Medtronic News

Medtronic Starts Landmark Study of Hypertension Treatment

U.S. Clinical Trial of Symplicity(R) Renal Denervation System(TM) Enrolls First Patient

MINNEAPOLIS, Oct 26, 2011 (BUSINESS WIRE) --

Medtronic Inc. (NYSE: MDT) announced today the start of SYMPLICITY HTN-3, the company's U.S. clinical trial of the Symplicity(R) Renal Denervation System(TM)for treatment-resistant hypertension. The first patient in this landmark study was enrolled at the Prairie Heart Institute at St. John's Hospital in Springfield, Ill.

Treatment resistant hypertension, defined as persistently high blood pressure despite three or more antihypertensive medications of different types, 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.

Renal denervation is a minimally invasive, catheter-based procedure that modulates the output of nerves that line the walls of the arteries leading to the kidneys. The targeted nerves are part of the sympathetic nervous system, which has been found to play a central role in blood pressure regulation.

SYMPLICITY HTN-3 is a randomized controlled trial designed to evaluate the safety and effectiveness of renal denervation with the Symplicity Renal Denervation System in patients with treatment-resistant hypertension.

The study will enroll approximately 530 treatment-resistant hypertension patients across 60 U.S. medical centers. All patients and hypertension follow-up assessors will be blinded to the randomization assignments to remove any potential for bias. The primary endpoints of the study are the change in blood pressure from baseline to six months and incidence of major adverse events up to six months following randomization.

More information about SYMPLICITY HTN-3 and renal denervation is available online at www.SymplifyBPtrial.com.

"Renal denervation has the potential to extend the lives of millions of people who suffer from treatment-resistant hypertension," said Krishna Rocha-Singh, M.D., medical director of the Prairie Vascular Institute and the Prairie Education and Research Cooperative. "Based on the results of prior clinical studies and contemporary clinical practice, this interventional technique could be one of the most significant advances in our approach to addressing this insidious disease to be developed in decades."

The Prairie Heart Institute has significant prior experience with renal denervation from having been the top U.S. site for SYMPLICITY HTN-1, the original feasibility study of the Symplicity Renal Denervation System for treatment-resistant hypertension. The site's principal investigators (PIs) are Richard Katholi, M.D., and Nilesh Goswami, M.D.

The national PIs of SYMPLICITY HTN-3 are George Bakris, M.D., and Deepak L. Bhatt, M.D., M.P.H. Dr. Bakris is professor of medicine and director of the Hypertension Center at the University of Chicago Medical Center and president of the American Society of Hypertension. Dr. Bhatt is associate professor of medicine at Harvard Medical School, chief of cardiology for the VA Boston Healthcare System and director of the Integrated Interventional Cardiovascular Program at Brigham and Women's Hospital and the VA Boston Healthcare System.

The Symplicity Renal Denervation System consists of a proprietary generator and flexible catheter. The Symplicity catheter is introduced through a separate catheter placed through the skin into the femoral artery, located in the upper thigh, and is then threaded up into the renal artery leading to each kidney. It is connected to the Symplicity generator, which produces low-power radio-frequency (RF) energy.

Once in place within the renal artery, the tip of the Symplicity catheter is placed against the arterial wall in several places where it delivers RF energy to the surrounding sympathetic nerves according to a proprietary, computer-controlled algorithm. The treatment does not involve a permanent implant and is performed under conscious sedation.

The Symplicity Renal Denervation System has been successfully used since 2007 to treat more than 2,000 patients worldwide. It has been commercially available in Europe and Australia since April 2010. The Symplicity System is not approved by the U.S. Food and Drug Administration (FDA) for commercial distribution in the United States. The FDA granted Medtronic approval for the SYMPLICITY HTN-3 protocol in August.

Clinical research to date shows that renal denervation with the Symplicity Renal Denervation System may provide a significant and sustained reduction in blood pressure levels for many patients with treatment-resistant hypertension. Published in *The Lancet* (Dec. 4, 2010), results from SYMPLICITY HTN-2 -- a randomized, controlled trial of 106 patients in Europe and Australia -- showed that patients with treatment-resistant hypertension randomized to renal denervation achieved a mean blood pressure reduction of 32/12 mmHg (millimeters of mercury) at six months, whereas the patients in the control group randomized to anti-hypertensive medications alone had blood pressures that did not vary from baseline (1/0 mmHg). The overall occurrence of adverse events did not differ between groups.

Hypertension is the leading attributable cause of death worldwide. It is a significant, costly and escalating global healthcare problem affecting approximately 1.2 billion people, and is associated with an increased risk of heart attack, stroke, heart failure, kidney disease and death.1 Among adults aged 40-70 years old, each increment of 20 mmHg in systolic blood pressure (the top number) or 10 mmHg in diastolic blood pressure (the bottom number) doubles the risk of cardiovascular disease.2 Hypertension is estimated to have a direct cost to the global healthcare system of more than $500 billion annually.

Although pharmaceutical therapy plays a primary role in hypertension management, drugs alone are not effective for all patients. As a result, despite lifestyle changes and the availability of modern antihypertensive agents, approximately 50 percent of patients with hypertension remain uncontrolled and approximately 15-20 percent of those are treatment resistant.3

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.

i Lawes, CM., et al. "Global burden of blood-pressure-related disease." 2001 *The Lancet* 371. 9623 (2008): 1513-1518.
ii Lewington S, Clarke R, Qizilbash N, et al. "Age-specific relevance of usual blood pressure to vascular mortality: A meta-analysis of individual data for one million adults in 61 prospective studies". *TheLancet.* 2002;360:1903-13.
iii Circulation.<http://www.ncbi.nlm.nih.gov/pubmed/20019324> 2010 Feb 23;121(7):e46-e215. Epub 2009 Dec 17. Heart disease and stroke statistics 2010 update: a report from the American Heart Association.

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Medtronic Inc.
Public Relations:
Joe McGrath, 707-591-7367

or
Investor Relations:
Jeff Warren, 763-505-2696

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