

## **Renal Denervation Technology from St. Jude Medical Demonstrates Safe, Rapid and Sustained Reduction in Blood Pressure**

The Associated Press

ST. PAUL, Minn. & MUNICH--(BUSINESS WIRE)--Aug 28, 2012--St. Jude Medical, Inc. (NYSE:STJ), a global medical device company, today announced that interim data demonstrated the company's EnligHTN™ renal denervation system is safe and effective for the treatment of resistant hypertension. Data released during the ESC (European Society of Cardiology) Congress 2012 for the EnligHTN I (ARSENAL) trial demonstrated that on average patients with resistant hypertension experienced a rapid systolic blood pressure reduction of 28 mmHg points after 30 days that remained stable with a reduction of 27 mmHg points three months after treatment.

The EnligHTN renal denervation system from St. Jude Medical produced a safe and rapid 28-point systolic blood pressure reduction in one month for patients with drug-resistant hypertension. (Image provided courtesy of St. Jude Medical, Inc.) Renal denervation is a specialized ablation procedure that has been clinically proven to reduce blood pressure in patients with hypertension that is resistant to medical therapy. A typical normal blood pressure is below 120 systolic (the first number) and 80 diastolic (the second number), and is expressed as 120/80 mmHg. Hypertension, or high blood pressure, is a blood pressure greater than 140/90 mmHg.

Patients that enrolled in the EnligHTN I trial had an average baseline blood pressure of 176/96 mmHg. Their blood pressure remained resistant despite being on three antihypertensive medications, including a diuretic. Patients who underwent a renal denervation procedure using the EnligHTN technology demonstrated a rapid 22-mmHg point drop in systolic blood pressure just prior to their discharge from the hospital. A further 6-point drop in systolic blood pressure was demonstrated at the 30 day milestone and was sustained at three months.

The total 28- mmHg point reduction of systolic blood pressure after 30 days is double the reduction than that of competitive technology in the same time frame. This rapid reduction is important because it provides earlier improvements in patients who have been resistant to other treatments. Three month results demonstrated the technology remained safe and effective with a blood pressure reduction that remained superior to that of competitive technology.

"The risk of cardiovascular death is cut in half with every 20 mmHg decrease in systolic blood pressure, so it is a tremendous benefit to patients that the EnligHTN renal denervation technology is able to reduce blood pressure very rapidly at one month and sustain that reduction," said the trial's Primary Investigator Dr. Costas Tsioufis, Prof. of Cardiology at University of Athens Hippocraton Hospital and Prof. of Medicine, Georgetown University, Washington DC. "The fact that this rapid and

sustained reduction was further confirmed with rigorous ambulatory blood pressure measurements gives me confidence to say that the EnligHTN system delivers a promising therapy for the treatment of resistant hypertension." Ambulatory blood pressure measurements presented during the hot line session at ESC further confirmed that the early drop delivered by the EnligHTN system was reliably sustained through the three month time period. Ambulatory rates are important because they are taken outside a clinical setting, where patient blood pressure is not impacted by external factors such as nervousness, and provide a reading that is more consistent and better reflective of real life.

Forty-six patients were treated with the EnligHTN system in the multicenter study. To be considered for enrollment, patients were required to have a systolic blood pressure above 160 mmHg (150 for patients with type 2 diabetes) and take at least three antihypertensive medications concurrently at maximally tolerated doses, including a diuretic.

According to Frank J. Callaghan, president of the St. Jude Medical Cardiovascular Division, "Hypertension can cause life-threatening health problems and affects more than one billion people around the world. St. Jude Medical is pleased to offer the EnligHTN renal denervation system, which provides to our customers a safe, rapid and sustained treatment for patients at risk with the potential to make immediate and positive changes." Hypertension is a root cause of various life-threatening health problems, including heart disease, stroke, and kidney failure. It impacts more than 1 billion people globally, many of whom do not respond to conventional treatment with medication.

**About the EnligHTN Renal Denervation System** The EnligHTN system is a multi-electrode ablation technology for renal denervation. With its unique basket design, each placement of the ablation catheter administers a reliable and repeatable treatment pattern. Compared to single-electrode ablations systems, the multi-electrode EnligHTN system has the potential to improve consistency, save time as well as result in workflow and cost efficiencies. Additionally, minimal catheter repositioning may result in a reduction of contrast and fluoroscopic (x-ray) exposure.

Using the new EnligHTN system, an ablation catheter delivers radiofrequency (RF) energy to create lesions (tiny scars) along the renal sympathetic nerves – a network of nerves that help control blood pressure; the intentional disruption of the nerve supply has been clinically found to cause systolic blood pressure to decrease.

The technology includes a guiding catheter, ablation catheter and ablation generator. The generator uses a proprietary, temperature-controlled algorithm to produce effective lesions. St. Jude Medical announced CE Mark approval for the EnligHTN renal denervation system in May 2012.

**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

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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](http://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 June 30, 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.

Photos/Multimedia Gallery Available: <http://www.businesswire.com/cgi-bin/mmg.cgi?eid=50387808&lang=en>

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