Medtronic News

Medtronic Launches Two New Clinical Programs to Evaluate the Use of Symplicity™ 1 Renal Denervation System across Multiple Conditions

MINNEAPOLIS--(BUSINESS WIRE)--Feb. 13, 2012-- Medtronic, Inc. (NYSE: MDT) announced today the start of two clinical initiatives evaluating the broader, real-world clinical use of the company's Symplicity™ renal denervation system across multiple conditions. Furthering its leadership in the development of renal denervation therapy, Medtronic launched the Global SYMPLICITY Patient Registry, which will evaluate the real-world, long-term impact of renal denervation in more than 5,000 patients, as well as SYMPLICITY-HF, the first clinical trial to examine renal denervation in patients with chronic heart failure and renal impairment.

Renal denervation therapy is a minimally invasive, catheter-based procedure that modulates the output of nerves that line the walls of the arteries leading to the kidneys. These nerves impact the sympathetic nervous system, which affects the major organs that are responsible for regulating blood pressure: the brain, the heart, the kidneys and the blood vessels.

"These research initiatives represent part of Medtronic's broad commitment to partner with the medical community to explore the use of renal denervation in a number of disease states characterized by hyperactive sympathetic nervous system drive," said Sean Salmon, Senior Vice President and President, Coronary & Renal Denervation, Medtronic. "Data from the Global SYMPLICITY Registry and the SYMPLICITY-HF clinical trial will build upon the substantial renal denervation data Medtronic has generated in patients with treatment-resistant hypertension to date."

ABOUT THE GLOBAL SYMPLICITY REGISTRY

The Global SYMPLICITY Patient Registry is a first-of-its-kind database that will include a minimum of 5,000 patients and facilitate the collection of real-world data on the use of the Symplicity™ renal denervation systemin patients with a number of conditions associated with hyperactive sympathetic nervous system drive, including treatment-resistant hypertension and heart failure. The multi-center, prospective, open-label, registry will collect comprehensive data evaluating procedural and long-term safety of renal denervation, as well as efficacy and clinical outcomes. The global registry will enroll a minimum of 5,000 patients at approximately 200 centers worldwide to track patients with hyperactive sympathetic nervous system drive, including treatment-resistant hypertension, heart failure, insulin resistance, chronic kidney disease, and sleep apnea.

"Having one comprehensive platform will allow researchers to efficiently and effectively collect robust clinical data and gain important insights into the effects of renal denervation in other disease processes where increased sympathetic tone is believed to be important," said Michael Böhm, MD, PhD, President, German Society for Cardiology, Chairman, Department of Internal Medicine, University of Saarland, Homburg/Saar, Germany and Global SYMPLICITY Registry co-chair. "The Global SYMPLICITY Registry will allow clinicians worldwide to benchmark procedural practices in diverse patient populations, as well as better understand acute and long-term clinical, quality of life, and cost-effectiveness outcomes."

ABOUT THE SYMPLICITY-HF CLINICAL STUDY

SYMPLICITY-HF is a phase II clinical study designed to evaluate the safety and physiologic response to renal denervation with the Symplicity system in patients with chronic heart failure and renal impairment. The study will enroll approximately 40 adult subjects with chronic heart failure and renal impairment in Europe and Australia.

The principal investigators of the study are Professor Henry Krum, Director of Cardiovascular Research and Education at the Monash University, Victoria, Australia, and Professor Michael Böhm, Director of Klinik für Innere Medizin III and Chief of Cardiology at the University of the Saarland, Homburg/Saar, Germany.

“In heart failure, reduced cardiac output and renal function are associated with increased sympathetic activity, particularly in the heart and kidneys,” said Professor Henry Krum, Director of Cardiovascular Research and Education at the Monash University, Victoria, Australia. “The SYMPLICITY-HF clinical trial will examine whether regulating sympathetic activity through renal denervation may also provide benefit in patients with both heart failure and renal insufficiency, two other conditions characterized by hyperactive sympathetic nervous system drive.”

ABOUT HEART FAILURE AND RENAL DENERVATION

To date, heart failure treatment has mostly focused on pharmaceutical management of neurohormonal systems including blocking the renin-angiotensin-aldosterone system with ACE inhibitors and addressing the sympathetic nervous system with beta-blockers. These pharmaceutical interventions have resulted in improvements in mortality, hospitalization and quality of life of heart failure patients, but the toll of this disease remains intolerably high. Unfortunately, conventional doses of beta blockers do not deliver complete blockade of the sympathetic nervous system and are not tolerated by many patients. In contrast, renal denervation allows the selective reduction of the kidney’s contribution to central sympathetic drive without blunting other compensatory mechanisms.

ABOUT THE SYMPLICITY™ RENAL DENERVATION SYSTEM

The Symplicity™ renal denervation system consists of a flexible catheter and proprietary generator, which are used to perform a procedure termed renal denervation (RDN). In a straight-forward endovascular procedure, similar to an angioplasty, the physician inserts the small, flexible Symplicity™ catheter into the femoral artery in the upper thigh and threads it into the renal artery. Once in place within the renal artery, the Symplicity™ generator is activated to deliver a controlled, low-power radio-frequency (RF) energy routine according to a proprietary algorithm, or pattern, aiming to deactivate the surrounding renal nerves. This, in turn, reduces hyper-activation of the sympathetic nervous system, which is an established contributor to chronic hypertension. The procedure does not involve a permanent implant.

The Symplicity renal denervation systemhas been successfully used since 2007 to treat more than 2,000 patients with treatment-resistant hypertension worldwide. It has been commercially available in Europe and Australia since April 2010. The Symplicity renal denervation system is not approved by the U.S. Food and Drug Administration (FDA) for commercial distribution in the United States.

The FDA granted Medtronic approval to conduct SYMPLICITY HTN-3, the company’s U.S. clinical trial of the Symplicity renal denervation system for treatment-resistant hypertension, in August 2011. More information about HTN-3 can be found at www.symplifybptrial.com.

In collaboration with leading clinicians, researchers and scientists worldwide, Medtronic offers the broadest range of innovative medical technology for the interventional and surgical treatment of cardiovascular disease and cardiac arrhythmias.

ABOUT MEDTRONIC

Medtronic, Inc. (www.medtronic.com), headquartered in Minneapolis, is the global leader in medical technology – alleviating pain, restoring health and extending life for millions of people around the world.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

1Symplicity is a trademark of Medtronic Inc. and is registered in one or more countries of the world.

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