St. Jude Medical Announces FDA Approval of New Version of Remote Patient Monitoring System

The Associated Press

ST. PAUL, Minn.--(BUSINESS WIRE)--Jan 16, 2013--St. Jude Medical, Inc. (NYSE:STJ), a global medical device company, today announced U.S. Food and Drug Administration (FDA) approval of the next-generation Merlin.net ™ Patient Care Network (PCN), a secure, Internet-based remote care system for patients with implanted medical devices. The newest version of Merlin.net PCN provides clinicians with additional insight into changes in their patients' heart failure status through advanced impedance and lead monitoring capabilities, improving the management of patients at risk of sudden cardiac death or ventricular and atrial arrhythmias.

To assist physicians in accurately diagnosing and managing patients with heart failure, the new version of Merlin.net PCN enables the remote transmission of patient data measured from CorVue® Thoracic Impedance Monitoring, a diagnostic feature that tracks and reports changes in impedance that may reflect changes in heart failure status, monitored by St. Jude Medical implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds). The algorithm assesses impedance changes in multiple vectors of the heart throughout the day and provides the flexibility to customize diagnostic reports for each patient.

"Merlin.net PCN's ability to monitor when there is a significant impedance change is an important advancement to remote monitoring technologies," said Dr. Richard Waters of the Stockton Cardiology Medical Group in Stockton, Calif. "Clinicians using this technology will be able to detect heart failure symptoms earlier than ever before, optimizing care for patients who are at risk of worsening heart failure." The latest version of Merlin.net PCN also features the LeadAssurance™ Alert, which builds upon existing lead monitoring capabilities by bundling new and existing notifications into one comprehensive alerting suite. Data from the LeadAssurance Alert offers nightly remote alert checks on high-voltage devices to ensure that lead performance is continually monitored and all diagnostics are reported to clinicians.

Merlin.net PCN gathers and stores data from the implant procedure, in-clinic follow-up visits and from remote device transmissions sent from a patient's home. Remote transmissions are sent via Merlin@home™ Transmitter, a system that allows patient data from an implanted cardiac device to be wirelessly downloaded and securely transmitted for clinician review. In order to ensure physicians have convenient access to device information, the Merlin@home remote transmitter is now the first remote monitoring technology available that securely transmits using a patient's home broadband Internet connection. Patients using a Merlin@home transmitter are able to transmit data to their physician via a broadband Internet connection, cellular network and standard phone line. With an increasing number of patients lacking access to traditional landlines, a broadband Internet solution provides an alternative

for patients and ensures remote monitoring capabilities are available to those who would otherwise be unable to transmit important clinical data to their clinicians.

“The next-generation Merlin.net PCN was designed to advance disease management of cardiac conditions,” said Eric S. Fain, M.D., president of the St. Jude Medical Implantable Electronic Systems Division (IESD). “In addition to advancing monitoring features, we have added broadband capabilities to increase patient access to home monitoring technology. As a company, we continue to focus on developing innovative remote monitoring technologies that enable earlier interventions for clinicians and accessible solutions for patients.” The remote monitoring capabilities facilitated by the Merlin@home transmitter permit automated follow-up appointments and daily device checks to occur wirelessly, with limited patient action required. This reduces unnecessary visits to the physician's office, while allowing physicians to become aware of changes with the patient's condition or device more quickly. In addition to giving physicians more timely access to important patient and device data, the wireless monitoring system allows physicians to compile a more complete patient record by easily transferring cardiac device data into electronic health record (EHR) systems.

About Merlin.net Patient Care Network (PCN) Implantable cardiac devices are designed to capture and record information about device performance and patient heart rhythms that is vital to patient care. Merlin.net PCN organizes this information for fast analysis and easy review and allows data to be sent directly to a clinic's or a hospital's (EHR) system so the data is included in the patient’s comprehensive personal health record.

With immediate access to patient information through the secure Merlin.net PCN website, physicians can remotely monitor and assess patient device data and determine the level of care needed. Alert notification delivery times can be customized to fit in with physician determined clinic hours, including any after-hours processes the clinic might provide.

The Merlin.net PCN system adheres to patient privacy standards and requirements for the electronic transmission of health information, as set forth by the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

About St. Jude Medical St. Jude Medical develops medical technology and services that focus on putting more control into the hands of those who treat cardiac, neurological and chronic pain patients worldwide. The company is dedicated to advancing the practice of medicine by reducing risk wherever possible and contributing to successful outcomes for every patient. St. Jude Medical is headquartered in St. Paul, Minn. and has four major focus areas that include: cardiac rhythm management, atrial fibrillation, cardiovascular and neuromodulation. For more information, please visit sjm.com.

Forward-Looking Statements This news release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties. Such forward-looking statements include the expectations, plans and prospects for the Company, including potential clinical

successes, anticipated regulatory approvals and future product launches, and projected revenues, margins, earnings and market shares. The statements made by the Company are based upon management's current expectations and are subject to certain risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. These risks and uncertainties include market conditions and other factors beyond the Company's control and the risk factors and other cautionary statements described in the Company's filings with the SEC, including those described in the Risk Factors and Cautionary Statements sections of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2011 and Quarterly Report on Form 10-Q for the fiscal quarter ended September 29, 2012. The Company does not intend to update these statements and undertakes no duty to any person to provide any such update under any circumstance.

CONTACT: St. Jude Medical, Inc.

J.C. Weigelt, 651-756-4347 Investor Relations jweigelt@sjm.com Kristi Warner, 651-756-2085 Media Relations kwarner@sjm.com KEYWORD: UNITED STATES NORTH AMERICA MINNESOTA INDUSTRY KEYWORD: TECHNOLOGY DATA MANAGEMENT SOFTWARE HEALTH CARDIOLOGY MEDICAL DEVICES FDA MANAGED CARE SOURCE: St. Jude Medical, Inc. Copyright Business Wire 2013 PUB: 01/16/2013 08:00 AM/DISC: 01/16/2013 08:00 AM
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