

Press Release

SORIN GROUP CARDIAC RHYTHM MANAGEMENT ANNOUNCES CE MARK AND FIRST IMPLANT OF A NEW-GENERATION CRT-D DEVICE DESIGNED TO PROVIDE HEMODYNAMIC MANAGEMENT OF HEART FAILURE

New PARADYM™ Cardiac Resynchronization Therapy-Defibrillator features sonR™ breakthrough technology for continuous adjustment of cardiac resynchronization

Paris – April 28, 2008 – Sorin Group Cardiac Rhythm Management announced today the first implant in a clinical trial of its new-generation PARADYM™ 8770 sonR™¹ cardiac resynchronization therapy defibrillator (CRT-D). This system contains a unique technology named sonR™ designed to adjust CRT delivery based on hemodynamic response as opposed to conventional CRT-D devices, that monitor the electrical activity of the heart. PARADYM™ sonR™ is the first device delivering continuous management of resynchronization therapy during patients' everyday life.

Previous clinical studies have shown that up to 25% of patients, who meet the criteria for CRT and who are implanted with a CRT-D device do not benefit from the therapy. Studies suggest that, in order to improve therapy success rate², 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). Manual programming of CRT settings can be guided using echocardiography, but echo optimization is not applied for all patients because it is a time-consuming and non-standardized procedure. Moreover, patient status can change over time, due to many factors (modifications of drug regimen, life-style changes, and modification of heart dimension). It is therefore crucial to re-assess and re-adjust the CRT settings on a regular basis.

Fred Hrkac, President of Sorin Group Cardiac Rhythm Management (CRM) Business Unit commented: "The sonR™ sensor is one of our most promising innovations in the treatment of heart failure because it allows to automatically re-adjust the CRT settings. Whereas conventional devices look at the heart as a "clock", new PARADYM™ sonR™ looks at the heart as a "pump", measuring vibrations generated by heart contraction. Thanks to this innovative approach, we provide the medical community and their patients with a completely new system, and this is in line with our vision to become an innovative leader in hemodynamic management of heart failure".

The new PARADYM™ device with its sonR™ functionality is designed to measure and evaluate the performance of the cardiac pump, and to adapt the CRT settings to the patients' cardiac status automatically and recurrently during patients' everyday life.

A multi-centre clinical trial including 150 patients is currently being conducted across Europe. The first sonR™ systems, the PARADYM™ sonR™ CRT-D, including the sonR™ FIX atrial lead, were implanted by Prof. Angelo Auricchio from Cardiocentro Ticino in Lugano, Switzerland, Dr Peter Paul Delnoy from Isala Clinics in Zwolle, Netherlands, and Dr Neil Sulke from Eastbourne General Hospital in the United Kingdom.

¹ Not available for distribution in the United-States

² Incremental benefit of Sequential vs Simultaneous CRT - B. Van Gelder - Am J Cardiol 04

Dr Peter Paul Delnoy declared: "Optimal resynchronization of the ventricles in heart failure patients is crucial for the success of the therapy. With the new sonR™ sensor, the device is designed to adjust CRT settings for each patient recurrently during daily life including both rest and exercise."

The PARADYM™ family also includes a single-chamber (VR 8250), and a dual-chamber (DR 8550) implantable cardioverter defibrillator for the management of arrhythmias.

"I'm excited about the comprehensive range of therapeutic tools that PARADYM™ DR offers. I like the small profile and the high energy output (42J) which provides extra safety margin for patients with high defibrillation thresholds. That, coupled with SafeR™ to reduce unnecessary ventricular pacing and PARAD+™ to reduce inappropriate shocks, makes this an ideal ICD for my patients", said Dr Franck Krümel from the Herz-und Gefässzentrum Bad Bevensen, Germany, primary investigator of the PARADYM™ Clinical Release study, who implanted the first PARADYM™ DR.

About heart failure and resynchronization therapy

According to the European Society of Cardiology (ESC) and the American Heart Association (AHA), more than 10 million³ Europeans and 5 million⁴ Americans suffer from heart failure, the most costly cardiovascular disease.

Cardiac resynchronization therapy defibrillators are indicated in advanced heart failure patients who might be at risk for Sudden Cardiac Death (SCD). CRT-D devices are capable of resynchronizing the contractions of the ventricles (the heart's lower chambers) by delivering low-energy impulses to improve the pumping performance of the heart. They also provide patients with defibrillation support when abnormally fast, life-threatening heart rhythms occur.

About the Sorin Group

The Sorin Group (Bloomberg: SRN.IM; Reuters: 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. The Sorin Group includes these brands: Dideco, CarboMedics, COBE Cardiovascular, Stöckert, Mitroflow, ELA Medical, Sorin Biomedica, Bellco and Bellco-Soludia. At the Sorin Group 4,500 employees work to serve over 5,000 public and private treatment centers in more than 80 countries throughout the world.

For more information, please visit: www.sorin.com or www.sorin-crm.com, or contact

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³ European Heart Journal – ESC Guidelines for the diagnosis and treatment of Chronic Heart Failure: full text (update 2005) – p. 3

⁴ Circulation – Journal of the American Association – ACC/AHA 2005 Guideline Update for the Diagnosis and Management of Chronic Heart Failure in the Adult – Summary Article – p. 1826