Design of new Ellipse ICD inspired by feedback from over 200 physicians from around the world

The Associated Press

ST. PAUL, Minn.--(BUSINESS WIRE)--Apr 16, 2012-- St. Jude Medical, Inc. (NYSE:STJ), a global medical device company, today announced CE Mark Approval of the Ellipse(TM) implantable cardioverter defibrillator (ICD). Designed with feedback from more than 200 physicians from around the world, the Ellipse ICD provides the benefits of advanced features and power in the industry's smallest high-energy ICD.

ICDs are advanced implantable cardiac devices that treat potentially lethal, abnormally fast heart rhythms (ventricular tachycardia or ventricular fibrillation) that often lead to sudden cardiac death (SCD).

The Ellipse ICD's unique shape was conceptualized by physicians during focus groups in which they crafted in clay their vision for the ideal device design. The physician-inspired shape is unlike any currently available, with each of the enhancements designed to increase patient comfort or make the device easier to implant. The angled header and rounded edges were designed to improve the way a cardiac lead wraps around the device once connected, which can result in a smaller pocket for the device.

"Its thinness, longevity and new discrimination algorithms constitute the answers to the three main concerns of patients and their doctors: decreasing the volume of the can, reducing the risk for infection during ICD replacement and minimizing inappropriate shock," said Dr.

L.R.C. Dekker, cardiologist from the Cardiac Center of the Catharina Hospital in Eindhoven, The Netherlands, who implanted the first Ellipse ICD in Europe.

Within its unique design, the device contains new features in addition to the industry-leading feature set provided in the Fortify(TM) ICD.

These features include expanded ShockGuard(TM) technology for protection against inappropriate and unnecessary therapy, high energy delivery, CorVue(TM) congestion monitoring, and enhanced ST Monitoring to offer greater insight into ischemia-related ventricular arrhythmias.

Additionally, the Ellipse ICD adds SecureSense(TM) RV lead noise discrimination, a new algorithm that offers a strong set of lead monitoring capabilities. The new feature can differentiate lead noise from true ventricular tachycardia (VT) or ventricular fibrillation (VF) episodes, which provides the ability to automatically withhold tachycardia therapy in the presence of lead noise. The new feature is expected to help physicians more proactively lower the risk of lead-related complications.

"St. Jude Medical has a strong commitment to ongoing investment in research and development initiatives, and routinely incorporates physician feedback in the planning and design of our devices," said Eric Fain, M.D., president of the St. Jude Medical Cardiac Rhythm Management Division. "The launch of the Ellipse family of ICDs further enhances our robust and comprehensive offering of cardiac rhythm management devices which, along with our Unify Quadra CRT-D system, represents the most advanced portfolio of high voltage devices available in the industry." The updated programming in ShockGuard technology provides more accurate sensing and is able to better discriminate between rhythms that require defibrillation and those that do not. New algorithms and enhanced detection capabilities include the ability to better discriminate between lead noise and arrhythmias that require therapy, as well as which heart chamber is causing the arrhythmia. These improvements are projected to reduce inappropriate therapy by 74% for all rhythms, allowing for more effective therapy1.

Expanded ST Segment monitoring, together with the Merlin.net(TM) Patient Care Network and patient alerts, provide timely information to clinics that allow for better management of arrhythmias. The Ellipse ICD also incorporates the CorVue congestion monitoring algorithm. This feature alerts physicians when a patient's heart failure may be worsening, as evidenced by changes in electrical signals that can be correlated to increased congestion, or fluid retention, in the chest area.

Similar to the St. Jude Medical Fortify(TM) ICD, the Ellipse ICD adheres to the International Standards Organization (ISO) DF4 connector specification. The DF4 connector reduces the number of connections between the defibrillation lead and the device, which can streamline the implant procedure and improve patient comfort by reducing the bulk of wires in the patient's chest. St. Jude Medical first began using DF4 technology in early 2009.

St. Jude Medical's high-voltage portfolio is augmented by the Durata(TM) cardiac defibrillation lead, featuring Optim(TM) insulation. Optim insulation is a hybrid material that combines the biostability and flexibility of high-performance silicone rubber with the strength, tear resistance and abrasion resistance of polyurethane, to provide increased durability and flexibility. St. Jude Medical has ongoing prospective, actively monitored registries monitoring the performance of its Optim-insulated leads, representing over 10,000 patients enrolled at 292 sites, with over five years and 24,000 patient-years of data, which continue to confirm its excellent reliability.

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. The Company does not intend to update these statements and undertakes no duty to any person to provide any such update under any circumstance.

1 Results based on stored electrogram clip testing. Data on File, St.

Jude Medical Test Reports, doc 60037875 and 60041229. Reduction of inappropriate therapy is based upon a reduction in false positive results and ATP set as the first therapy in all rate zones.

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