Medtronic News

# Medtronic Symplicity™ Renal Denervation System Demonstrates Significant and Sustained Blood Pressure Reduction out to Three Years

*Data from Two Clinical Trials Presented at the 61st Annual Scientific Session of the American College of Cardiology Show Consistent Effectiveness and Safety Up to Three Years*

MINNEAPOLIS & CHICAGO--(BUSINESS WIRE)--Mar. 25, 2012--Medtronic, Inc. (NYSE:MDT), announced that the Symplicity™ renal denervation system provides safe, significant and sustained blood pressure reduction up to three years in patients with treatment-resistant hypertension, according to data from two clinical trials presented at the 2012 American College of Cardiology (ACC) meeting. Results from the SYMPLICITY HTN-1 trial showed sustained safety and effectiveness of renal denervation with the Symplicity system up to three years, and results from the SYMPLICITY HTN-2 trial showed safe, sustained and significant blood pressure reduction one year following the procedure. These data were presented today during an oral session at ACC.12 dedicated to renal denervation (RDN) as a novel therapy for treatment of treatment-resistant hypertension.

Renal denervation therapy is a minimally invasive, catheter-based procedure that modulates the output of nerves that lie within the renal artery wall and lead into and out of the kidneys. These nerves are part of the sympathetic nervous system, which affects the major organs that are responsible for regulating blood pressure: the brain, the heart, the kidneys and the blood vessels. The Symplicity renal denervation system is not approved by the U.S. Food and Drug Administration (FDA) for commercial distribution in the United States.

## Three-Year Follow-up of SYMPLICITY HTN-1 Trial

SYMPLICITY HTN-1 is a series of pilot studies involving 153 patients at 19 centers in Australia, Europe and the United States. Subjects in the SYMPLICITY HTN-1 trial maintained an average blood pressure reduction of -33/-19 mm Hg at 36 months (n=24) from baseline ($p<.001$) following treatment with the Symplicity system. An increasing proportion of patients who completed follow-up had at least a 10 mm Hg reduction in systolic blood pressure. At 6 months 71 percent of patients were classified as responders, which increased to 100 percent among the patients who completed three year follow-up. There was no evidence of renal impairment, no patients were hospitalized due to hypotension, and no procedure-related serious adverse events were seen.

“As the duration of follow-up in these SYMPLICITY clinical trials grows, so too does our confidence in the enduring safety and effectiveness of the Symplicity system,” said George Bakris, M.D., professor of medicine and Director of the ASH Comprehensive Hypertension Center at the University of Chicago Medicine and president of the American Society of Hypertension. “These are the longest term data to date involving renal denervation and results from these studies adds to the growing body of evidence about this technology.”

## One-Year Follow-up of SYMPLICTY HTN-2 Trial

The SYMPLICITY HTN-2 trial is an international, multi-center, prospective, randomized, controlled study of the safety and effectiveness of renal denervation in patients with treatment-resistant hypertension. One hundred-six (106) patients were randomly allocated in a one-to-one ratio to undergo renal denervation with previous treatment or to maintain previous treatment alone (control group) at 24 participating centers. 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.

The analysis included data from 47 patients initially treated, who at 12 month follow-up sustained their significant drop in blood pressure (-28/-10 mm Hg [$p<0.001$] from baseline) with no significant difference from the previously reported 6 month follow-up

(-32/-12 mm Hg [p=0.16]). In addition, 35 qualified patients in the control group who received renal denervation 6 month post randomization also showed a similar drop in blood pressure to the treatment arm at 6 months post procedure (-24/-8 mm Hg [p= 0.15] from 6 month treatment arm). Safety results were sustained with no significant decline in kidney function and no late vascular complications.

"These results demonstrate that the Symplicity system has the potential to provide long-term safety and efficacy for patients who have been unable to achieve target blood pressure levels despite multiple medications," said Murray Esler, M.D., Ph.D., principal investigator of the SYMPLICITY HTN-2 trial and associate director of the Baker IDI Heart and Diabetes Institute of Melbourne, Australia. “We are extremely pleased with these results to date and our follow-up continues."

ABOUT TREATMENT-RESISTANT HYPERTENSION

Treatment-resistant hypertension, defined as persistently high blood pressure despite three or more anti-hypertensive medications of different types including a diuretic, puts approximately 120 million people worldwide at risk of premature death from kidney disease and cardiovascular events such as stroke, heart attack and heart failure. Research suggests that nearly one third of treated hypertensive individuals are considered resistant to treatment.i Additionally, these patients have a three-fold increase in risk of cardiovascular events compared to individuals with controlled high blood pressure.ii

ABOUT THE SYMPLICITY™ RENAL DENERVATION SYSTEM

The Symplicity renal denervation systemhas been successfully used since 2007 to treat more than 4,000 patients with treatment-resistant hypertension worldwide. It was launched commercially in April 2010 and is currently available in parts of Europe, Asia, Africa, Australia and the Americas.

The Symplicity™ renal denervation system consists of a flexible catheter and proprietary generator. In an endovascular procedure, similar to an angioplasty, the physician inserts the small, flexible Symplicity™ catheter into the femoral artery in the upper thigh and threads it into the renal artery. Once the catheter tip is in place within the renal artery, the Symplicity™ generator is activated to deliver a controlled, low-power radio-frequency (RF) energy routine according to a proprietary algorithm, or pattern, aiming to deactivate the surrounding renal nerves. This, in turn, reduces hyper-activation of the sympathetic nervous system, which is an established contributor to chronic hypertension. The procedure does not involve a permanent implant.

The FDA granted Medtronic approval for the protocol for SYMPLICITY HTN-3, the company’s U.S. clinical trial of the Symplicity renal denervation system for treatment resistant hypertension in August 2011. More information about HTN-3 can be found at www.symplifybptrial.com.

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.

iEgan, Brent M., et al. “Uncontrolled and Apparent Treatment Resistant Hypertension inthe United States, 1988-2008.” *Circulation* 124. 9 (2011): 1046-1058.

ii Doumas, Michael, et al. “Benefits from Treatment and Control of Patients with Resistant Hypertension.”*International Journal of Hypertension* 2011 (2011) Article ID 318549, 8 pages, 2011. doi:10.4061/2011/318549.

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