Sorin Group Announces First U.S. Implant of PARADYM RF SonR CRT-D for RESPOND CRT IDE Clinical Trial

Business Wire

Sorin Group (MIL:SRN), a global medical device company and leader in the treatment of cardiovascular diseases, announces the first U.S. implant of its PARADYM SonR CRT System for the RESPOND CRT IDE Clinical Trial. Dr. B. A. Smith, Electrophysiologist, Piedmont Heart Institute, Atlanta, GA, performed the procedure on May 30.

The RESPOND CRT trial is designed to evaluate the safety and effectiveness of the SonR CRT system in a multi-center, randomized, two-arm, double-blinded, prospective trial enrolling more than 1,000 patients in the United States and other geographies.

The SonR system's innovative hemodynamic sensor assesses the patient's left ventricular contractility, a key indicator of cardiac performance. Based on the patient's heart activity and needs, the algorithm automatically optimizes atrioventricular (AV) delay and interventricular (VV) delay settings – with the goal of improving the patient's response to CRT. The SonR system is the first and only CRT hemodynamic sensor-based system designed to automatically adjust these timings on a weekly basis, at rest and exercise.

"We are excited to be participating in the RESPOND CRT Trial," said Dr. B. A. Smith. "We believe the SonR CRT optimization system will improve outcomes in heart failure patients who currently do not effectively respond to CRT." CRT systems treat heart failure by synchronizing the patient's ventricles to improve the heart's pumping efficiency and blood flow. Studies have shown, however, that approximately one-third of patients with advanced heart failure do not effectively respond to CRT.[1,2] A major cause of poor CRT response is inappropriate AV and VV timing.

"The SonR system provides an innovative sensor that offers a potential major breakthrough in treating CRT patients," said Jagmeet P. Singh, M.D., Ph.D., Director of the Resynchronization and Advanced Cardiac Therapeutics Program at Massachusetts General Hospital in Boston and U.S. principal investigator of the RESPOND CRT trial. "With the large number of patients being studied in the RESPOND CRT trial, we hope to gather valuable data that further demonstrates patient benefit that can be derived from the SonR system's CRT optimization." The RESPOND CRT study is designed to build upon Sorin's earlier clinical experience, gained during the CLEAR clinical study and published in the September 2012 issue of the peer-reviewed journal Europace. The CLEAR study evaluated the SonR CRT optimization system in 238 European patients with advanced heart failure. Results showed improvement in 76 percent of patients receiving SonR CRT optimization at

12 months, compared with 62 percent of patients with standard CRT programming (p=0.0285).[3,4] SonR CRT received CE mark approval in October 2011 and is currently one of the most widely used CRT optimization systems in Europe.

“The SonR system is an example of Sorin Group’s commitment to innovative technology designed to provide unique solutions for improving therapy efficacy,” said Stefano Di Lullo, Sorin Group, President of the CRM Business Unit. “We’ve seen excellent clinical results from other studies of SonR. The new RESPOND CRT trial will help us build on that foundation with a much larger patient population. Our goal is to obtain FDA approval in the United States where more than 5 million Americans suffer from heart failure.[5] Many of these individuals can benefit from CRT therapy and its optimization.” About the SonR RESPOND CRT Trial RESPOND CRT is a multi-center, randomized, two-arm, double-blinded, prospective trial. Starting in the first half of 2013 in the United States, the trial will enroll more than 1,000 patients in over 100 worldwide investigational sites, with approximately one-third of patients in the United States. The primary effectiveness endpoint is the proportion of patients within each treatment group that respond to CRT therapy with an improvement in NYHA class or an improvement in quality of life at 12 months and do not experience a heart failure-related adverse event or death. Patients will be followed for 24 months.

About SonR
The SonR optimization system consists of the SonR hemodynamic sensor embedded in the SonRtip TM atrial pacing lead and the PARADYM TM RF SonR CRT-D device. The result of a 10-year clinical science program, the SonR sensor is designed to uniquely measure patient’s cardiac muscle vibrations related to the first heart sound. These real-time measurements are transmitted to the CRT-D device which uses them to determine the best settings for the patient. Every week, the system automatically optimizes to adapt to the patient’s changing condition. SonR measurements correspond to LVdP/dt max, the gold standard for assessing left ventricular contractility, a key indicator of cardiac performance. The SonR CRT optimization system received CE Mark in October 2011 and is currently one of the most widely used CRT systems in Europe. SonR is the only CRT hemodynamic sensor-based optimization system that is designed to automatically optimize patients every week and, importantly, while the patient is active, providing real-life optimization.

About CRT Therapy
Cardiac Resynchronization Therapy is a therapy that delivers timely electrical pulses to the chambers of the heart. This allows the heart to beat in a more coordinated and synchronized manner, and therefore more effectively. Studies have shown that around one-third of patients with advanced heart failure do not effectively respond to CRT. In order to improve therapy success rate, it is important to offer each patient a tailor-made programming of the timing between electrical impulses sent to different parts of the heart (CRT settings) on a regular basis. Current optimization methods include echocardiography and other device-based timing features. Echocardiography is difficult and time-consuming while other device-based CRT optimization features have shown limited benefits.[6] Most of these current methods require manual steps. They are typically performed only once and while the patient

is resting.

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, 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 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.

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[3] Ritter P, Delnoy PP, Padeletti L et al. A Randomized pilot study of optimization of cardiac resynchronization therapy in sinus rhythm using a peak endocardial acceleration sensor vs. standard methods. Europace 2012 Sep; 14(9):1324-33.
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