

News Release

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St. Jude Medical Announces FDA Approval of Accent RF and Anthem RF Pacemakers Equipped With Wireless Technology

Products represent important next step in health care connectivity with the introduction of the first pacemaker devices with automatic test results and complete diagnostics that can be accessed via wireless communication in a clinic or remotely

ST. PAUL, Minn. – July 21, 2009 – St. Jude Medical, Inc. (NYSE:STJ) today announced U.S. Food and Drug Administration (FDA) approval of its Accent™ RF pacemaker and Anthem™ RF CRT-P (cardiac resynchronization therapy pacemaker). The company also announced FDA and European CE Mark approval of version 4.0 of the Merlin.net® Patient Care Network (PCN), which supports the Accent RF and Anthem RF devices.

The Accent and Anthem product family features RF telemetry that enables secure, wireless communication between the implanted device and the programmer used by the clinician or a home monitor, making it the first integrated system of pacing devices with wireless telemetry from implant through follow-up. Wireless communication is used when clinicians implant the device and during follow-up appointments, which can be performed in the clinic or via remote monitoring from the patient's home.

“The Accent RF pacemaker and Anthem RF CRT-P are representative of St. Jude Medical’s dedication to providing early insight into actionable information for physicians,” said Eric S. Fain, M.D., president of the St. Jude Medical Cardiac Rhythm Management Division. “The pacemakers were designed in response to physician and patient needs for devices that provide timely, actionable information. Using the remote monitoring capabilities, physicians can more efficiently follow patients, while patients enjoy the convenience of care from home.”

Patient device follow-up can be scheduled to take place automatically, in a hands free manner, with no patient interaction required. Information from the device is then captured by the Merlin@home® transmitter, and becomes available for viewing by the clinician via Merlin.net PCN. In addition to fast access to device data, Merlin.net PCN also allows physicians to compile a more complete patient record, by easily transferring cardiac device data into electronic health records (EHRs).

The Accent RF pacemaker and Anthem RF CRT-P have several features that simplify patient management. These features include AT/AF Alerts, AutoCapture® Pacing System technology that measures the heart’s reaction to pacing beat-by-beat, and the VIP® algorithm that enables the heart’s intrinsic rhythm to prevail when appropriate, thereby reducing unnecessary ventricular pacing.

The AT/AF Alert feature helps to better assist physicians in accurately diagnosing and managing patients with fast rates in the heart’s upper chambers, called atria. This feature is designed to notify physicians

when a rapid atrial rate, atrial tachycardia or atrial fibrillation (AT/AF), exceeds a programmed value or occurs over an extended period of time. The devices also can be programmed to notify the patient of AT/AF episodes, as well as device- and lead-related issues, through a two-tone audible alert. In addition, the patient's clinic can be informed through the home monitoring system. These features will allow the physician to more proactively manage patients' atrial arrhythmias, such as AF.

"The automatic alerts provided by the RF telemetry built in to the Accent RF and Anthem RF devices enhance my ability to manage patients' heart conditions and disease progression, something that is particularly important for patients with heart failure or other co-morbidities," said Steven Greenberg, M.D., coordinator of the Arrhythmia and Pacemaker Center at St. Francis Hospital in Roslyn, New York. "Rather than checking the device a few times a year, the daily alerts allow me to know about important changes in my patient's condition or device functions so I can act more quickly in addressing any issues."

AutoCapture Pacing System technology allows the devices to be programmed to automatically monitor and adjust the level of electrical energy needed for stimulating the patient's heart, confirming that the heart is responding to the stimulation. This feature provides the dual benefit of added safety for the patient and increased efficiency for physicians, as vital threshold tests are performed automatically.

The St. Jude Medical Ventricular Intrinsic Preference (VIP) algorithm allows the device to monitor the heart beat-by-beat and provide pacing only when necessary. Allowing the patient's natural heart rhythm to work on its own when possible has been shown to benefit overall heart health.

With the combination of advanced features and efficiencies provided by the company's consolidated Unity device platform, the Accent RF pacemaker and Anthem RF CRT-P offer significantly improved battery longevity and an industry-leading seven-year warranty.

Cardiac pacemakers are used to treat bradycardia, which is a heart rate that is too slow. These devices monitor the heart and provide electrical stimulation when the heart beats too slowly for each patient's specific physiological requirements.

A CRT-P resynchronizes the beating of the heart's lower chambers (ventricles), which often beat out of sync in heart failure patients. Studies have shown that CRT can improve the quality of life for many patients with heart failure, a progressive condition in which the heart weakens and loses its ability to pump an adequate supply of blood. An estimated 5 million Americans suffer from heart failure, with 550,000 new cases diagnosed each year.

About Merlin.net Patient Care Network

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 or hospital's Electronic Health Records (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.



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Version 4.0 of Merlin.net PCN provides an additional feature called DirectTrend™ Viewer, which graphically displays patient trends and disease progression. This allows physicians to more effectively and efficiently manage patients through interactive views of patient data over time.

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. Headquartered in St. Paul, Minn., St. Jude Medical employs approximately 14,000 people worldwide and has four major focus areas that include: cardiac rhythm management, atrial fibrillation, cardiovascular and neuromodulation. For more information, please visit www.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 Quarterly Report on Form 10-Q for the fiscal quarter ended April 4, 2009. The Company does not intend to update these statements and undertakes no duty to any person to provide any such update under any circumstance.