LivaNova

Health innovation that matters

NEWS RELEASE

LivaNova Concludes PRELUDE Study for Transcatheter Mitral Valve Replacement System

Company now focused on INTERLUDE CE Mark trial, building upon positive patient outcomes

London, August 6, 2018 — LivaNova PLC (NASDAQ: LIVN), a market-leading medical technology company, today announced the conclusion of the PRELUDE feasibility study for its Caisson Transcatheter Mitral Valve Replacement (TMVR) system. The PRELUDE first-in-human study evaluated the Company's TMVR system to treat moderate to severe mitral regurgitation (MR) using a transseptal approach. This is a less invasive approach using a tube (catheter) through an incision in the groin, instead of an opening in the chest, to replace a patient's mitral valve. Following the positive patient outcomes from the PRELUDE study, the Company will now focus on enrolling patients in the INTERLUDE CE Mark trial and finalizing the protocol for the U.S. pivotal trial, ENSEMBLE, with the U.S. Food and Drug Administration (FDA).

"Patients with moderate to severe mitral regurgitation are often too sick for traditional open-heart surgery. We saw encouraging outcomes in patients within the PRELUDE trial. Follow-up results showed positive acute valve performance, which was maintained over time, along with improved quality of life," said Principal Investigator Dr. Mathew Williams, Chief of Adult Cardiac Surgery and Director of the Heart Valve Program at NYU Langone Health. Williams, who has performed the most LivaNova TMVR implants to date, added, "We are pleased to continue our TMVR research with the INTERLUDE trial."

MR is a condition in which a patient's mitral valve does not close tightly, allowing blood to flow backward into the heart. As a result, blood cannot move through the heart or to the rest of the body as efficiently, causing fatigue and shortness of breath. Only a small percentage of the millions of people with moderate to severe MR are treated because of prohibiting factors that can include advanced age, impaired heart function and multiple comorbidities.[1,2]

1. *Lloyd-Jones D, Adams RJ, Brown TM, et al; American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Heart disease and stroke statistics—2010 update: a report from the American Heart Association. Circulation. 2010; 121(7):e46-e215.*
2. *Mirabel M, Iung B, Baron G, et al. What are the characteristics of patients with severe, symptomatic, mitral regurgitation who are denied surgery? Eur Heart J. 2007;28(11):1358-1365.*

“At LivaNova, we believe our transseptal approach for TMVR is an ideal and less invasive treatment option for patients who suffer from mitral regurgitation, since they are typically very ill. The initial PRELUDE study results have been meaningful and suggest that our TMVR system is durable over time, while demonstrating its fully repositionable and retrievable capabilities,” said Paul Buckman, LivaNova General Manager of TMVR.

The INTERLUDE trial will be conducted in North American and European centers with enrollment completion expected by 2020.

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.A.), 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

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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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