Medtronic News

Medtronic Reports Strong Safety and Sustained Clinical Efficacy Results of the Symplicity(TM) Renal Denervation System from the Global SYMPLICITY Registry

(Thomson Reuters ONE via COMTEX) --Six and 12-Month Data from Largest Real-World Patient Population

Consistent with Symplicity Randomized Clinical Trial

MINNEAPOLIS and AMSTERDAM - September 2, 2013 - Medtronic, Inc. (NYSE: MDT), announced today at the European Society of Cardiology (ESC) Congress, new data from the Global SYMPLICITY Registry that continue to affirm the strong safety profile of the Symplicity(TM) renal denervation system in a real-world patient population. Among the 1,158 patients analyzed in the registry with follow-up information available for this analysis, major complications or serious adverse events related to delivery of radio frequency (RF) energy to the renal artery were rare, including one procedural dissection (0.09 percent) and one re-intervention at 6 months (0.09 percent).

The primary goal of the Global SYMPLICITY Registry is to confirm procedural safety with the Symplicity system. Available data for the secondary efficacy analysis showed significant and sustained blood pressure reductions after renal denervation with the Symplicity system at all time points up to 12 months in both in-office and ambulatory blood pressure measurement, compared to baseline. The Symplicity renal denervation system is available for investigational use only in the United States.

"It is encouraging that preliminary data with this sizeable patient cohort in a real-world setting continue to demonstrate a strong safety profile and significant clinical efficacy for renal denervation with the Symplicity system, similar to what we've been seeing in the randomized, controlled clinical trial, Symplicity HTN-2," said Michael Bohm, MD, PhD, Chairman, Department of Internal Medicine, University of Saarland, Homburg/Saar, Germany and Global SYMPLICITY Registry co-chair.

Data presented by Prof. Bohm during an oral session at ESC 2013 in Amsterdam on Tuesday, September 2, 2013 reported patients with systolic blood pressure of >=180 mm Hg at baseline (n=51) had an average in-office blood pressure reduction of -29/-17 mm Hg from baseline at six months [p<0.001] and -37/-23mm Hg from baseline at 12 months (n=9) [p=0.001 SBP/p=0.0005 DBP]. Patients with similar characteristics to the Symplicity HTN-2 trial, with a systolic blood pressure of ³160 mm Hg (or >=150 mm Hg in patients with diabetes) had an average in-office blood pressure reduction of -19/-8 mm Hg from baseline at six months (n=313) [p<0.001] and -22/-11 mm Hg from baseline at 12 months (n=79) [p<0.001]. Average reductions in available ambulatory blood pressure measurements were -10/-5mm Hg from baseline to six months (n=132) [p<0.0001].

The Global SYMPLICITY Registry is a multi-center, prospective, observational registry designed to collect comprehensive data evaluating procedural and long-term safety of the Symplicity system, clinical efficacy for both in-office and ambulatory blood pressure measurement, and long-term cardiovascular outcomes from hypertension such as stroke, myocardial infarction, heart failure and cardiovascular death. More than two thirds (66%) of registry patients treated to date fall within current ESC consensus paper recommendations for catheter-based renal denervation, including a systolic blood pressure of >= 160 mm Hg (>= 150 mmHg Diabetes II) and were taking at least three classes of anti-hypertensive medications, including diuretic, prior to treatment with renal denervation.1

"We are pleased that enrollment and analysis of the registry continues to meet our goal of establishing procedural safety and efficacy of the Symplicity system, which we expect will ultimately help reduce the risk of cardiovascular events associated with treatment-resistant hypertension such as stroke and ischemic heart disease," said Dr. Bohm.

As the largest renal denervation registry in the world to date and the first-of-its-kind to evaluate this novel treatment in a real-world, uncontrolled population, The Global SYMPLICITY Registry will enroll more than 5,000 patients in a minimum of 200 centers with planned follow-up to five years. The registry also will gather data for other diseases characterized by elevated sympathetic drive, such as diabetes mellitus type 2, heart failure and chronic kidney disease.

With the continued success of the Global SYMPLICITY Registry, Medtronic strengthens its position as the global leader in the research and development of renal denervation therapies. Ultimately, Medtronic's global Symplicity clinical program will involve more than 8,000 patients worldwide.

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. 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,

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.

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.

- end -

1 Mahfoud F et al. Expert consensus document from the European Society of Cardiology on catheter-based renal denervation, Eur Heart J April 2013

Contacts:

Wendy Dougherty

Public Relations

+1-763-381-1204

Jeff Warren

Investor Relations

+1-763-505-2696

---

https://news.medtronic.com/2013-09-02-Medtronic-Reports-Strong-Safety-and-Sustained-Clinical-Efficacy-Results-of-the-Symplicity-TM-Renal-Denervation-System-from-the-Global-SYMPLICITY-Registry