

Study evaluates sensitivity and positive predictive value of Sleep Apnea Monitoring (SAM) feature in implantable pacemakers

The Associated Press

MILAN--(BUSINESS WIRE)--Jun 12, 2012-- Sorin Group, (MIL:SRN) (Reuters Code: SORN.MI), a global medical device company and a leader in the treatment of cardiovascular diseases, announced today the first patient enrolment in the DREAM clinical trial. The primary objective of the study is to evaluate sensitivity and positive predictive value of Sleep Apnea Monitoring (SAM) in pacemaker patients, compared to polysomnography, the gold standard test to diagnose sleep apnea disorders.

This European multi-center, non-randomized, longitudinal study uses REPLY(TM) 2001, a new implantable pacemaker from Sorin Group, featuring SAM. This innovative feature is designed to screen and monitor Sleep Apnea Syndrome (SAS)² in bradyarrhythmia patients implanted with a pacemaker, using sensors embedded in the implanted device. SAS, the most common sleep breathing disorder, is associated with increased cardiovascular morbidity and mortality^{3,4}. The prevalence of SAS in patients suffering from bradyarrhythmia is shown to be high.

Results from a 2007 study demonstrated that 3 out of 5 patients implanted with a pacemaker had some degree of SAS, and that 1 out of 5 suffered from severe SAS⁵. Unfortunately, the vast majority of sleep apnea patients remain undiagnosed⁶. During Cardiostim 2012 - 18th World Congress in Cardiac Electrophysiology and Cardiac Techniques, Sorin is supporting a Scientific Session dedicated to the role of cardiologists in sleep apnea managements on Wednesday, June 13th from 14:00 to 15:30.

According to the principal study investigator, Pascal Defaye, M.D. at University Hospital, Grenoble, France, "screening and monitoring sleep apnea in pacemaker patients makes sense. Sleep breathing disorders are common in patients implanted with pacemakers. Because sleep apnea increases the risk of hypertension and cardiovascular diseases, being able to screen and monitor this syndrome with a new pacemaker feature will, I believe, help improve our patients' condition in the long run".

"Sorin Group is relentlessly dedicated to improving patient care" said Stefano Di Lullo, Sorin Group, President of the CRM Business Unit. "We are proud to initiate a study that aims to evaluate a new and advanced SAS feature that will help physicians better manage their patients' cardiovascular co-morbidities.

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

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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.

For more information, please visit www.sorin.com.

1 Not available for sales or distribution in the USA² Refer to product Implant Manual for Indications³ Shahar E, Whitney CW, Redline S et al.

Sleep-disordered breathing and cardiovascular disease: cross-sectional results of the Sleep Heart Health Study. *Am J Respir Crit Care Med* 2001;163:19-254 Peker Y, Hedner J, Kraiczi H et al. Respiratory disturbance index: an independent predictor of mortality in coronary artery disease. *Am J Respir Crit Care Med* 2000;162:81-65 Garrigue S, Pépin JL, Defaye P et al. High prevalence of sleep apnea syndrome in patients with long-term pacing: the European multicenter polysomnographic study. *Circulation* 2007; 115: 1703-17096 Young T, Palta M, Dempsey J et al. The occurrence of sleep-disordered breathing among middle-aged adults. *N Engl J Med* 1993;328:1230-5 CONTACT: Martine Konorski Director, Corporate Communications Sorin Group Tel: +33 (0)1 46 01 33 78 Mobile: +33 (0)6 76 12 67 73 e-mail:martine.konorski@sorin.com or Francesca Rambaudi Director, Investor Relations Sorin Group Tel: +39 02 69969716 e-mail:investor.relations@sorin.com KEYWORD: EUROPE ITALY INDUSTRY KEYWORD: HEALTH BIOTECHNOLOGY CARDIOLOGY CLINICAL TRIALS MEDICAL DEVICES PHARMACEUTICAL OTHER HEALTH SOURCE: Sorin Group Copyright Business Wire 2012 PUB: 06/12/2012 04:45 AM/DISC: 06/12/2012 04:45 AM <http://www.businesswire.com/news/home/20120612005669/>

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