Medtronic News

Medtronic Randomizes First Patients in SYMPLICITY HTN-4, the First U.S. Renal Denervation Clinical Study for Patients with Moderate Uncontrolled Hypertension

Thomson Reuters ONE via COMTEX) --Medtronic's Second Randomized, Controlled Renal Denervation Clinical Trial in the U.S. Will Potentially Expand Access to the Symplicity(TM) Renal Denervation System for Even Larger Uncontrolled Hypertension Patient Population

MINNEAPOLIS - December 17, 2013 - Medtronic, Inc. (NYSE: MDT), announced today that the first patients were randomized in SYMPLICITY HTN-4, evaluating the Symplicity(TM) renal denervation system in patients with moderate uncontrolled hypertension (systolic blood pressure greater than or equal to 140 and less than 160 mm Hg, despite treatment with three or more anti-hypertensive medications of different classes). SYMPLICITY HTN-4, which randomized its first patients at Medical University of South Carolina (MUSC), Piedmont Heart Institute and Duke University Medical Center, builds upon SYMPLICITY HTN-3, the only other renal denervation clinical trial in the United States. In the United States, the Symplicity renal denervation system is available for investigational use only.

"SYMPLICITY HTN-4 demonstrates Medtronic's commitment to providing randomized safety and efficacy data for renal denervation in a wide variety of patients, as well as helping increase our understanding of the potential benefit of renal denervation for more patients with treatment resistant hypertension," said Nina Goodheart, vice president, general manager, Renal Denervation, Medtronic.

SYMPLICITY HTN-4 will enroll up to 580 patients with systolic blood pressures greater than or equal to 140 and less than 160 mm Hg at approximately 100 sites, continuing to target a patient population in line with the Joint National Committee on the Prevention, Detection, Evaluation and Treatment of High Blood Pressure (JNC-7), the American Heart Association and the European Society of Hypertension's definition of uncontrolled hypertension. Similar to the U.S. pivotal trial, SYMPLICITY HTN-3 study evaluating patients with uncontrolled hypertension with a systolic blood pressure greater than or equal to 160 mm Hg, the SYMPLICITY HTN-4 study will be blinded and include a sham control.

The principal investigators of SYMPLICITY HTN-4 are David Kandzari, M.D., director and chief scientific officer, Interventional Cardiology and Interventional Cardiology Research, Piedmont Heart Institute, Atlanta, GA, and Michael Weber, M.D., professor of medicine, Division of Cardiovascular Medicine, at the SUNY Downstate College of Medicine in Brooklyn, New York. For more information about SYMPLICITY HTN-4, please go to www.symplifybptrial.com.

Approximately 120 million people with high blood pressure worldwide are considered to have uncontrolled hypertension, with systolic blood pressures at or above 140 mm Hg, despite all efforts to control blood pressure with both lifestyle and medical management strategies.1,2,3 In the United States, only approximately 60 percent of hypertension patients taking medicine have their disease under control.4 Uncontrolled hypertension is associated with a hyperactive sympathetic nervous system and is directly linked with a high risk of heart attacks, stroke, heart failure, kidney disease and death.1 Most patients living with uncontrolled hypertension are prescribed three to five classes of anti-hypertensive medications, which can equate to taking 10 or more pills each day and are subsequently subjected to numerous side effects that may negatively impact quality of life.

About the Symplicity Clinical Trial Program

Medtronic continues to lead the advancement of research and development in renal denervation worldwide with more clinical studies ongoing than any other manufacturer with the longest follow-up data out to three years. Medtronic's rigorous clinical evaluation program of the Symplicity renal denervation system will involve more than 8,000 patients worldwide, including the U.S., Europe and Japan, with more than 1,200 of these patients participating in randomized clinical trials.

- SYMPLICITY HTN-1: A series of pilot studies at 19 centers in Australia, Europe and the United States with 153 patients with systolic blood pressure >=160 mm Hg enrolled. SYMPLICITY HTN-1 is the longest running clinical trial investigating the safety and efficacy of renal denervation.

- SYMPLICITY HTN-2: A randomized, controlled clinical trial of 106 patients at 24 centers in Europe, Australia and New Zealand to investigate renal denervation in patients with treatment-resistant hypertension randomly allocated in a one-to-one ratio to undergo renal denervation with previous treatment or to maintain previous treatment alone.

- SYMPLICITY HTN-3: Pivotal U.S. clinical trial of the Symplicity renal denervation system for uncontrolled hypertension completed enrollment of 535 patients across nearly 90 U.S. medical centers in May 2013. The results are expected to be available during the first half of 2014.

- SYMPLICITY HTN-4: First randomized, controlled trial to investigate renal denervation for uncontrolled hypertension in U.S. patients with systolic blood pressure greater than or equal to 140 and less than 160 mm Hg. Enrollment began in November 2013.

- Global SYMPLICITY Registry: Prospective, multi-center, open-label registry of 5,000 patients in 200+ centers, designed to document the long-term safety and effectiveness of renal denervation in real-world patient populations, as well as gather data for other diseases characterized by elevated sympathetic drive.

- SYMPLICITY-HF: 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.

- Symplicity Spyral(TM) Catheter Feasibility Study: Prospective, single-arm, non-randomized clinical study of Medtronic's multi-electrode catheter, which completed enrollment of 50 patients in Australia and New Zealand designed to evaluate acute procedure safety and change in office blood pressure from baseline at six months.

- HTN-Japan: Open-label study being conducted in approximately 100 patients across up to 18 centers in Japan, designed to randomize subjects 1:1 to renal denervation versus no denervation with both groups receiving fully-tolerated doses of antihypertensive medications.

- SYMPLICITY HTN-India: Open-label study being conducted in approximately 40 patients across several centers in India, designed to evaluate the safety and efficacy of renal denervation in the local population.

About the Symplicity(TM) Renal Denervation System

The Symplicity renal denervation system is backed by more than five years of clinical experience in more than 5,000 patients with uncontrolled hypertension and is available in more than 80 countries throughout the world. The Symplicity system is a minimally invasive, device-based treatment option available outside of the United

States to those with sympathetic over-activation. It consists of a flexible catheter and proprietary generator with which algorithms were carefully and specifically developed through years of clinical experience to enhance the safety and effectiveness of the renal denervation procedure. The Symplicity system received CE (Conformite Europeene) Mark in 2008.

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.

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

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