St. Jude Medical Announces FDA Approval of AssuraT Implantable Defibrillators with Features That Reduce Inappropriate Shocks

The Associated Press

ST. PAUL, Minn.--(BUSINESS WIRE)--May 8, 2012-- St. Jude Medical, Inc.

(NYSE:STJ), a global medical device company, today announced U.S. Food and Drug Administration (FDA) approval of its Assura(TM) portfolio of implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds). The new implantable defibrillators feature SecureSense(TM) RV Lead Noise Discrimination, an algorithm that expands the St. Jude Medical ShockGuard(R) Technology and offers advanced sensing options designed to reduce the incidence of inappropriate shocks for patients with these devices.

"The Assura product portfolio offers new features that protect patients from unnecessary defibrillation therapy," said Mark A.

Coppess, M.D., at The Stern Cardiovascular Foundation in Memphis, Tenn. "The SecureSense RV Lead Noise Discrimination algorithm is important because it provides a way to distinguish oversensing due to lead issues from real episodes that warrant life-saving treatment." The SecureSense RV Lead Noise Discrimination algorithm is expected to assist physicians by providing advanced alerts as well as more proactively lowering the risk of lead-related complications through its ability to automatically withhold tachycardia therapy in the presence of lead noise (over-sensing of electrical signals). The technology differentiates lead noise from true ventricular tachycardia (VT) or ventricular fibrillation (VF) episodes that require life-saving therapy.

In addition, ShockGuard technology features specific programming that distinguishes between rhythms that require defibrillation therapy and those that do not, such as benign arrhythmias. DecisionTx(TM) programming offers advanced sensing technology designed to avoid sensing unwanted signals (T-waves) and more anti-tachycardia pacing options, which can convert many fast ventricular arrhythmias painlessly and avoid the need for high-voltage shocks. Using ShockGuard with DecisionTx programming, 98.5 percent of patients are projected to be free of inappropriate shocks after one yeari.

"For some patients, the fear of receiving a shock can either prevent them from receiving a potentially life-saving device, or cause anxiety that reduces their quality of life once they receive the device. These devices directly address this patient concern and provides physicians additional tools to manage individual patient needs," said Eric S.

Fain, M.D., president of the St. Jude Medical Cardiac Rhythm Management Division.

"The launch of the Assura family of implantable defibrillators further strengthens our cardiac rhythm management product portfolio and provides physicians with the broadest range of options to deliver safe, effective therapy." The Assura family of devices will allow St. Jude Medical to continue to offer industry leading 40 J in delivered energy, in addition to TailoredTherapy(TM) features that give physicians more options for customizing therapy for patients, such as DeFT Response(TM) Technology. The DeFT Response Technology feature is designed to meet the needs of patients with high or varying defibrillation thresholds, helping physicians to ensure appropriate delivery of life-saving therapy. The Assura product portfolio includes the Quadra Assura(TM) CRT-D, the Unify Assura(TM) CRT-D and the Fortify Assura(TM) ICD.

An ICD is an advanced implantable device that treats potentially lethal, abnormally fast heart rhythms (ventricular tachycardias or ventricular fibrillation), which often lead to sudden cardiac death (SCD). Approximately 325,000 people per year in the U.S. die suddenly of SCD.

A CRT-D device resynchronizes the beating of the heart's lower chambers (ventricles), which often beat out of sync in heart failure patients, and provides back up treatment for SCD, which is a risk factor associated with certain types of heart failure. Studies have shown that CRT (cardiac resynchronization therapy) 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. About five million Americans suffer from heart failure, with 550,000 new cases diagnosed every year, according to the American Heart Association.

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 March 31, 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.

i. Daubert, JP, et al. Inappropriate Implantable Cardioverter-Defibrillator Shocks in MADIT II: Frequency, Mechanisms, Predictors, and Survival Impact. JACC. 2008;51(14):1357-1365.

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