St. Jude Medical Announces First Patient Enrollment in EnligHTN II Renal Denervation Study

The Associated Press

ST. PAUL, Minn.--(BUSINESS WIRE)--Jan 30, 2013--St. Jude Medical, Inc. (NYSE:STJ), a global medical device company, today announced enrollment of the first patient in the EnligHTN II trial. This post-market clinical study will further evaluate the safety and efficacy of the EnligHTN ™ Renal Denervation System in patients with uncontrolled hypertension. According to the World Health Organization (WHO), one in three adults worldwide has elevated blood pressure - a condition that increases the risk of heart attack, stroke and kidney failure.

The EnligHTN Renal Denervation System from St. Jude Medical. (Photo: Business Wire) The EnligHTN II (Int E r n ationa l non-randomized, s i ngle-arm, lon g -term follow-up study of patients with uncontrolled H yper T ensio N) trial expands upon the research conducted in the EnligHTN I trial, which demonstrated that patients with drug-resistant hypertension treated with the St. Jude Medical EnligHTN system had a rapid and sustained drop in blood pressure. After thirty days, systolic blood pressure was reduced by an average of 28 mmHg that remained stable with a reduction of 26 mmHg points six months after treatment, an important finding as the risk of cardiovascular death drops by half with every systolic decrease of 20 mmHg.

“There is convincing evidence from studies like the EnligHTN I trial linking renal denervation to improved blood pressure in patients who have drug-resistant hypertension,” said Dr. Johannes Brachmann at Klinikum Coburg in Coburg, Germany. “Expanding this research to patients with less severe forms of hypertension is important as this minimally invasive approach allows for a shorter procedure time and a potentially faster recovery time, which may benefit more patients with uncontrolled hypertension.” Hypertension occurs when blood pressure in the arteries is elevated, requiring the heart to work harder than normal to circulate blood throughout the body. A typical normal blood pressure reading is below 120 systolic and 80 diastolic – expressed as 120 / 80 mmHg. To date, 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 above160 mmHg, despite being on three or more anti-hypertensive medications including a diuretic.

The EnligHTN II study aims to broaden this scope by evaluating the mean reduction in systolic blood pressure at six months across all enrolled patients post renal denervation and within sub-groups with varying degrees of kidney functionality. The study will be conducted at 40 sites in Europe and Australia and will enroll approximately 500 patients with uncontrolled hypertension.

“St. Jude Medical is dedicated to conducting research that will contribute to the body of evidence supporting the effectiveness of renal denervation in reducing hypertension,” said Frank J. Callaghan, president of the St. Jude Medical Cardiovascular and Ablation Technologies Division. “Through the course of the EnligHTN II study, we expect to gain additional insights into the benefits and sustainability of blood pressure reductions achieved through use of the EnligHTN Renal Denervation System in an expanded patient population.” 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 renal denervation 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.

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.

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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