic aortic valve stenosis. They were undergoing open-heart aortic valve replacement (AVR), with and without coronary artery bypass grafting, and included patients receiving conventional or mini-sternotomy.

Perceval was found to be noninferior to, or equally as safe and effective as, sutured AVR with respect to the primary endpoint demonstrating freedom from MACCE at 91.6% for the Perceval group and 92.0% for the sutured AVR group. Additionally, the rate of early death after one year was low (1% in both groups) considering the need for coronary artery bypass grafting in almost one-quarter of the patient cohort.

The study showed that the use of Perceval sutureless AVR resulted in significantly lower procedure times. Cardiopulmonary bypass procedure times for isolated AVR and AVR combined procedures were shortened by 22% and 18%, respectively. Cross-clamp time for isolated AVR and AVR combined procedures was reduced by 30% and 21%, respectively. Further, significant improvement of functional status after surgery (using the New York Heart Association Functional Classification) and benefits persisted at one year.

In the control arm of the study, various stented AVR models in five sizes were used based on surgeon preference. The sutureless valve arm used four sizes of Perceval valves. Importantly, no difference was found with regard to paravalvular and central leak, demonstrating that Perceval ensures sealing at the aortic annulus equivalent to sutured valves. The rate of reintervention, stroke, endocarditis or other valve-related complications was also low in both groups. Implant success rates were statistically comparable, validating that Perceval allows for a safe and reproducible implant procedure. PERSIST-AVR data showed a higher permanent pacemaker implantation (PPI) rate with sutureless valves compared to sutured AVR, especially for the largest size valve. PPI has been found to be substantially reduced with modified intraoperative approaches and an emphasis on proper valve sizing.[1,2]

“The PERSIST-AVR data demonstrate that the Perceval sutureless aortic valve replacement is as safe and effective as traditional sutured valves. We are pleased with the findings from this important study, which validate many critical benefits of Perceval,” said Dr. Brian Duncan, Vice President of Medical Affairs at LivaNova. “We continue to pursue innovation for our heart valve technologies and have introduced design enhancements with the next-generation Perceval Plus™ valve to mitigate PPI rates and further advance treatment of aortic valve stenosis. We are seeing very promising initial results, building on our strong body of evidence from clinical experience with Perceval, which now extends to more than 13 years.”

Now with the primary endpoint achieved and with up to three years of data from the study, long-term follow-up will be discontinued for PERSIST-AVR and emphasis will be placed on the study results analysis and the Company’s next-generation valve, Perceval Plus.

To date, more than 50,000 patients worldwide have been treated with the Perceval valve. To learn more about Perceval, visit www.livanova.com**.**

About LivaNova

LivaNova PLC is a global medical technology and innovation company built on nearly five decades of experience and a relentless commitment to provide hope for patients and their families through innovative medical technologies, delivering life-changing improvements for both the Head and Heart. Headquartered in London, LivaNova employs approximately 4,000 employees and has a presence in more than 100 countries for the benefit of patients, healthcare professionals and healthcare systems worldwide. LivaNova operates as two businesses: Cardiovascular and Neuromodulation, with operating headquarters in Mirandola (Italy) and Houston (U.S.), respectively.

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

Safe Harbor Statement

This news release contains "forward-looking statements" concerning our goals, beliefs, expectations, strategies, objectives, plans and underlying assumptions and other statements that are not necessarily based on historical facts. These statements include, but are not limited to, statements regarding Perceval and findings from the PERSIST-AVR clinical study. Actual results may differ materially from those indicated in our forward-looking statements as a result of various factors, including those factors set forth in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2019, as supplemented by any risk factors contained in our Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K. We undertake no obligation to update the information contained in this press release to reflect subsequently occurring events or circumstances.

References

1. *Yanagawa et al. A simple modification to lower incidence of heart block with sutureless valve implantation J Thorac Cardiovasc Surg. 2016;152:630-632.*

2. *Vogt et al. Sutureless Aortic Valve and Pacemaker Rate: From Surgical Tricks to Clinical Outcomes. The Annals of thoracic surgery. 2019;108:99-105.*

LivaNova PLC Media Contact

Deanna Wilke, +1 (281) 727-2764
VP, Corporate Communications
Corporate.Communications@livanova.com

###