Sorin Group Receives PMDA Approval and Announces Commercial Launch of the Mitroflow® Aortic Pericardial Heart Valve in Japan

The Associated Press

MILAN, Italy--(BUSINESS WIRE)--Dec 4, 2012--Sorin Group, (Reuters Code: SORN.MI) a global medical company and a leader in the treatment of cardiovascular diseases, announced today that it received the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) approval for the Mitroflow ® Aortic Pericardial Heart Valve.

Thanks to its unique design, the Mitroflow valve has demonstrated excellent hemodynamic performance, outstanding durability with 21 years of published long-term results and ease of use in 30 years of clinical use worldwide 1, 2.

With the pericardium layer mounted on the outside of valve stent, the Mitroflow valve maximizes the internal orifice area allowing for maximum valve opening with no obstruction to blood flow and an unimpeded leaflet opening. The valve delivers excellent hemodynamic performance with low pressure gradients, large effective orifice areas and left ventricular mass regression also in patients with small annuli.

With its innovative design, the valve is easy to suture, conformable to the native annulus and adaptable to difficult anatomies 1,3.

“I am very pleased that the Mitroflow valve is now available in Japan. Mitroflow's low profile and ease of implant are ideally suited to Japanese patients who often have a small or narrow aortic root. In addition, Mitroflow provides patients with the benefits of long-term durability combined with excellent hemodynamic performance,” said Prof. Yoshiki Sawa, Department of Cardiovascular Surgery at Osaka University Graduate School of Medicine, in Suita, Japan.

“The PMDA approval of the Mitroflow valve in Japan is a key achievement for Sorin Group,” said Michel Darnaud, President of the Cardiac Surgery Business Unit, Sorin Group. “Sorin Group is strongly committed to improving patient outcomes and we are pleased to provide Japanese patients and cardiothoracic surgeons with a state-of-the-art therapy for aortic valve replacement.” The Mitroflow aortic pericardial heart valve will be distributed in Japan by JLL, Japan Lifeline Co., Ltd.

1- CA Yankah, et al. - Aortic valve replacement with the Mitroflow pericardial bioprosthesis: Durability results up to 21 years. - J Thorac Cardiovasc Surg. 2008;136:688-696 2- The ISTHMUS Investigators - The Italian study on the Mitroflow postoperative results (ISTHMUS): a 20-year, multicentre evaluation of Mitroflow pericardial bioprosthesis - European Journal of Cardio-thoracic Surgery 39 (2011) 18-26 3- WRE Jamieson, et al. - Hemodynamic performance of mitroflow aortic pericardial bioprosthesis - optimizing management for the small aortic annulus. -- Thorac Cardiovasc Surg. 2010 Mar;58(2):69-75 About Sorin Group Sorin Group (

www.sorin.com) is a global, medical device company and a leader in the treatment of cardiovascular diseases. The Company develops, manufactures and markets medical technologies for cardiac surgery and for the treatment of cardiac rhythm disorders. With 3,750 employees worldwide, Sorin Group focuses on three major therapeutic areas: cardiopulmonary bypass (extracorporeal circulation and autotransfusion systems), cardiac rhythm management and heart valve repair and replacement. Every year, over one million patients are treated with Sorin Group devices in more than 80 countries.

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