SORIN GROUP INITIATES TRIUMPH-CRT CLINICAL TRIAL WITH WORLD’S FIRST TRIPLE-SITE VENTRICULAR (TRI-V) PACING CRT-D DEVICE

The study will evaluate whether response to cardiac resynchronization therapy (CRT) may be improved in selected heart failure patients through Tri-V pacing.

Milan, Italy, September 1st, 2015 — Sorin Group, (Reuters Code: SORN.MI), a global medical device company and a leader in the treatment of cardiovascular diseases, announced today the start of patient enrollment in its TRIUMPH-CRT clinical trial in Europe.

The TRIUMPH CRT study, which will be conducted using Sorin Group’s Paradym CRT-D Tri-V device, is designed to investigate the benefits of individually optimized Tri-V pacing over standard biventricular pacing in patients with a non-Left Bundle Branch Block (LBBB) morphology.

While standard CRT-D devices deliver ventricular pacing at two different ventricular sites, Paradym CRT-D Tri-V paces the ventricles at three different locations thanks to a special connector that enables the use of three ventricular leads without the need for any separate adaptor.

“There is a need to find alternative CRT solutions for patients that have a poor response to the standard therapy. The TRIUMPH-CRT trial focuses specifically on non-LBBB heart failure patients, and we want to demonstrate that individually optimized Tri-V pacing will help to significantly improve their ventricular function”, said Professor Jean-Claude Daubert, M.D., Hôpital Pontchaillou, University of Rennes, France, the study’s principal investigator. “In addition, using a specially designed Tri-V device with a dedicated connector will streamline the implant procedure and limit further complications”.

The first patients enrolled in the study were successfully implanted at Hôpital Paris Saint-Joseph, Paris, in the electrophysiology department of Dr Serge Cazeau, M.D., cardiologist, and at Hospital Universitario y Politécnico La Fe, Valencia, Spain by Dr. Oscar Cano, M.D., electrophysiologist.

Non-LBBB patients represent more than one third of CRT implants¹ yet the evidence of a benefit for these patients is weak. The current European Guidelines consider non-LBBB as a Class II indication for which the decision to implant a CRT should be individualized based on other clinical criteria.² Poor response to Cardiac Resynchronization Therapy (CRT) in non-LBBB patients is suspected to be due to complex forms of electrical and mechanical dyssynchronies. Acute studies have suggested that non-LBBB patients may respond better to CRT if they are treated with Tri-V pacing rather than standard biventricular pacing.3,4

“This landmark study has the potential to transform the standard of care for patients with heart failure who do not respond to CRT today and further reasserts our commitment to improving individual patient outcome,” said Stefano Di Lullo, Sorin Group, President of the CRM Business Unit.
About the TRIUMPH-CRT Trial

TRIUMPH-CRT is a multicenter, international, prospective, randomized trial which will enroll 216 patients in Europe. The objective of the primary endpoint is to demonstrate that individually optimized triple-site pacing (Tri-V pacing) is superior to standard biventricular pacing in reverse ventricular remodeling. The endpoint will be assessed by measuring the left Ventricle End-Systolic Volume (LVESV) by echocardiography at 12 months post implant. The echocardiographic findings will be assessed by an independent core laboratory.

The patient population will be restricted to non-LBBB patients and will be followed for 12 months. Patients will be randomized in a 1:1 configuration:

- Standard biventricular pacing (1 lead in the right ventricle and 1 lead in the left ventricle) through classical implantation procedure
- Tri-V pacing with per-operative individual optimization of the placement of the third lead guided by echocardiography.

For patients in the Tri-V group, the placement of the third lead will be performed by per-operative echocardiography measuring the left pre-ejection interval (LPEI), defined as the time interval between the onset of QRS and the onset of LV ejection.

The objective of the lead placement optimization at implant is to improve left-ventricular efficiency and to decrease the LPEI as much as possible compared to standard biventricular pacing. A reduction in LPEI results in a shortened ventricular systole and is associated with improved LV filling and reduced interventricular delay.

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 3,900 employees worldwide, the company focuses on two major therapeutic areas: Cardiac Surgery (cardiopulmonary products for open heart surgery and heart valve repair or replacement products) and Cardiac Rhythm Management (pacemakers, defibrillators and non invasive monitoring to diagnose and deliver anti-arrhythmia therapies as well as cardiac resynchronization devices for heart failure treatment). Every year, over one million patients are treated with Sorin Group devices in more than 80 countries.

References:
3: Anselme F, Thibault B, Delay M, Mondoly P, Renesto F, Cazeau S. Effect of RV lead(s) site optimization and tri-ventricular pacing in patients undergoing cardiac resynchronization therapy: results from METEOR Study. Europace Journal 2009;11(Sup 2), Abstract 668
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