

New Data from St. Jude Medical Study of EnligHTN Renal Denervation System Presented

Business Wire

St. Jude Medical, Inc. (NYSE:STJ), a global medical device company, today announced new results from the EnligHTN I study, confirming safe, rapid and sustained reduction in blood pressure measurements a year and a half post-procedure. Data presented at the 25th annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium, indicates that patients with drug-resistant hypertension treated with the EnligHTN™ Multi-Electrode Renal Denervation System averaged a 24 mmHg (millimeters of mercury) reduction in systolic blood pressure as measured in an office setting.

The EnligHTN (TM) Multi-Electrode Renal Denervation System from St. Jude Medical, Inc. The EnligHTN system is not approved for use in the U.S. (Photo: Business Wire) “Convincing clinical evidence continues to emerge that supports the benefits of renal denervation in improving systolic blood pressure for patients with drug-resistant hypertension,” said professor Stephen Worthley, from St. Andrew’s Hospital in Adelaide, Australia, a primary investigator in the EnligHTN I trial, who delivered the findings at TCT. “The 18-month results of the EnligHTN I study point to an overall reduction in hypertension, which is important as even modest improvements can have significant health benefits for patients who live with this life-threatening condition. This also supports that the early reduction in blood pressure remains sustained out to 18-months, confirming the durability of this procedure using the EnligHTN catheter.” Eighteen-Month Data Findings: An average systolic blood pressure reduction of 24 mmHg points was reported The longer-term safety profile for renal denervation was supported by showing no clinically significant changes in kidney function At 18-months, 77 percent of patients responded to the therapy, which is defined as a blood pressure reduction of at least 10 mmHg when measured during an office visit as compared to baseline A prospective, multi-center feasibility study, the EnligHTN I trial treated 46 patients in Australia and Europe whose high blood pressure was considered drug-resistant despite taking three or more anti-hypertensive medications including a diuretic. Patients enrolled in the study had an average blood pressure of 176 / 96 mmHg and on average were taking 4.7 medications to control their hypertension. Patients in the study will continue to be followed for two years after their procedure.

Previous results from the EnligHTN I trial indicate an average reduction of 26 mmHg at six-months, 27 mmHg at one year and 24 mmHg at 18-months.

“St. Jude Medical has invested in a robust clinical program to build the body of clinical evidence intended to support renal denervation as the standard of care for the treatment of drug-resistant hypertension,” said Frank J. Callaghan, president of the St. Jude Medical Cardiovascular and Ablation Technologies Division. “These new data from our first renal denervation study demonstrate this therapy is durable and

can benefit patients struggling to control their hypertension.” Renal Denervation and the EnligHTN System The EnligHTN system is a multi-electrode ablation technology for renal denervation, a minimally invasive procedure to treat patients with drug-resistant hypertension. The system delivers a series of radiofrequency (RF) energy ablations to create lesions (tiny scars) along the renal sympathetic nerves – a network of nerves leading to the kidneys that help control blood pressure. A normal blood pressure is typically at or below 120 systolic and 80 diastolic, which is expressed as 120 / 80 mmHg. Hypertension is categorized as a blood pressure reading greater than 140 / 90 mmHg. The risk of cardiovascular death is cut in half with every 20 mmHg decrease in systolic blood pressure.

Compared to single-electrode ablation systems, the non-occlusive basket design of the multi-electrode EnligHTN system has the potential to improve procedural accuracy, save time as well as result in workflow and cost efficiencies. This also allows for continuous blood flow to the kidney during the procedure.

In May 2012, the first-generation EnligHTN Multi-Electrode Renal Denervation System earned European CE Mark approval and was launched in several markets. The company also announced CE Mark approval of the next-generation EnligHTN system in August 2013. Featuring an advanced generator, the next-generation system delivers simultaneous ablations via the multi-electrode catheter, reducing total ablation time by more than 80 percent, from approximately 24 minutes to four minutes. The EnligHTN systems are not yet approved for use in the U.S.

St. Jude Medical is conducting multiple renal denervation studies to add to the body of evidence supporting the potential of renal denervation therapy. In June 2013, the company announced the FDA approval to start a U.S. clinical trial, EnligHTN IV, evaluating the use of the EnligHTN Multi-Electrode Renal Denervation System to treat 590 patients at up to 80 sites across the U.S. and Canada with drug-resistant high blood pressure. The EnligHTN IV trial is now enrolling patients in the U.S.

Earlier this year, the company announced the EnligHTNment trial. This landmark study is the first large-scale trial designed with hard endpoints that will evaluate the long-term effects of renal denervation to see if the therapy also reduces the risk of heart attack, stroke, heart failure requiring hospitalization, as well as cardiovascular death in patients with uncontrolled or resistant hypertension.

According to the World Heart Federation, one billion people globally have high blood pressure which occurs when blood pressure in the arteries is elevated, requiring the heart to work harder to circulate blood throughout the body. Hypertension is referred to as a “silent killer” because it presents no warning signs or symptoms and oftentimes people do not realize they have it.

The European Society of Cardiology (ESC) and the European Association of Percutaneous Cardiovascular Interventions (EAPCI) recently 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.

To learn more about renal denervation or view the EnligHTN Multi-Electrode Renal

New Data from St. Jude Medical Study of EnligHTN Renal Denervation System

Published on Medical Design Technology (<http://www.mdtmag.com>)

Denervation System, TCT attendees can visit St. Jude Medical at booth #617.

Source URL (retrieved on 02/01/2015 - 3:04pm):

<http://www.mdtmag.com/news/2013/10/new-data-st-jude-medical-study-enlightn-renal-denervation-system-presented>