



SORIN GROUP INITIATES CLEAR STUDY IN EUROPE

First Patient with NewLiving CHF Biventricular Pacemaker enrolled in the CLEAR study

Milan, Italy - December 6, 2005 - Sorin Group Cardiac Rhythm Management (CRM) Business Unit, an innovative leader in the hemodynamic management of heart failure, announced today that the first patient has been enrolled in the CLEAR (Clinical Evaluation of Advanced Resynchronization) multicenter clinical study. Patients included in the CLEAR study have advanced heart failure.

Heart failure is a progressive condition in which the heart muscle weakens and gradually loses its ability to pump enough blood through the body. It affects 10 million Europeans and more than 22 million people worldwide and is expected to almost triple in 2020.

Cardiac resynchronization therapy (CRT) aims at increasing cardiac pump efficiency by resynchronizing the contractions of their ventricles.

Under the new 2005 European Society of Cardiology heart failure guidelines, cardiac resynchronization devices have been designated as standard-of-care treatment (Class 1A) for indicated heart failure patients already on optimal medical therapy.

The objective of the CLEAR study is to prove that the PEA (Peak Endocardial Acceleration) sensor, a unique feature of Sorin's NewLiving™ CHF pacemaker, helps physicians to optimize delivery of CRT without having to perform lengthy assessment procedures.

In current clinical practice, CRT settings are customized through an echocardiography-based procedure. With PEA sensor, physicians no longer need to conduct time-consuming echocardiographic assessments. In fact, NewLiving CHF analyzes the signal generated by the PEA sensor, which reflects the strength with which the heart contracts, to tailor programming of CRT settings to individual patients in order to maximize therapy efficacy.

Optimal CRT settings can be determined during standard pacemaker checks, which dramatically simplifies patient follow-up.

The first patient, which was enrolled in the CLEAR study on Friday November 25, 2005, was a 74-year-old woman in NYHA Class III with a history of congestive heart failure due to ischemic cardiomyopathy. Dr. Herbert Nägele, a heart failure expert who has been involved in numerous previous CRT trials is the study investigator at the St. Adolf-Stift hospital in Reinbek, Germany. "I am proud to take part in the initiation of this innovative study that will validate the clinical benefits of Sorin's PEA breakthrough technology for heart failure patients. This study will be of particular interest to the cardiologist community because it will confirm that with PEA heart failure patients can be better managed without having to undergo resource- and time-consuming procedures," said Dr. Nägele.

The CLEAR study is a controlled, randomized, single-blind study. Advanced heart failure patients (NYHA Class III or Class IV) implanted with Sorin's NewLiving CHF are randomized to two groups. In the first group a PEA-based optimization of CRT settings will be performed at each follow-up visit, while in the second group these settings will be programmed according to the investigating center's standard clinical practice.

The study is designed to demonstrate the superiority of the PEA-based approach regarding NYHA class and quality of life improvement, as well as reduction of heart failure-related hospitalizations.

A secondary objective of the study is to show that PEA trends stored by NewLiving CHF allow assessment of the patient's clinical status, especially before and during acute heart failure episodes.

The principal investigator for the study is Dr. Philippe Ritter, InParys, Saint Cloud, France, one of the pioneers of cardiac resynchronization therapy.

The study will enroll 310 patients at 57 sites in six European countries: Italy, Spain, France, Germany, the UK and the Netherlands. Enrollment is anticipated to be completed by mid 2007.

“We are very pleased to have begun this important study with leading European clinical investigators” said Andre-Michel Ballester, President of Sorin Group Cardiac Rhythm Management (CRM) Business Unit. “We believe CLEAR will change the patterns of patient management in the field of heart failure. This can potentially improve patient care, outcomes and reduce healthcare costs. CLEAR reasserts our commitment to be innovative leaders in the hemodynamic management of heart failure”.

NewLiving CHF, was launched in early October in Europe. The device is not available for sale in the United States.

Information about the Sorin Group:

Sorin Group (Reuters code: SORN.MI), a world leader in the development of medical technologies for cardiac surgery, offers innovative therapies for cardiac rhythm dysfunctions, interventional cardiology and the treatment of chronic kidney diseases. Sorin Group includes: Dideco, CarboMedics, COBE Cardiovascular, Stöckert, Mitroflow, ELA Medical, Sorin Biomedica, Bellco and Soludia. Sorin Group has about 4,700 employees working at facilities in more than 80 countries throughout the world to serve over 5,000 public and private treatment centers.

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