Medtronic News

Medtronic Announces Data From Largest Real-World Patient Population Confirm Strong Safety Profile and Clinical Efficacy of Renal Denervation with the Symplicity(TM) System

First Look at Data from Global SYMPLICITY Registry Shows Renal Denervation with the Symplicity(TM) System Meets Performance Expectations in Real-World Setting

MINNEAPOLIS and PARIS - MAY 21, 2013 - Medtronic, Inc. (NYSE: MDT), announced today the first results from the Global SYMPLICITY Registry, which reaffirmed the safety of the renal denervation procedure with the Symplicity(TM) renal denervation system in a real-world patient population. Among the 617 registry patients with follow-up information available for this first analysis, no major complications or serious adverse events related to delivery of radio frequency (RF) energy to the renal artery were reported. Of these patients, only two experienced access site vascular complications immediately post-procedure. There was a 9 percent incidence of renal vessel irregularity on angiography due to the application of RF energy to the vessel wall following the procedure; none interfered with brisk renal blood flow and all are believed to have resolved shortly after the procedure.

While the primary goal of the Global SYMPLICITY Registry is to verify procedure safety with the Symplicity system, available data for the secondary efficacy analysis at 6-months showed renal denervation also has a significant reduction in both office and ambulatory blood pressure compared to baseline. Patients with systolic blood pressure (SBP) of ³180 mm Hg and diastolic blood pressure (DBP) of ³100 mm Hg had an average office blood pressure reduction of -30/-16 mm Hg (n=17) [SBP p<0.0002; DBP p<0.0008] from baseline at 6 months. Patients with a SBP ³160 mm Hg (or ³150 mm Hg in patients with diabetes) (n=114) had an average office blood pressure reduction of -18/-9 mm Hg) [p<.0001]; average blood pressure reduction for these patients who also had ambulatory blood pressure* measurement (n=29) was -11/-4 mm Hg [p<.0001] from baseline. These data will be presented during an oral session at EuroPCR 2013 in Paris on Thursday, May 23, 2013.

"These data speak strongly to the safety and efficacy of the renal denervation procedure with the Symplicity system; it is encouraging to see these positive results in a real-world setting," said Felix Mahfoud, M.D., interventional cardiologist at the University Hospital Homburg/Saar, Germany. "The significant reductions in blood pressure seen in these patients could substantially reduce cardiovascular risk, as we know that in middle age even a 2 mm Hg decrease in systolic blood pressure can lead to a decrease risk of death from stroke by 10 percent and lower risk of death from ischemic heart disease or other vascular cause by 7 percent."

The Global SYMPLICITY Registry is a multi-center, prospective, observational registry that will collect comprehensive data evaluating renal denervation and long-term cardiovascular outcomes from hypertension such as stroke, myocardial infarction, heart failure and cardiovascular death. It is the largest patient cohort in renal denervation to date, and the first of its kind to evaluate the real-world use of renal denervation in a large and diverse patient population in an uncontrolled setting. The 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.

"The Global SYMPLICITY Registry demonstrates our unwavering commitment to advancing the collective understanding of renal denervation and leveraging this knowledge to develop renal denervation technology solutions that meet critical physician and patient needs," said Nina Goodheart, Vice President, General Manager, Renal Denervation, Medtronic. "We are encouraged by this first look at results from the Global SYMPLICITY Registry, which help confirm the safety of renal denervation with the Symplicity system, and allow us to monitor patient outcomes in a broader, more diverse population than in a clinical trial setting."

With the Global SYMPLICITY Registry, Medtronic strengthens its global leadership position in the research and development of renal denervation therapies. Ultimately, Medtronic's global Symplicity clinical program will involve more than 8,000 patients worldwide. The Symplicity renal denervation system is only available for investigational use in the United States and Japan.

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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*Ambulatory blood pressure monitoring is a noninvasive method of obtaining blood pressure readings over 24 hours, while the patient is in their own environment to provide an accurate representation of their blood pressure.

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

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