Sorin Group Receives SFDA Approval and Announces Commercial Launch of REPLY(TM) and ESPRIT(TM) Families of Pacemakers in China

The Associated Press

NANJING, China--(BUSINESS WIRE)--Sep 13, 2012--Sorin Group, (MIL:SRN) (Reuters Code: SORN.MI), a global medical device company and a leader in the treatment of cardiovascular diseases, announces today the marketing approval from China's State Food and Drug Administration (SFDA) and full commercial launch in China of the REPLY and ESPRIT families of pacemakers. Both families include easy-to-use functions and patient safety features, with REPLY, at 8ccs, maintaining its position as the world's smallest dual-chamber pacemaker.

The REPLY and ESPRIT families have several common attributes: some of the industry's smallest devices, uncompromised longevity, and SMARTCHECK™, a tool designed to simplify device checks by automating follow up tests at the click of a button. In addition, each device presents its own unique features: The REPLY pacemakers, the smallest dual-chamber pacemakers on the market, offer the exclusive pacing mode, SafeR™, which constantly monitors and promotes the patient's natural cardiac activity. SafeR is the world's first pacing mode to maintain over 99% intrinsic conduction 1. Delivering unnecessary pacing to the right ventricle has been shown to significantly increase the risk of heart failure and atrial fibrillation, two conditions that can prove fatal and place a heavy cost burden on healthcare systems. Recently-published results have shown that SafeR nearly eliminates unnecessary ventricular pacing 1 and adds 2 year 2 device longevity. The ESPRIT pacemakers include numerous algorithms designed for patient safety: continuous lead impedance measurements to monitor the lead integrity, automatic adjustment of atrial and ventricular sensing, and ventricular autothreshold to automatically adjust pacing output in case of changing thresholds, thereby enhancing the device performance and longevity. "I have worked closely with Sorin Group for the last 15 years. Sorin is strongly committed to better patient outcomes," said Professor Frédéric Anselme, MD, PhD, Rouen University Hospital, France . "Sorin's new small and long-lasting REPLY and ESPRIT devices have brought tremendous benefits to thousands of European patients. These clinical benefits will now be made available to patients in China who will also be given chances to rely on their heart's natural conduction when it's intact," he added.

"Sorin Group is the market leader in the cardiac surgery segment in China. Sorin Group has a long tradition of delivering innovative therapies for the management of cardiac arrhythmia and heart failure patients over the last 40 years," Jerry Wang, General Manager, Sorin Group China . "We are very proud to be able to bring the world's smallest pacemaker family to patients and physicians in China." 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, Sorin Group focuses on three major therapeutic areas that include: 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.

1 Davy JM, Hoffmann E, Frey A et al. Near elimination of ventricular pacing in SafeR mode compared to DDD modes: a randomized study of 422 patients. Pacing Clin Electrophysiol 2012;35(4):392–402.Benkemoun H, Sacrez J, Lagrange P et al. Optimizing pacemaker longevity with pacing mode and settings programming: results from a pacemaker multicenter registry. Pacing Clin Electrophysiol 2012;35(4):403–8.

2 Benkemoun H, Sacrez J, Lagrange P et al. Optimizing pacemaker longevity with pacing mode and settings programming: results from a pacemaker multicenter registry. Pacing Clin Electrophysiol 2012;35(4):403–8.

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