Medtronic News

Medtronic Global SYMPLICITY Registry Shows Strong Safety Profile of the Symplicity(TM) Renal Denervation System

Six-Month Analysis of First 1,000 Patients Enrolled in Real-World Patient Registry Presented at ACC.14

MINNEAPOLIS and WASHINGTON, D.C. - March 30, 2014 - Medtronic, Inc. (NYSE: MDT), announced today further analysis of six-month follow-up data from the first 1,000 patients enrolled in the Global SYMPLICITY Registry, which continue to demonstrate the safety of the Symplicity(TM) renal denervation system. Presented today during a late-breaking clinical trial session at the 63rd Scientific Sessions of the American College of Cardiology (ACC), the results of this observational, open-label study show that renal denervation with the Symplicity(TM) renal denervation system resulted in significant reductions in both office and 24-hour ambulatory blood pressure compared to baseline, with very low adverse event rates to six months. The Symplicity(TM) renal denervation system is available for investigational use only in the United States.

"The Global SYMPLICITY Registry provides further evidence confirming the well-established safety profile of renal denervation with the Symplicity system," said Michael Böhm, M.D., Ph.D., chairman, Department of Internal Medicine, University of Saarland, Homburg/Saar, Germany and Global SYMPLICITY Registry co-chair. "Presented on the heels of SYMPLICITY HTN-3, this real-world experience provides a significant contribution to the discussion about the efficacy of renal denervation and offers additional perspective when considering the option of renal denervation in clinical practice for high-risk patients suffering from uncontrolled hypertension who may have limited treatment options."

Yesterday, Medtronic announced the full results of the SYMPLICITY HTN-3 clinical trial, which were presented March 29, 2014 in late-breaking session at ACC and published simultaneously in *The New England Journal of Medicine*. SYMPLICITY HTN-3, the first and only blinded, randomized, sham controlled study of renal denervation for treatment-resistant hypertension, met its primary safety endpoint but did not meet its primary or powered secondary efficacy endpoints.

The Global SYMPLICITY Registry is the largest and the first-of-its-kind to evaluate uncontrolled hypertension patients and the safety of renal denervation procedure with the Symplicity(TM) renal denervation system in a real-world setting. The primary goal of the registry is to confirm procedural safety with the Symplicity system and monitor the office and 24-hour ambulatory blood pressure, as per standard of care at the enrolling centers.

Of the 1,000 patients enrolled at the time of the analysis, six-month safety data were available for 913 patients. The data showed renal denervation with the Symplicity system was associated with adverse events in less than one percent of patients, with no cases of renal artery stenosis resulting from the procedure.

Of all patients available for six-month follow-up, overall office systolic blood pressure reduction was 11.9 mm Hg (n=751), and 24-hour ambulatory systolic blood pressure reduction was 7.9 mm Hg (n=404). For patients with office blood pressure >= 160 mm Hg and ambulatory blood pressure >= 135 at baseline receiving greater >= 3 antihypertensive medication classes had a blood pressure reduction of 20.2 mm Hg at 6 months (n=244).

The Global SYMPLICITY Registry will seek to enroll more than 5,000 patients in a minimum of 200 centers with planned follow-up to five years. The registry will also gather data for other co-morbid diseases often associated with hypertension and by elevated sympathetic drive, such as diabetes mellitus type 2, heart failure and chronic kidney disease.

In collaboration with leading clinicians, researchers and scientists, Medtronic offers the broadest range of innovative medical technology for the interventional and surgical treatment of cardiovascular diseases and cardiac arrhythmias. The company strives to offer products and services that deliver clinical and economic value to healthcare consumers and providers worldwide.

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.

Contacts:
Wendy Dougherty
Public Relations
+1-763-381-1204

Jeff Warren
Investor Relations
+1-763-505-2696

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