LivaNova

Health innovation that matters

NEWS RELEASE

LivaNova Receives FDA 510(k) Clearance for B-Capta, the New In-Line, Blood-Gas Monitoring System Integrated into the S5 Heart-Lung Machine

Intuitive, optical-based technology system now available around the world

London, April 20, 2021 – LivaNova PLC (NASDAQ:LIVN), a market-leading medical technology and innovation company, today announced it received U.S. Food and Drug Administration (FDA) 510(k) clearance for B-Capta®, the new in-line, blood-gas monitoring system integrated into the market-leading S5® heart-lung machine (HLM). The system is designed to easily and accurately monitor arterial and venous blood gas parameters even during long and complex pediatric and adult cardiopulmonary bypass procedures. B-Capta, which received CE Mark in May 2020 and completed a successful limited commercial release in Europe, will now be available globally.

B-Capta's innovative sensing technology provides accurate and continuous measurements that allow the perfusionist to quickly react to parameter changes. The system's intuitive user interface reduces set-up time, aligning parameters to those of the hospital's Laboratory Blood Gas Analyzer (ABL) and includes accurate oxygen partial pressure (pO2), a key measurement when performing Goal-Directed Perfusion (GDP).

"B-Capta significantly extends the in-line, blood-gas monitoring options available to our customers for continuous monitoring of key patient physiological parameters consistent with clinical guidelines during extracorporeal life support procedures," said Marco Dolci, LivaNova Senior Vice President, Global Operations and R&D. "Now integrated into our world-leading S5 HLM, the optical-based technology used for B-Capta provides accurate and reliable monitoring of patient blood gas parameters."

Other advantages of B-Capta include:

- **A "ready-to-go" set-up**, meaning the device does not require calibration at the beginning of the procedure, which is especially beneficial during emergency cases.
- **Visual and audible indicators** for when parameters fall outside of thresholds selected by the user.
- **Integration into the S5 HLM**, eliminating the need for additional external monitors and providing an unobstructed view for the perfusionist. Plus, all patient and procedure parameters remain in the same location, which improves the overall workflow and reduces stress levels felt by perfusionists during procedures.

- **Arterial and venous sensors that fit all disposable cuvette sizes**, allowing the perfusionist to use the same sensor for both adult and pediatric procedures.

"The launch of B-Capta reinforces our strategic direction, furthers our partnership with perfusionists and proves why we are the leaders in the extracorporeal circulation space," said Paul Buckman, LivaNova President, North America. "B-Capta is a key enrichment to our S5 HLM platform, and the first of a number of new innovations our customers can expect from us."

LivaNova also received 510(k) clearance for its S5 PRO™ HLM, an upgrade of the world-renowned heart-lung machine that features B-Capta as a primary component, along with a new level sensor and improved software with a new alarm system.

Visit the LivaNova website for more information on B-Capta and the Company's complete portfolio of leading cardiopulmonary products.

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. **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 B-Capta. 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, 2020, 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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