St. Jude Medical EnligHTNment Study Highlighted at EuroPCR during Trials That May Change Clinical Practice Session

ST. PAUL, Minn. and PARIS – May 21, 2013 – St. Jude Medical, Inc. (NYSE:STJ), a global medical device company, today announced the start of its landmark EnligHTNment clinical study. This is the largest randomized, prospective trial to determine whether renal denervation and medication offers additional health benefits beyond lowering blood pressure in patients with uncontrolled hypertension. The EnligHTNment study will evaluate the EnligHTN™ Multi-Electrode Renal Denervation System and its ability to reduce the risk of major cardiovascular events such as heart attack, stroke, heart failure and cardiovascular death.

Prior to the EnligHTNment trial, the majority of renal denervation studies have only tested the safety and efficacy of this technology in patients with drug-resistant hypertension, which is defined as systolic blood pressure above 160 mmHg, despite taking three or more anti-hypertensive medications including a diuretic.

“The EnligHTNment trial will provide key insight into whether renal denervation therapy can reduce common cardiovascular complications of high blood pressure that often leave patients disabled or, in some cases, can even be fatal,” said Professor Thomas Lüscher, chairman, cardiology and cardiovascular center at the University Hospital in Zurich, Switzerland, a principal investigator for the trial. “Learning more about renal denervation's impact on major cardiovascular diseases will provide critical information on the health effects and potential benefits of the therapy in patients who currently don't have an adequate treatment option.”

Renal denervation represents an important area of research in the management of hypertension for the estimated one billion people globally who live with this life-threatening condition. Hypertension occurs when blood pressure in the arteries is elevated, requiring the heart to work harder than normal to circulate blood through the body.

The EnligHTNment study is a prospective, randomized, controlled study of approximately 4,000 patients with a systolic blood pressure greater than 160 mmHg. Patients enrolled around the world at up to 150 sites will be randomized to medical therapy plus renal denervation or medical therapy alone. All patients will be followed for five years under an event-driven trial design. Primary endpoints for the study include major cardiovascular events such as heart attack, stroke, heart failure with hospitalization and cardiovascular death. Secondary endpoints include the reduction of in-office and ambulatory blood pressure and changes in renal function.

Renal denervation therapy in the EnligHTNment study will use the EnligHTN Renal Denervation System. Prior studies of this system have demonstrated that patients with drug-resistant hypertension had a safe,
rapid and sustained drop in blood pressure. After thirty days, systolic blood pressure was rapidly reduced by an average of 28 mmHg. At six months, it remained stable with an average reduction of 26 mmHg. It is important to note that the risk of cardiovascular death is cut in half with every 20 mmHg decrease in systolic blood pressure.

“St. Jude Medical is pleased to start the landmark EnligHTNment trial to learn more about the long-term effects of uncontrolled hypertension and to see how we can better assist physicians in treating at-risk patients,” said Frank J. Callaghan, president of the St. Jude Medical Cardiovascular and Ablation Technologies Division. “We are committed to being a leader in clinical research and have put in place a team of highly respected thought leaders to run this trial. We look forward to working with the steering committee and study investigators in the coming years.”

Principal investigators in the study include:
- Prof. Michael Böhm, director and chief of internal medicine and cardiology at the University of Saarland in Homburg/Saar, Germany
- Prof. Thomas F. Lüscher, MD, chairman, cardiology and cardiovascular center at the University Hospital in Zurich, Switzerland
- Stuart Connolly, MD, PhD, PHRI, Hamilton, Ontario, Canada

Additionally, a steering committee has also been established to work closely with the principal investigators to provide ongoing oversight and guidance of the EnligHTNment trial.

Committee members include:
- William Gray, MD, interventional cardiologist, Columbia University Medical Center / New York-Presbyterian Hospital, United States
- Dr. Melvin Lobo, PhD, FRCP, hypertension specialist, William Harvey Research Institute/Barts Health Trust
- Felix Mahfoud, MD, interventional cardiologist and hypertension specialist, University of Saarland, Germany
- William McKane, PhD FRCP, nephrologist, Sheffield Teaching Hospitals NHS Foundation Trust, United Kingdom
- Prof. Atul Pathak, MD, PhD, cardiologist and clinical pharmacologist, University Hospital Toulouse, France
- Prof. Kalyanam Shivkumar, MD, PhD, electrophysiologist, University of California, Los Angeles, United States
- Prof. Dirk J. van Veldhuisen, MD, cardiologist and HF specialist, University Medical Center Groningen, The Netherlands

About Renal Denervation and the EnligHTN System

Renal denervation is a catheter-based ablation procedure that potentially provides lasting reduction in blood pressure for patients with resistant hypertension. A catheter is introduced through the femoral artery in the leg to access the renal arteries that connect to the kidneys, where radiofrequency (RF) energy is delivered to create lesions (tiny scars) along the renal sympathetic nerves – a network of nerves that help control blood pressure. This intentional disruption of the nerve supply causes systolic and diastolic blood pressure to decrease.

The EnligHTN system is a multi-electrode ablation technology that features a unique, non-occlusive basket design that delivers a predictable pattern of four evenly-spaced ablations with each catheter.
placement. This allows for continuous blood flow to the kidney during the procedure. Compared to single-electrode ablation systems, the multi-electrode EnligHTN system has the potential to improve consistency and save time, which may result in improved workflow and cost efficiencies.

The EnligHTN technology includes a guiding catheter, ablation catheter and ablation generator. The generator uses a proprietary, temperature-controlled algorithm to produce effective lesions. Additionally, minimal catheter repositioning may result in a reduction of contrast and fluoroscopic (X-ray) exposure.

Recently, the European Society of Cardiology (ESC) and the European Association of Percutaneous Cardiovascular Interventions (EAPCI) issued guidelines recommending the use of catheter-based renal denervation for the treatment of high blood pressure in patients with difficult-to-treat, drug-resistant hypertension.

In 2012, the EnligHTN Renal Denervation System earned European CE Mark approval and was launched in several markets. It is not yet approved for use in the U.S.

To learn more about renal denervation or see a demo of the EnligHTN Renal Denervation System, EuroPCR attendees can visit St. Jude Medical at booth # F16 of the exhibition hall, or visit us on the web for show-specific information at: http://www.sjmprofessional.com/europcr.

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 29, 2012 and Quarterly Report on Form 10-Q for the fiscal quarter ended March 30, 2013. The Company does not intend to update these statements and undertakes no duty to any person to provide any such update under any circumstance.