Medtronic News

Medtronic Presents Final Three-Year Data From Symplicity HTN-1 Showing Significant and Sustained Drops in Blood Pressure After Treatment with the Symplicity(TM) Renal Denervation System

Thomson Reuters ONE via COMTEX) --Final Clinical Outcomes from First and Longest-Running Renal Denervation Clinical Study Presented During European Society of Cardiology Congress and Accepted for Publication in The Lancet

MINNEAPOLIS AND AMSTERDAM -- September 3, 2013 -- Medtronic, Inc. (NYSE: MDT), announced today at the European Society of Cardiology (ESC) Congress the final three-year results from Symplicity HTN-1, the first and longest running clinical study investigating the safety and efficacy of renal denervation, which also have been accepted for publication in The Lancet. Eighty-eight (88) treatment-resistant hypertension patients were available for 36 month evaluations following treatment with the Symplicity(TM) renal denervation system. These 88 patients demonstrated sustained reductions in blood pressure year-over-year with an average reduction of -32/-14 mm Hg [p<0.01]. Of these 88 patients, approximately 50 percent achieved goal of a systolic blood pressure <140 mm Hg despite having a mean systolic blood pressure of 169.8 mm Hg pre-denervation. There were very few clinically significant late adverse events reported through three years of follow up.

"We are pleased to find that we're seeing sustained and significant blood pressure reductions overall in all patients who reached the three year time point following their denervation procedure. Achieving goal of below 140 mm Hg in about half of these patients is impressive considering that these patients had very high baseline blood pressures despite being on multiple pharmaceutical agents," said Professor Henry Krum, Principal Investigator of Symplicity HTN-1 and Chair of Medical Therapeutics, Professor of Medicine and Director of the Monash Centre of Cardiovascular Research and Education in Therapeutics, Melbourne, Australia who presented the data today at ESC. "These were patients who were out of hypertension treatment options before they received renal denervation, so reductions of blood pressure of this magnitude may dramatically decrease their risk for stroke, heart attack, heart failure and kidney disease in the years to come."

Symplicity HTN-1 is a series of pilot studies at 19 centers in Australia, Europe and the United States. The open-label studies enrolled 153 patients with treatment-resistant hypertension, defined as having a systolic blood pressure >=160 mm Hg while taking >=3 antihypertensive drugs at optimal dosages, including a diuretic. The patients consented to be followed for either one, two, or three years after treatment with renal denervation. Follow-up is now complete for the 88 patients who were followed to three years. Symplicity HTN-1 is the largest cohort of patients with the longest follow up data for renal denervation to date.

Patients treated with renal denervation experienced consistent reductions in blood pressure regardless of advanced age, the presence of diabetes or impaired baseline renal function. Safety follow-up between 24 and 36 months demonstrated continued stable renal function; two orthostatic hypotension events in one subject resolved with medication changes, and one renal artery stenosis at 24 months, possibly related to the renal denervation procedure. Adverse events due to co-morbid diseases such as infection and non-renal surgical complications were also reported.

About Treatment-Resistant Hypertension

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 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. Most patients living with uncontrolled hypertension are prescribed three to five classes of anti-hypertensive medications, which can equate to taking four or more pills each day and are subsequently subjected to numerous side effects that may negatively impact quality of life.

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 8,000 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 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. The Symplicity renal denervation system is currently available for investigational use only in the United States.

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 involves 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: 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 moderate uncontrolled hypertension in U.S. patients with systolic blood pressure greater than or equal to 140 and less than 160 mm Hg. Enrollment is expected to begin in fall 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.

- Symplicity HTN-Japan: Open-label study being conducted in approximately 100 patients across 11 centers in Japan, designed to randomize subjects 1:1 to renal denervation versus no denervation with both groups receiving maximal 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.

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.

- end -

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

1 Egan, Brent M., et al. "Uncontrolled and Apparent Treatment resistant Hypertension in the United States, 1988-2008." Circulation 124. 9 (2011): 1046-1058.

2 Chobanian AV, Bakris GL, Black HR, Cushman WC, Green LA, Izzo JL, Jr., Jones DW, Materson BJ, Oparil S, Wright JT, Jr., Roccella E, Joint National Committee on Prevention DE, Treatment of High Blood Pressure. National Heart L, Blood I, National High Blood Pressure Education Program Coordinating C. Seventh report of the joint national committee on prevention, detection, evaluation, and treatment of high blood pressure. Hypertension. 2003;42:1206----1252.

3 Staessen JA, Li Y, Thijs L, Wang JG. Blood pressure reduction and cardiovascular prevention: An update including the 2003----2004 secondary prevention trials. Hypertension research: official journal of the Japanese Society of Hypertension. 2005;28:385----407

Contacts:

Wendy Dougherty

Public Relations

+1-763-381-1204

Jeff Warren

Investor Relations

+1-763-505-2696

This announcement is distributed by Thomson Reuters on behalf of Thomson Reuters clients.

The owner of this announcement warrants that:

(i) the releases contained herein are protected by copyright and other applicable laws; and

(ii) they are solely responsible for the content, accuracy and originality of the

information contained therein.

Source: Medtronic, Inc. via Thomson Reuters ONE

HUG#1726456

---

https://news.medtronic.com/2013-09-03-Medtronic-Presents-Final-Three-Year-Data-From-Symplicity-HTN-1-Showing-Significant-and-Sustained-Drops-in-Blood-Pressure-After-Treatment-with-the-Symplicity-TM-Renal-Denervation-System