Key Clinical Data for St. Jude Medical's Structural Heart Technologies Revealed at EuroPCR

The Associated Press

ST. PAUL, Minn. & PARIS--(BUSINESS WIRE)--May 16, 2012-- St. Jude Medical, Inc. (NYSE:STJ), a global medical device company, today announced that significant clinical data for its structural heart portfolio is being presented during EuroPCR. Among the highlights are first-in-man and six-month data for the company's Portico(TM) Transcatheter Aortic Heart Valve and results from a multicenter study for AMPLATZER(TM) Cardiac Plug (ACP) technology.

St. Jude Medical's Transcatheter Aortic Valve Implantation (TAVI) Technology Information about the St. Jude Medical Portico valve will be presented during a Glimpse of the Future session on Friday, May 18 from 9:00 to 12:00 in the Maillot Room. The Emerging Technologies for Transcatheter Aortic Valve Therapies session will include a pre-recorded live case using the St. Jude Medical Portico valve, andpresentsix-month data from the first-in-man experience by Dr. Ganesh Manoharan of Royal Victoria Hospital in Belfast, U.K.

The company continues to enroll patients in its trial, which was designed to study the safety and effectiveness of the Portico valve.

In addition to the three centers already implanting in the UK, the first implant of the valve in Bad Neuheim, Germany was recently completed, marking the initiation of the European clinical trial in Germany.

The primary endpoint for patients in the five-center study is 30-day, all-cause mortality with secondary safety and effectiveness endpoints; patients will be followed for one year. The technology remains on track for a limited European launch in 2012. It is not approved in the United States.

The Portico transcatheter heart valve is a next-generation technology that uses a minimally-invasive catheter to deliver and position the valve in the heart. It was designed to help increase physician control and placement accuracy during valve deployment, and can be repositioned at the implant site or retrieved before it is released from the delivery system - an advancement over earlier generations of valves.

AMPLATZER Cardiac Plug Data Results from the AMPLATZER Cardiac Plug European Post-Market Observational Study will be presented in several sessions during EuroPCR.

The ACP was designed to close the Left Atrial Appendage (LAA), a tubular-shaped, muscular pouch connected to the atrium of the heart.

The ACP is intended for patients diagnosed with non-valvular atrial fibrillation (AF) to help prevent blood clots from forming in the heart and may lessen the risk of stroke. During episodes of AF, atrial contractions are rapid and irregular, which pools blood in the LAA and increases the likelihood of a clot to form. If a clot is released from the LAA, it can enter circulation and potentially cause a stroke.

The prospective, observational study is a non-randomized evaluation of 204 patients treated at 15 European investigative centers to assess closure and adverse event rates associated with the ACP for LAA closure. The multicenter study enrolled patients with a history of paroxysmal, persistent or permanent nonvalvular AF implanted with the ACP.

A late-breaking trial session on Interventions for Structural Heart Disease will take placeon Thursday, May 17, from 15:00 to 16:20 in Room 241. During the session, Left Atrial Appendage Closure with the ACP: Results of the European Post-Market Observational Studywill be presented by Dr. Kevin Walsh, cardiologist at the Mater Misericordiae University Hospital in Dublin, Ireland.

The LAA Closure: Clinical Outcomes session presented on Tuesday, May 15 included data from the European post-market observational study. It was presented by Dr. Jai-Wun Park, the head of cardiology, angiology and intensive care medicine at Asklepios Hospital Harburg in Hamburg, Germany.

-- Acute Safety Results from ACP European Multicenter Post-Market Observational Study - These acute results demonstrate a successful procedure for patients representing a real-world demographic. The excellent implant success rate, with a high technical success of 96.6 percent and rate of safety events, compares favorably with other devices and prior ACP publications. The implant closure rate (occlusion) was 99.5 percent, which means that the area of the LAA was successfully sealed where harmful clots could form and potentially cause stroke.

Tuesday's session also included a presentation from Dr. David Meerkin, director of the structural and congenital heart disease unit at the Shaare Zedek Medical Center in Jerusalem, Israel. The data was derived from a single-center experience with LAA closure in a high-risk group of patients.

-- One-Year Outcomes Following LAA Occlusion in High-Risk Patients with Atrial Fibrillation - Outcomes demonstrated that in a high-risk group of patients, the ACP was used safely and effectively to occlude the LAA. The study observed 30 patients for at least one year with relative or absolute contraindications to oral anticoagulation. A total of 49.9 patient years of follow-up were completed with only one TIA due to clots, which contrasts a CHADS2 prediction of 4.1 strokes during this timeframe.

The data from both these clinical outcomes demonstrate that the safety and effectiveness of the ACP compares favorably with the results of previously reported LAA closure technologies and may be a viable alternative to anticoagulation therapy to help reduce stroke risk for patients with AF. The ACP is CE marked, but is not approved for sale in the United States.

Attendees can visit St. Jude Medical at booth F8 and F9 on Level 1 of the exhibition hall during EuroPCR or visit us on the web for show-specific information at: http://www.sjmprofessional.com/europcr [1].

EuroPCR is the official congress of the European Association of Percutaneous Cardiovascular Interventions (EAPCI), a leading international course for interventional cardiovascular specialists.

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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