LivaNova

Health innovation that matters

NEWS RELEASE

New Studies in the U.S. and Europe demonstrate LivaNova Perceval Valve's Strong Performance and Economic Advantage in Aortic Disease Treatment

Recently published data reinforces the ability of Perceval to optimize the surgical approach to aortic valve replacement

London, January 17, 2018 – LivaNova PLC (NASDAQ:LIVN), a market-leading medical technology company, today announced the publication of three separate studies highlighting the unique performance of its sutureless aortic valve, Perceval®.

The results from the Perceval Aortic Heart Valve Study in North America, performed under a U.S. Food and Drug Administration (FDA) Investigational Device Exemption (IDE), were published in the Journal of Thoracic and Cardiovascular Surgery[1]. The study confirmed that Perceval achieves positive safety and efficacy outcomes whether or not an open or minimally invasive surgical approach is used. The multi-center, prospective, non-randomized, single-arm clinical trial included 300 patients from 18 U.S. centers.

The primary endpoints of this landmark study included safety (mortality and morbidity) and effectiveness (clinical status, hemodynamic performance and quality of life) at one year and highlighted positive outcomes for Perceval, including:

- Substantial functional improvement with 97.6% of patients in New York Heart Association (NYHA) class I/II after surgery.
- Significant improvement in quality of life metrics.
- Overall low hospital mortality (1.3%) and rate of ≥ moderate paravalvular leak (1.3%).

In addition, two separate articles were recently published and serve as further proof of the favorable economic profile of the Perceval valve.

1 Suri et al, "Prospective US Investigational Device Exemption Trial of a Sutureless Aortic Bioprosthesis: One-Year Outcomes", JTCVS 2018 – Article in press, DOI: https://doi.org/10.1016/j.jtcvs.2018.08.121

The second article[2] compares costs associated with the Perceval sutureless valve to those of traditional sutured valves. In the study at the Poliambulanza Hospital in Brescia, Italy, Perceval was assigned to patients at higher surgical risk, while a cohort of patients at lower surgical risk was treated with traditional sutured valves. Daily per patient costs were calculated and included preoperative tests, operating costs, disposables, drugs, blood components and personnel costs.

The results demonstrated that hospital costs excluding the prosthesis were similar in the two groups, despite the higher risk of complexity for the cases in the Perceval group. “Despite higher operative risks in the Perceval group, hospital mortality, morbidity and resource consumption did not differ,” said Dr. Giovanni Troise, Head Cardiac Surgeon at Poliambulanza Hospital. “Operating times were shorter with the sutureless device. This improvement, coupled with the increasing adoption of minimally invasive approaches, should further favor the Perceval valve’s market acceptance.”

The third article[3] assessed the incremental cost-utility of surgical sutureless aortic valves compared to transcatheter aortic valves, for the treatment of intermediate- to high-risk patients in the U.S., Germany, France, Italy, UK and Australia. The cost-utility study relied on a meta-analysis comparing efficacy and safety outcomes. The study analyzed more than 1,400 patients treated with either surgical sutureless valves (95% of which were Perceval patients) or transcatheter aortic valves. A simulation estimated the long-term consequences following patient discharge from hospital.

Due to lower in-hospital and overall mortality rates, the study showed that patients treated with Perceval are expected to live an average of 1.14 quality-adjusted life-years (QALYs) greater than those treated with a transcatheter aortic valve.

Lifetime cost savings were reported across the board in all geographies under analysis. “These relevant findings acknowledge the clinical and economic relevance of adding sutureless valves as an integral part of your Structural Heart program,” said Dr. Mattia Glauber, Head Cardiac Surgeon at Istituto Clinico Sant’Ambrogio in Milan, Italy. “Our institution performs Perceval implantations on a routine basis via right anterior thoracotomy - the ultimate minimally invasive surgical procedure. This approach generates clear patient benefits, economic advantages and represents an ideal complement to transcatheter aortic valves in the appropriate patient risk category.”

2 Villa et al, “Sutureless aortic valve replacement in high risk patients neutralizes expected worse hospital outcome: A clinical and economic analysis”, Cardiology Journal 2018 – Epub ahead of print+, DOI: 10.5603/CJ.a2018.0098 https://journals.viamedica.pl/cardiology_journal/article/view/CJ.a2018.0098

3 Povero et al, “Cost-utility of surgical sutureless bioprostheses vs TAVI in aortic valve replacement for patients at intermediate and high surgical risk”, ClinicoEconomics and Outcomes Research 2018:10 733–745, DOI https://doi.org/10.2147/CEOR.S185743

“These three publications add to the already significant body of evidence available on Perceval,” said Alistair Simpson, LivaNova General Manager of Cardiac Surgery. “We are delighted to see the positive clinical results generated by Perceval, and to read that our unique valve is being recognized as a financially viable option for the treatment of aortic valve diseases. Achieving cost reductions while improving outcomes is of paramount importance to healthcare systems worldwide. We are proud to see that Perceval is helping realize both.”

For more information on the Perceval valve, please visit www.livanova.com.

Important Safety Information

INDICATIONS

EUROPE: The Perceval prosthesis is indicated for the replacement of diseased native or a malfunctioning prosthetic aortic valve via open heart surgery. The prosthesis is indicated for use in adult patients who are diagnosed to have aortic valve stenosis or steno-insufficiency.

USA: The Perceval bioprosthesis is indicated for the replacement of diseased, damaged or malfunctioning native or prosthetic aortic valves.

CANADA: The Perceval S bioprosthesis is intended for use in patients aged ≥ 65 years when the aortic valve pathology is in an advanced stage to require the replacement of the native or malfunctioning previously implanted prosthesis.

AUSTRALIA: Perceval S prosthesis is indicated for the replacement of a diseased native or a malfunctioning prosthetic aortic valve via open heart surgery. The prosthesis is indicated in patients who meet the following criteria: 1) subjects of age ≥ 65 years 2) subjects with aortic valve stenosis or steno-insufficiency.

TOP POTENTIAL SIDE EFFECTS

The risks or potential adverse events associated with cardiac valve replacement with a bioprosthesis include, but may not be limited to: cardiac arrhythmias, death, endocarditis, heart failure, hemorrhage, intravalvular and/or paravalvular leak, stroke or any related neurologic disorders, structural valve deterioration, reoperation and explant. Beyond the previously mentioned adverse events, specific events related to the implant of the Perceval prosthesis may include, but not be limited to dislodgment and/or migration of the prosthesis. MRI conditional.

For professional use. Please contact us through our website to receive instructions for use containing full prescribing information, including indications, contraindications, warnings, precautions and adverse events. Not approved in all geographies. Consult your labeling.

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: 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 within the meaning of Section 27A of the United States Securities Act of 1933, as amended, and 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 LivaNova's 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 news release are based on information presently available to LivaNova and assumptions that LivaNova believes to be reasonable, but are inherently uncertain. As a result, LivaNova's actual results, performance or achievements may differ materially from those expressed or implied by these forward-looking statements, which are not guarantees of future performance or actions that may be taken by LivaNova and involve known and unknown risks, uncertainties and other factors that are, in some cases, beyond LivaNova's control. You should carefully consider the risks and uncertainties that affect LivaNova, including those 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 the United States Securities and Exchange Commission.

All information in this news 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 news 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 news release.

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