

LivaNova Presents New Data at European Association for Cardio-Thoracic Surgery Annual Meeting Demonstrating Benefits of Perceval Sutureless Valve

New PERSIST-AVR study results and SURE-AVR registry data analysis underscore utility of Perceval as a minimally invasive surgical approach for patients with aortic valve stenosis

London, October 12, 2020 – LivaNova PLC (NASDAQ:LIVN) a market-leading medical technology and innovation company, today announced new data from the [Perceval® Sutureless Implant Versus Standard-Aortic Valve Replacement \(PERSIST-AVR\) clinical study](#) and the [Sorin Universal Registry on Aortic Valve Replacement \(SURE-AVR\)](#). Results from a PERSIST-AVR sub-analysis demonstrated better clinical outcomes for patients with aortic valve stenosis who received the Perceval sutureless surgical aortic valve via minimally invasive cardiac surgery (MICS) than patients who received a stented valve through the same access. Data from a SURE-AVR sub-analysis further supported positive findings for Perceval using MICS or full sternotomy. The results were presented during a series of presentations at the [34th Annual Meeting of the European Association for Cardio-Thoracic Surgery \(EACTS\)](#).

“The new PERSIST-AVR data presented at EACTS highlight that the Perceval valve is a reliable and essential technology to be considered as part of any comprehensive valve program and an essential complement to transcatheter technology. Due to its innovative sutureless design, Perceval facilitates minimally invasive cardiac surgery and offers these patients significant benefits such as decreased procedure times, fewer complications and fewer re-hospitalizations,” said Dr. Brian Duncan, Vice President of Medical Affairs at LivaNova. “New findings from SURE-AVR presented at EACTS further demonstrate important benefits from innovation in our next-generation Perceval Plus valve resulting in improved patient outcomes.”

PERSIST-AVR Clinical Study

The prospective, randomized, multi-center, international PERSIST-AVR study assessed the safety, efficacy and noninferiority of the sutureless Perceval valve compared with standard stented bio-prostheses using conventional or mini-sternotomy. A total of 910 patients with severe symptomatic aortic valve stenosis were enrolled in 12 countries. A total of 578 patients underwent isolated aortic valve replacement (AVR).

PERSIST-AVR results presented during EACTS showed that patients who received Perceval during a mini-sternotomy in isolated AVR had a significantly lower incidence of:

- Major adverse cardiovascular and cerebrovascular events (MACCEs) – 5.2% of the Perceval group versus 10.8% of the stented valve group
- New onset of atrial fibrillation – 4.2% in the Perceval group versus 11.4% in the stented valve group
- Stroke – 1% in the Perceval group versus 5.4% in the stented valve group

Prof. Roberto Lorusso, Full Professor in the Cardio-Thoracic Surgery Department of the Maastricht University Medical Centre, the Netherlands, presented the new PERSIST-AVR data. “In this sub-cohort, Perceval significantly reduced MACCEs at one-year follow up, reduced re-hospitalization days and demonstrated a 30% reduction in cross-clamping time, providing patients with a minimally invasive and less traumatic surgical solution compared to stented valves,” said Prof. Lorusso. “This

data is encouraging as it provides further evidence that Perceval facilitates MICS and simplifies complex procedures when time matters.”

SURE-AVR Registry

The ongoing, prospective, international SURE-AVR registry used real-world data to compare outcomes of patients who received Perceval using MICS or conventional full sternotomy. SURE-AVR is collecting data on outcomes from patients at 60 sites in 18 countries. One sub-analysis presented at EACTS was based on data from 980 isolated AVR patients at 52 international institutions. A total of 676 patients underwent MICS and 304 received a full sternotomy. Results showed that Perceval enables MICS, providing a rate of successful implantation similar to that of full sternotomy.

Dr. Marco Solinas, Cardiac Surgeon, G. Monasterio Foundation Heart Hospital, Massa, Italy, presented the SURE-AVR registry data at EACTS. “These real-life results from an international registry showed that implanting Perceval during MICS resulted in significantly shorter ICU stays than a complete sternotomy and that Perceval in isolated AVR is associated with early- and mid-term good clinical and hemodynamic results both in MICS and full sternotomy,” said Dr. Solinas. “Furthermore, Perceval in MICS results in comparable cross-clamping time to full-sternotomy, eliminating the main concern for broader MICS adoption and reinforcing the role of Perceval as a MICS enabler.”

Analysis of the SURE-AVR registry also provided initial real-world clinical performance data of the Perceval Plus™ valve. Perceval Plus is designed to enhance the Perceval platform by decreasing permanent pacemaker implantation (PPI) rates and improving durability, further advancing the treatment of aortic valve stenosis. Of patients enrolled in SURE-AVR between March 2011 and February 2020, 1,374 underwent AVR with the Perceval valve and 121 with the Perceval Plus valve.

PD Dr. Maximilian Scherner, Department of Cardiac and Thoracic Surgery, University Hospital Magdeburg, Germany, presented data from SURE-AVR related to Perceval Plus during EACTS. “Perceval Plus further improved patient outcomes with reduced pacemaker implantation rates compared to Perceval, while both valves were associated with overall low morbidity and mortality,” said PD Dr. Scherner. “Changes to the design did not impact the sealing at the annulus, and both Perceval and Perceval Plus demonstrated a low percentage of paravalvular regurgitation.”

LivaNova received CE Mark for Perceval in 2011 followed by U.S. Food and Drug Administration approval in 2016. The company received CE Mark for Perceval Plus in 2018. To date, more than 50,000 patients worldwide have been treated with the Perceval valve. To learn more about Perceval and Perceval Plus, 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, Perceval Plus and findings from the PERSIST-AVR clinical study and SURE-AVR registry. 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.

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