Study confirms ICD therapy improves long-term survival of patients with heart failure

The Associated Press

ST. PAUL, Minn.--(BUSINESS WIRE)--May 10, 2012-- St. Jude Medical, Inc. (NYSE:STJ), a global medical device company, today announced results of the SCD-HeFT (Sudden Cardiac Death in Heart Failure Trial) 10-Year Follow-up Study at Heart Rhythm 2012, the Heart Rhythm Society's 33rd Annual Scientific Sessions in Boston. The study demonstrated implantable cardioverter defibrillator (ICD) therapy significantly reduces mortality for at least 11 years in patients with moderate heart failure (HF).

The SCD-HeFT 10-Year Follow-up Study was led by Dr. Gust H. Bardy at the Seattle Institute for Cardiac Research (SICR), who was also the principal investigator in the original SCD-HeFT trial, and was sponsored by the National Heart, Lung, and Blood Institute (NHLBI) and the National Institutes of Health (NIH) with a subsidiary grant provided by St. Jude Medical. It adds to the results of the original trial by further comparing the mortality data of the remaining SCD-HeFT patients in the three arms of the study (ICD therapy, placebo and amiodarone) and provides additional data regarding survival benefits of ICD therapy. Mortality status was available for 2,291 patients, or 91 percent, of the original 2,521 SCD-HeFT trial participants, with a median follow-up duration of 11 years for survivors. This substantial amount of patient data has resulted in significant findings for these patient groups.

"While the original findings of the SCD-HeFT trial advanced the standard of care for patients with heart failure, the follow-up data are critical to define long-term ICD mortality benefits," said Dr.

Jeanne Poole, Professor of Medicine at the University of Washington, who presented the data in a late-breaking clinical trial session at Heart Rhythm 2012. "The SCD-HeFT findings demonstrate that patients experience the lifesaving benefit of ICD therapy over a decade of clinical heart failure." Among the findings, the long-term mortality of patients with a conservatively programmed, shock-only ICD was significantly lower than patients who did not receive a device. The absolute 12-year mortality rate for patients originally randomized to the ICD group was 5 percent lower than the group originally randomized to the placebo group (despite a significant number of the control patients receiving devices after the end of the original trial). As seen in the original SCD-HeFT trial results, the mortality difference was much more significant in patients with New York Heart Association (NYHA) Class II than NYHA Class III HF (who did not have the benefit of cardiac resynchronization therapy at the time of the trial). The survival benefit was also greatest in patients with an ischemic etiology (HF caused by impaired coronary artery blood flow).

"St. Jude Medical is proud to have supported the SCD-HeFT follow-up study, a trial

that provides physicians with important information on the long-term efficacy of ICD therapy," said Dr. Mark Carlson, chief medical officer and senior vice president of research and clinical affairs for the St. Jude Medical Cardiac Rhythm Management Division.

"We'll continue to support trials providing physicians with clinically relevant information that can help them to improve patient outcomes." The original SCD-HeFT data demonstrated superiority of ICD therapy over the control group, with a median follow up of nearly five years.

The control patients were treated using optimal medical therapy (OMT) alone. A second comparison was conducted comparing the use of amiodarone (a medication used to treat irregular heartbeats) to the control group. The study was instrumental in changing the national reimbursement policy for ICD therapy. The original trial remains the largest, longest, prospective, randomized, multicenter trial of ICD therapy.

The original SCD-HeFT was sponsored by the NHLBI and NIH with supplementary sponsorship by Medtronic and Wyeth Ayerst, and results were provided to the Centers for Medicare and Medicaid Services who approved payment of ICD therapy in ischemic and non-ischemic systolic dysfunction patients with left ventricular ejection fractions (EF) less-than or equal to 35 percent and with NYHA Class II and Class III congestive HF.

Heart failure occurs when the heart is unable to pump enough blood to meet the body's demands. It usually occurs due to progressive dysfunction of the heart muscle over time, rather than an acute and abrupt event. Heart Failure results in the build-up of fluids, or congestion, throughout the body, which can lead to shortness of breath, swelling, and potentially lethal heart rhythm abnormalities.

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.

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.

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