St. Jude Medical Announces Preliminary Third-Party Validation of Registry Data for Optim-Insulated Defibrillation Leads

The Associated Press

ST. PAUL, Minn.--(BUSINESS WIRE)--Nov 8, 2012--St. Jude Medical, Inc. (NYSE:STJ), a global medical device company, today announced the Population Health Research Institute (PHRI), an academic health science research institute, has completed a preliminary analysis of data received from ongoing prospective registries that monitor the performance of the Durata™ and Riata™ ST Optim implantable cardioverter defibrillator (ICD) leads. The analysis was performed independently by PHRI using St. Jude Medical databases and the results are published beginning on page 240 of the second edition of the 2012 St. Jude Medical Product Performance Report (PPR), released today on sjmprofessional.com.

PHRI analyzed data from three actively monitored registries; the OPTIMUM, SCORE and SJ4 Post-Approval registries, all sponsored by St. Jude Medical. The combined data from these registries currently represents 10,987 leads implanted at 293 sites.

The findings from PHRI's initial analysis of the combined Optim-insulated lead registries, include: 0.06 percent rate of all-cause insulation abrasion (includes all types of abrasion and other mechanical types of insulation damage) 0.31 percent rate of all-cause mechanical failure (includes any insulation abrasion, conductor fracture, failure of a crimp, weld, or bond, or other mechanical failure) "PHRI conducted this independent analysis of the combined lead registries and found that the rates of insulation abrasion and mechanical failure of Riata ST Optim and Durata leads appear to be very low," said Dr. John Cairns, professor of Medicine and former dean of Medicine at University of British Columbia in Vancouver. "The strengths of these registries are their prospective designs, the use of pre-specified and standard lead failure definitions, and the adjudication of all outcomes by expert personnel." PHRI convened a committee of independent physicians chaired by Dr. John Cairns, an internationally recognized expert in cardiology clinical trials who has no affiliations with the cardiac rhythm management device industry, to perform the analysis. Additional committee members include Dr. Stuart Connolly, professor and director of the Division of Cardiology at McMaster University, Dr. Jeff Healey, associate professor of Cardiology at McMaster University, Dr. Andrew Epstein, professor of Medicine at the University of Pennsylvania and chief of Cardiology at the Philadelphia Veterans Administration Medical Center, and Dr. Christopher Buller, professor of Medicine at The University of Toronto and director of Cardiac Catheterization and Intervention at St. Michael's Hospital.

"PHRI's independent analysis of Optim-insulated defibrillation lead data continues to support the safety and reliability of our Durata leads," said Dr. Mark Carlson, chief medical officer and senior vice president of Research and Clinical Affairs for the St. Jude Medical Implantable Electronic Systems Division. "We will continue to closely

monitor the performance of our high-voltage leads in order to support our efforts to provide safe, reliable devices to physicians around the world." The committee will continue to meet on an ongoing basis to review data as it is collected, which will be reported in future St. Jude Medical Product Performance Reports.

About PHRI The Population Health Research Institute (PHRI) was founded in 1999 as a joint Institute of Hamilton Health Sciences Corporation (HHS) and McMaster University; it is now one of the largest and most cited academic cardiovascular research groups worldwide. The institute's vision is to conduct large simple studies to address questions of international importance and relevance. Its research programs explore the causes and prevention of cardiovascular disease, diabetes, obesity and societal influences on health, perioperative vascular complications, and stroke.

PHRI has conducted more than 50 global trials and epidemiological studies in more than 1500 centers in 83 countries, involving over 500,000 patients, leading to more than 800 publications in the last 10 years in prestigious medical journals such as the New England Journal of Medicine, The Lancet, the Journal of the American Medical Association, the British Medical Journal, Circulation, the Journal of the American College of Cardiology and the European Heart Journal. Several of the discoveries made by scientists at the PHRI have influenced prevention and treatment practices worldwide.

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.

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