

New Data Reinforce Significant Blood Pressure Reduction Sustained to Two Years Using the Symplicity(TM) Renal Denervation System

The Associated Press

24-Month Clinical Update from Symplicity HTN-2 Presented Today at the 62nd Annual Scientific Session of the American College of Cardiology

MINNEAPOLIS and SAN FRANCISCO - March 10, 2013 - Medtronic, Inc. (NYSE: MDT) today announced 24-month data from Symplicity HTN-2, the first randomized clinical trial investigating renal denervation. Presented for the first time today at the 62nd Annual Scientific Session of the American College of Cardiology, the data show patients treated with the Symplicity(TM) renal denervation system (n=66) sustained a significant drop in blood pressure (-31/-11 mm Hg from baseline [$p<0.01$]) at 24 months.

Additionally, 26 subjects in the control group who crossed-over and received renal denervation following assessment of the six-month primary endpoint (crossover group) had an average blood pressure reduction of -35/-13 mm Hg [$p<0.01$] at 24 months. These 24-month average blood pressure reductions demonstrate preservation of the blood pressure reduction for both groups reported previously at 6, 12, and 18-month follow-up. There were no device-related serious adverse events, no late vascular complications, and no significant decline in kidney function compared to pre-procedure values reported out to 24 months post-procedure. The Symplicity renal denervation system is only available for investigational use in the United States and Japan.

"Patients with treatment-resistant hypertension are at a significant risk for cardiovascular events, including heart attack, stroke and heart failure, making it critical that we find a new, effective and safe approach to help them achieve sustained blood pressure control," said Professor Henry Krum, 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 ACC.13. "These latest data add to the growing body of evidence demonstrating consistent blood pressure reduction with the Symplicity system and underscore its potential as an option for us to help our medication-refractory patients achieve better blood pressure control."

At 24 months, pulse pressure improved significantly for patients in this analysis following treatment with the Symplicity system (-18.5 mm Hg from baseline for the initial treatment group [$p<0.01$]; and -22.5 mm Hg from baseline for the crossover group [$p<0.01$]). Pulse pressure is the numeric difference between systolic and diastolic blood pressure and is important because higher values are reported to be associated with increased cardiovascular complications, especially in older patients. Pulse pressure, as well as systolic and diastolic blood pressure, is commonly

assessed when evaluating the efficacy of antihypertensive therapy.

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. The nerves passing to the kidneys 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 system's catheter and proprietary generator and algorithms were carefully and specifically developed through years of clinical experience to enhance the safety and effectiveness of the renal denervation procedure. The Symplicity renal denervation system has been successfully used for nearly six years to successfully treat thousands of patients with treatment-resistant hypertension worldwide.

About the SYMPLICITY HTN-2 Trial

The Symplicity HTN-2 trial is an international, multi-center, prospective, randomized, controlled study of renal denervation in patients with treatment-resistant hypertension. One hundred and 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. Patients in the control arm of the study were offered renal denervation following assessment of the trial's primary endpoint at six months following randomization.

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.[1], [2] Research suggests that nearly one third of treated hypertensive individuals are considered resistant to treatment.[3]

About the Symplicity(TM)Renal Denervation System

The Symplicity system's catheter and proprietary generator and algorithms were carefully and specifically developed through years of clinical experience to accomplish the renal denervation procedure. The Symplicity renal denervation system was launched commercially in April 2010 and is currently available in parts of Europe, Asia, Africa, Australia and the Americas. The Symplicity system is only available in the United States for investigational use.

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(TM) 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(TM) generator is activated to deliver a

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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 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 Symplicity 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.

[1] Egan, Brent M., et al. "Uncontrolled and Apparent Treatment Resistant Hypertension in the United States, 1988-2008." *Circulation* 2011;124:1046-1058.

[2] Hypertension and cardiovascular disease. World Heart Federation. 2011. <http://www.world-heart-federation.org/cardiiovascular-health/cardiiovascular-disease-risk-factors/hypertension/>. Accessed January 23, 2013.

[3] 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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