St. Jude Medical Announces First Patient Enrollment in EnligHTN III Renal Denervation Study of Next-Generation EnligHTN System

The Associated Press

ST. PAUL, Minn.--(BUSINESS WIRE)--May 14, 2013--St. Jude Medical, Inc. (NYSE:STJ), a global medical device company, today announced enrollment of the first patient in the EnligHTN III trial. This study will evaluate the safety and performance of the new second-generation EnligHTN ™ Renal Denervation System in patients with drug-resistant, uncontrolled hypertension.

The next-generation system utilizes the proven multi-electrode catheter paired with a new generator that features a high-tech, icon-friendly, touch screen user interface that provides simultaneous ablations using four electrodes. This advancement reduces total ablation time from approximately 24 minutes to four minutes. With its unique non-occlusive basket design, each placement of the ablation catheter using the EnligHTN system administers a predictable treatment pattern while allowing for continuous blood flow to the kidney throughout the procedure. Additionally, the new second-generation EnligHTN generator allows physicians to easily view and record procedure information.

“Lowering hypertension is important as the risk of cardiovascular death doubles with every 20 point increase in systolic blood pressure,” said Prof. Stephen Worthley of St. Andrew's Hospital in Adelaide, Australia, a principal investigator of the EnligHTN III trial. “The ability of the next-generation EnligHTN system to deliver simultaneous ablations and the intuitive touch screen on the generator are advancements that simplified use, markedly reduced procedure times and was well tolerated by our patients." The EnligHTN III study is an international, non-randomized clinical trial that will enroll up to 50 patients in Australia and New Zealand with drug-resistant hypertension, meaning their high blood pressure could not be controlled through medication. To qualify for the study, participants must have systolic blood pressure that remains greater than 160 mmHg as measured during office visits, despite the use of three antihypertensive medications concurrently at the maximum tolerated doses, one of which is a diuretic.

This study expands upon the research conducted in the EnligHTN I trial of the first generation EnligHTN system, which demonstrated that patients with drug-resistant hypertension had a safe, 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.

“St. Jude Medical has a long history of advancements in ablation technologies, which allowed us to quickly bring the first-generation EnligHTN system to the European market in early 2012,” said Frank J. Callaghan, president of the St. Jude Medical Cardiovascular and Ablation Technologies Division. “Now, less than one

year later, we are pleased to bring this innovative therapy to EnligHTN III, a new clinical study evaluating technology advancements in our next-generation system."
About Renal Denervation and the EnligHTN System Renal denervation is a minimally invasive, catheter-based ablation procedure used to treat patients with drug-resistant hypertension (or high blood pressure). The EnligHTN systems deliver radiofrequency (RF) energy from an ablation catheter to create lesions (tiny scars) along the renal nerves – a network of nerves thought to help control blood pressure. The intentional disruption of the nerve supply has been clinically found to cause systolic and diastolic blood pressure to decrease. Typically, normal blood pressure is 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.

In 2012, the first-generation EnligHTN Renal Denervation System earned European CE Mark approval and was launched in several markets. The second-generation EnligHTN system is not approved anywhere in the world. These systems are not approved for use in the U.S.

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.

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.

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.

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