Analysis of lead from Florida hospital shows no inside-out abrasion in Durata product

The Associated Press

ST. PAUL, Minn.--(BUSINESS WIRE)--Jun 22, 2012-- St. Jude Medical, Inc. (NYSE:STJ), a global medical device company, today issued the following statement: Through our investigation of the MAUDE database report submitted to the FDA on May 2, 2012, and information provided to the company by the FDA, including model number, implant and event dates, St. Jude Medical has identified a single Durata(R) lead that matches the available information. The FDA has confirmed that the serial number of this lead matches the serial number from the MAUDE report. Our analysis of the lead indicates it was damaged due to external abrasion, which is not the same as the inside-out abrasion that has been seen in our previous generation Riata(R) leads. Simultaneous to this announcement, the company has submitted a medical device report (MDR) to the FDA with our additional findings.

The identified lead was explanted at a Florida hospital, and the hospital has been very helpful in allowing the company to review the details of this case. The hospital has provided us with static and dynamic fluoroscopy and photographs of the extracted lead. The hospital also allowed us to inspect the lead at the hospital. One of our senior lead engineers traveled to the hospital to microscopically analyze the lead under the hospital's supervision.

Through our investigation, we have identified that the patient had an additional defibrillation lead that had been capped (and was no longer being used). In the fluoroscopic images, the two leads cross in the region mentioned in the filed MAUDE report. Based upon physical examination, our analysis indicates the damage to the Durata lead is consistent with external abrasion from contact with a calcified, or hardened, heart valve or possibly from lead-to-lead contact. External abrasion is a known cause of failure across all cardiac leads in the industry, which is different from the inside-out abrasion seen with externalized conductors observed in some Riata leads.

We recognize the importance of providing physicians with up-to-date and accurate information in a timely and responsible manner so that they can make informed patient care decisions. This case highlights the importance of appropriate analysis in determining the root cause of lead damage. It is our desire to work closely with physicians to understand the circumstances surrounding a device malfunction. We encourage physicians to report any case of lead failure to the manufacturer for further inspection and analysis to best ensure we are able to validate and communicate information in the interest of patient safety.

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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