LivaNova

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NEWS RELEASE

LivaNova Announces Availability of Safety and Technical Information for Valve-in-Valve Procedures on Perceval Platform

New details provide insights on the suitability of the sutureless aortic valve for future transcatheter solutions

London, February 25, 2019 – LivaNova PLC (NASDAQ:LIVN), a market-leading medical technology company, announced today that given the increasing viability of Valve-in-Valve (ViV) procedures, it has added new safety and technical information to the Perceval U.S. Instructions For Use (IFUs). This addition was made following completion of the Company's application to the U.S. Food and Drug Administration.

The use of transcatheter valves in failed bioprostheses has recently been recognized in both American and European Guidelines as an option for patients at high surgical risk. LivaNova is making this new information available to support clinicians considering whether or not to perform a ViV procedure on a Perceval foundation.[1] The Company implemented the change to provide heart teams with greater insight on how Perceval can accommodate future transcatheter valves, presenting even broader treatment options for patients.

"As a cardiologist, I appreciate the proactive approach LivaNova is taking to support professionals who are considering the feasibility of ViV procedures," said Dr. Danny Dvir, cardiologist at University of Washington, Seattle, and Chairman of the American Institute of Valvular Research. "The literature and the global VIVID registry, so far, show no reports of coronary ostia obstruction, which is encouraging. In addition, hemodynamic results of ViV within Perceval bioprostheses are very promising. ViV is a key way to give patients greater choice if the time comes to replace a surgical prosthesis."

Perceval combines the versatility of a sutureless valve, with more than 10 years of clinical experience. Its stent design makes it well suited for different applications and a broad patient population. This is particularly relevant for ViV procedures:

- The Perceval stent shape provides clear visibility and landmarks to facilitate transcatheter valve positioning.
- The nitinol stent allows for even circumferential expansion to accommodate future transcatheter valves.
- Perceval has a large internal diameter, providing more choices for future transcatheter valve selection.

“Giving Perceval patients the option to receive a transcatheter valve offers them access to more treatment choices and less invasive possibilities,” said Alistair Simpson, LivaNova General Manager of Cardiac Surgery. “By providing heart teams with this information for Valve-in-Valve applications, we are further demonstrating the role of Perceval as an essential component to any valve program.”

Important Safety Information

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: Central and paravalvular leak, cardiac disorders, structural valve deterioration, thromboembolism, reoperation. The safety and efficacy of valve-in-valve procedures in a Perceval valve have not been established. [1]The decision of performing Valve-in-Valve procedures is at the discretion of the cardiologist and/or hospital’s heart team, following careful assessment of the individual circumstances of each patient. Currently, no long-term data exists to support the efficacy of the procedure. Valve-in-Valve procedures in a Perceval valve should be performed according to indications provided by the transcatheter valve manufacturer.

MRI conditional.

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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