Medtronic News

Medtronic Presents Three-Year Results From SYMPLICITY HTN-2 Showing Significant and Sustained Drops in Blood Pressure After Treatment with the Symplicity(TM) Renal Denervation System

Thomson Reuters ONE via COMTEX) --Longest-term data from the first randomized, controlled trial of renal denervation presented at the 25th Annual Transcatheter Cardiovascular Therapeutics (TCT) Symposium

MINNEAPOLIS and SAN FRANCISCO - October 30, 2013 - Medtronic, Inc. (NYSE: MDT) presented three-year data from SYMPLICITY HTN-2, the first and longest-running randomized, controlled clinical trial of renal denervation, which continue to demonstrate results consistent with data reported previously at six, 12 and 24-months of follow-up. The data were presented for the first time during an oral abstract session on Tuesday, October 29, 2013 at the 25th Annual Transcatheter Cardiovascular Therapeutics (TCT) Symposium taking place this week in San Francisco. The Symplicity renal denervation system is available for investigational use only in the United States.

"As the first and longest-term experience in a randomized, controlled setting, these data mark a significant milestone for the renal denervation clinical community, as well as the single-electrode Symplicity system," said Robert J. Whitbourn, M.B.B.S., M.D., associate professor and director of the Cardiovascular Research Centre at St Vincent's Hospital in Melbourne. "These results continue to demonstrate the impact renal denervation can have on patients with uncontrolled hypertension, and these data are an important contribution to the growing body of evidence supporting renal denervation with the Symplicity system as a therapy option for this underserved population."

The data show an average blood pressure reduction of -33/-14 mm Hg [$p<0.01$] from baseline and an overall response rate (systolic blood pressure drop of greater than or equal to 10 mm Hg) of 85 percent for patients initially randomized to treatment with the Symplicity system and available for 36-month evaluation (n=40). Despite a mean systolic blood pressure of 183.5 ± 19.5 mm Hg pre-denervation, 50 percent of these patients achieved the goal of systolic blood pressure of <140 mm Hg. The safety profile of renal denervation with the Symplicity system was also maintained at three years, with no newly reported device or procedure related serious adverse events. None of the patients treated with the Symplicity system followed through three years required renal artery stenting.

In this trial, patients were required to have severe, uncontrolled hypertension with a systolic blood pressure greater than or equal to 160 mm Hg despite the use of three or more antihypertensive medications, including a diuretic. All patients were maintained on their usual antihypertensive medications and were randomly allocated in a one-to-one ratio to undergo renal denervation or no additional treatment (control group). At baseline, the randomized treatment and control patients had similar high blood pressures: 178/97 mm Hg and 178/98 mm Hg, respectively, despite both receiving an average daily regimen of five antihypertensive medications. Patients in the control arm of the study were offered renal denervation following assessment of the trial's primary endpoint at six months following randomization. This crossover treatment group experienced significant and sustained blood pressure reductions at 30 months after renal denervation with an average blood pressure reduction of -33/-13 mm Hg [$p<0.01$] from baseline (n=30).

The complete data were presented by Robert J. Whitbourn, M.B.B.S., M.D., during an oral abstract session titled Renal Denervation and Endovascular Intervention at 1:00 p.m. in Moscone West, 3rd Floor, Room 3022.

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, 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: First and only 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.

- 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 over 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 to those suffering with uncontrolled hypertension that disrupts the output of hyperactive sympathetic nerves within the renal artery wall, known to be central to the body's ability to regulate blood pressure. 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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Source: Medtronic, Inc. via Thomson Reuters ONE

HUG#1738912

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