LivaNova

Health innovation that matters

NEWS RELEASE

LivaNova Bi-Flow Cannula Receives CE Mark for ECMO Applications

Bi-Flow is first bidirectional femoral arterial cannula validated for 29 days' use

London, April 27, 2020 – LivaNova PLC (NASDAQ:LIVN), a market-leading medical technology and innovation company, today announced its Bi-Flow Extracorporeal Membrane Oxygenation (ECMO) cannula earned CE Mark approval for ECMO procedures where femoral artery cannulation can be applied. Bi-Flow previously received CE Mark in 2019 for cardiac surgery procedures requiring femoral artery cannulation. Now validated for up to 29 days of use, Bi-Flow ECMO is designed to reduce the risk of limb ischemia for patients receiving ECMO and it allows for safe, easy and reproducible procedures.

"After witnessing the potential of Bi-Flow in the cardiac surgery setting, the availability of the cannula for ECMO applications promises to redefine the standard of care for femoral artery cannulation during extracorporeal life support procedures," said Dr. Paulo Neves from Centro Hospitalar Vila Nova de Gaia in Portugal. "We are looking forward to having this cannula so we can treat critically ill patients in an effective way."

Limb ischemia, or tissue damage due to compromised blood flow, is a potentially devastating complication during Extracorporeal Life Support (ECLS). During ECLS procedures such as ECMO, a patient's blood is externally oxygenated and recirculated through the body to provide circulatory and respiratory support during severe heart, lung or combined heart-lung failure. In a clinical study in a cardiac surgery setting, Bi-Flow was easily inserted and removed without complications and was proven to provide simultaneous systemic and distal perfusion of the limb in a safe and reproducible way.[1]

"The Bi-Flow ECMO cannula is a truly game-changing technology that is designed to reduce the incidence of limb ischemia during long-term ECMO support," said Dr. Brian Duncan, Vice President of Medical Affairs at LivaNova. "I see real enthusiasm among clinicians for the availability of Bi-Flow ECMO as a potential solution for this difficult clinical problem."

Bi-Flow ECMO comes with a unique fixation device designed to ensure that it remains correctly positioned and to prevent dislocation due to patient movement. Its design is intended for longer term use and includes no-DOP tubing and PH.I.S.I.O. coating to improve biocompatibility, along with a tip designed to ensure adequate perfusion with low risk of hemolysis.

Recognized by the European Association for Cardio-Thoracic Surgery (EACTS) with the Techno-College Innovation Award in 2018, the original Bi-Flow is currently available in Europe, Canada and other select countries in one size (19 fr) for Cardiac Surgery. Bi-Flow ECMO is now in limited release and will become fully available in Europe and select countries in the coming months.

For more information, on the Bi-Flow bidirectional cannula, visit www.cannulae.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, 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.

References

1. *Marasco et al., A Phase 1 Study of a Novel Bidirectional Perfusion Cannula in Patients Undergoing Femoral Cannulation for Cardiac Surgery, Innovations, 2018.*

LivaNova PLC Media Contact

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

###