

## **LivaNova PLC Receives Regulatory Approval in Japan for the Solo Smart Stentless Tissue Aortic Valve**

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### **Solo Smart is a Native-Like Aortic Valve Replacement Option With Excellent Hemodynamic Performance and Clinical Outcomes**

LONDON, Feb. 29, 2016 (GLOBE NEWSWIRE) -- LivaNova, PLC (NASDAQ:LIVN) (LSE:LIVN), a global medical technology company and a leader in the treatment of cardiovascular diseases, today announced that it has received approval from Japan's Pharmaceutical and Medical Devices Agency (PMDA) for its Solo Smart stentless tissue valve, the only valve designed to provide superior hemodynamics with the ease of a stented bioprosthesis implantation.

Designed from bovine pericardium, the Solo Smart valve is fully biological with no synthetic material added, allowing the valve to mimic the healthy native aortic valve. Solo Smart maximizes the blood flow and delivers excellent hemodynamic performance and patient outcomes while providing a simplified implant procedure method with a removable stent for straightforward implantation and optimal positioning.

"Since their introduction in the 1990s, stentless bioprosthetic valves have represented a major stride in valve design and hemodynamic performance for aortic valve replacement options," said Alberto Repossini, M.D., Cardiac Surgery University of Brescia, Spedali Civili, Brescia, Italy. "Solo Smart is a unique prosthesis with a temporary stent removed during its implantation for optimal positioning. Once the stent is removed, Solo Smart becomes an entirely stentless valve, providing low pressure gradients and large orifice areas."<sup>1,2,3,4,5,6</sup>

Available also in Europe and the U.S., the Solo Smart stentless valve is designed for patients with an active lifestyle, those who are at risk of PPM (Patient Prosthesis Mismatch) or require a concomitant aortic valve replacement procedure.

"In collaboration with our established partner, Japan Lifeline, LivaNova is pleased to introduce the Solo Smart stentless valve for aortic valve replacement in Japan," said Michel Darnaud, President, Cardiac Surgery Business Unit, LivaNova. "With Solo Smart valve and its long-term data paired with simplified implantability, surgeons are empowered with state-of-the-art technology and the confidence to perform AVR procedures more effectively."

### **About LivaNova**

LivaNova PLC, headquartered in London, UK, is a global medical technology company formed by the merger of Sorin S.p.A, a leader in the treatment of cardiovascular diseases, and Cyberonics Inc., a medical device company with core expertise in neuromodulation. LivaNova transforms medical innovation into meaningful solutions for the benefit of patients, healthcare professionals, and healthcare systems. The company employs approximately 4,500 employees worldwide. With a presence in more than 100 countries, LivaNova operates as three business units: Cardiac Rhythm Management, Cardiac Surgery, and Neuromodulation, with operating headquarters in Clamart (France), Mirandola (Italy) and Houston (U.S.A.), respectively.

LivaNova is listed on NASDAQ and listed on the Official List of the UK's Financial Conduct Authority and traded on London Stock Exchange (LSE) under the ticker symbol "LIVN".

### **Safe harbor statement**

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended. These statements can be identified by the use of forward-looking terminology, including "may," "believe," "will," "expect," "anticipate," "estimate," "plan," "intend," "forecast," or other similar words. Statements contained in this press release are based on information presently available to LivaNova and assumptions that the parties believe to be reasonable. LivaNova is not assuming any duty to update this information if those facts change or if the assumptions are no longer believed to be reasonable. Investors are

cautioned that all such statements involve risks and uncertainties, including without limitation, statements concerning developing novel opportunities in heart failure, sleep apnea and percutaneous mitral valve, creating new innovative solutions that benefit patients, healthcare professionals, and healthcare systems, and building significant shareholder value. Important factors that may cause actual results to differ include, but are not limited to: risks that the new businesses will not be integrated successfully or that the combined companies will not realize estimated cost savings, value of certain tax assets, synergies and growth, or that such benefits may take longer to realize than expected; the inability of LivaNova to meet expectations regarding the timing, completion and accounting and tax treatments; risks relating to unanticipated costs of integration, including operating costs, customer loss or business disruption being greater than expected; reductions in customer spending, a slowdown in customer payments and changes in customer demand for products and services; unanticipated changes relating to competitive factors in the industries in which the company operates; the ability to hire and retain key personnel; the ability to attract new customers and retain existing customers in the manner anticipated; reliance on and integration of information technology systems; changes in legislation or governmental regulations affecting the company; international, national or local economic, social or political conditions that could adversely affect the company or its customers; conditions in the credit markets; risks to the industries in which LivaNova operates that are described in the "Risk Factors" section of the Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and other documents filed from time to time with the SEC by Cyberonics, Inc. and LivaNova and the analogous section in annual reports and other documents filed from time to time by Sorin S.p.A. with the Italian financial market regulator (CONSOB); risks associated with assumptions made in connection with critical accounting estimates and legal proceedings; LivaNova's international operations, which are subject to the risks of currency fluctuations and foreign exchange controls; and the potential of international unrest, economic downturn or effects of currencies, tax assessments, tax adjustments, anticipated tax rates, raw material costs or availability, benefit or retirement plan costs, or other regulatory compliance costs. The foregoing list of factors is not exhaustive. You should carefully consider the foregoing factors and the other risks and uncertainties that affect the parties' businesses, including those described in Cyberonics' Annual Report on Form 10-K, as amended from time to time, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other documents filed from time to time with the SEC by Cyberonics and LivaNova and those described in Sorin's annual reports, registration documents and other documents filed from time to time with CONSOB by Sorin. LivaNova does not give any assurance (1) that LivaNova will achieve its expectations, or (2) concerning any result or the timing thereof, in each case, with respect to any regulatory action, administrative proceedings, government investigations, litigation, warning letters, consent decree, cost reductions, business strategies, earnings or revenue trends or future financial results.

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<sup>1</sup> Repossini A, Rambaldini M, Lucchetti V, et al. Early clinical and hemodynamic results after aortic valve replacement with the Freedom SOLO bioprosthesis (experience of Italian multicenter study). *Eur J Cardiothorac Surg.* 2012;41(5):1104-111.

<sup>2</sup> Beholz S, Repossini A, Livi U, et al. The Freedom SOLO Valve for Aortic Valve Replacement: Clinical and Hemodynamic Results from a Prospective Multicenter Trial. *The Journal of Heart Valve Disease.* 2010;19:115-123.

<sup>3</sup> Horst M, Easo J, Hölzl PPF, et al. The Freedom Solo Valve: Mid-Term Clinical Results with a Stentless Pericardial Valve for Aortic Valve Replacement. *The Journal of Heart Valve Disease.* 2011;20:704-710.

<sup>4</sup> Clinical Experience With the Freedom Solo Stentless Aortic Valve in 277 Consecutive Patients. Thalmann M, Kaiblinger J, Krausler R, Pisarik H, Veit F, Taheri N, Kornigg K, Dinges C, Grabenwöger M, Stanger O. *Ann Thorac Surg.* 2014 Oct;98(4):1301-7.

<sup>5</sup> Clinical and haemodynamic outcomes in 804 patients receiving the Freedom SOLO stentless aortic valve: results from an international prospective multicentre study.

Grubitzsch H, Wang S, Matschke K, Glauber M, Heimansohn D, Tan E, Francois K, Thalmann M. *Eur J Cardiothorac Surg.* 2015 Mar;47(3):e97-e104

<sup>6</sup> Long term durability and haemodynamic performance of freedom solo stentless valve for aortic valve replacement: a european, multicenter experience". Repossini et al. Presented at AHA Congress – Nov 2015

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