Medtronic News

Medtronic Submits IDE to FDA for U.S. Randomized Clinical Trial for Uncontrolled Hypertension Patients with Systolic Blood Pressure Between 140-160 mm Hg

IDE Submission for Symplicity HTN-4 Expands the Indicated Patient Population and Builds upon Medtronic's Rigorous Global Clinical Trial Program for Hypertension Treatment

MINNEAPOLIS - March 7, 2013 - Medtronic, Inc. (NYSE: MDT), announced today that the company has submitted an Investigational Device Exemption (IDE) to the U.S. Food and Drug Administration (FDA) to study the Symplicity(TM) renal denervation system for the treatment of uncontrolled hypertension in patients with systolic blood pressure between 140-160 mm Hg despite treatment with three or more anti-hypertensive medications of different classes. The Symplicity renal denervation system currently is only available for investigational use in the United States.

Symplicity HTN-4 is the next step in Medtronic's global renal denervation clinical program designed to carefully and progressively build the clinical evidence platform for the treatment of hypertension. This is being accomplished through a series of trials, which include more than 250 patients already enrolled in the Symplicity HTN-1 and Symplicity HTN-2 studies, 530 patients being enrolled in the Symplicity HTN-3 study, and 5,000 patients being enrolled in the Global SYMPLICITY Registry. The robust SYMPLICITY global dataset with planned follow-up to 5 years in most studies will be utilized to evaluate not only blood pressure reduction, but also long-term cardiovascular outcomes from hypertension such as stroke, myocardial infarction, heart failure and cardiovascular death. Medtronic's rigorous clinical evaluation program of the Symplicity renal denervation system includes more than 8,000 patients worldwide, including studies in the U.S., China, and Japan, with over 1,200 of these patients participating in randomized clinical trials.

The Symplicity HTN-4 trial will be the company's second randomized clinical trial in the U.S., with a patient population in line with the Joint National Committee on the Prevention, Detection, Evaluation and Treatment of High Blood Pressure (JNC-7), the American Heart Association and the European Society of Hypertension definition of resistant hypertension. Symplicity HTN-4 builds upon the Symplicity HTN-3 study, Medtronic's pivotal U.S. clinical trial of the Symplicity renal denervation system for the treatment-resistant hypertension with systolic blood pressure greater than 160 mm Hg. Symplicity HTN-3 is the only clinical trial to date to receive an IDE approval to study renal denervation in the U.S. Medtronic aims to begin enrolling patients in the Symplicity HTN-4 trial in the second half of 2013, pending regulatory approval.

The principal investigators of Symplicity HTN-4 are David Kandzari, M.D., Director and Chief Scientific Officer, Interventional Cardiology and Interventional Cardiology Research, Piedmont Heart Institute, Atlanta, GA, and Michael Weber, M.D., Professor of Medicine, Division of Cardiovascular Medicine, at the SUNY Downstate College of Medicine in Brooklyn, New York.

"Symplicity HTN-4 demonstrates Medtronic's commitment to providing randomized safety and efficacy data for renal denervation in a wide variety of patients, as well as help increase our understanding of the potential benefit of renal denervation on patients with a less severe form of treatment-resistant hypertension," said Sean Salmon, Senior Vice President and President, Coronary & Renal Denervation, Medtronic. "We intend to continue to add to the substantial body of evidence Medtronic has generated to support the use of renal denervation in broader patient populations worldwide in conditions associated with hyperactive sympathetic nervous system drive, including uncontrolled and treatment-resistant hypertension, and heart failure."

Hypertension is a major and growing global public health concern. It affects an estimated 30-40 percent of the adult population1-3 and contributes directly to strokes, heart attacks, heart failure and cardiovascular mortality.4, 5 Numerous studies have demonstrated the continuous and consistent benefit in terms of risk reduction with controlling blood pressure.4-6 Despite the availability of numerous safe pharmacological therapies, the percentage of hypertensive patients achieving blood pressure control to guideline target blood pressure values remains low.

In the United States, the control rate for hypertensive patients taking medications is approximately 60 percent,7 leaving many uncontrolled hypertension patients at an increased cardiovascular risk. Many patients with uncontrolled hypertension meet the criteria for treatment resistant hypertension in that their systolic blood pressure is >= 140 mm Hg despite being on three or more anti-hypertensive medications. The risk inherent with persistently high blood pressure in these patients warrants special therapeutic considerations.8

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 accomplish the renal denervation procedure. The Symplicity renal denervation systemwas launched commercially in April 2010 and is currently available in parts of Europe, Asia, Africa, Australia, Canada and Latin America and has been used to treat thousands of patients with treatment-resistant hypertension worldwide.

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 both renal arteries in turn. Once the catheter tip is in place within the renal artery, the Symplicity(TM) generator is activated to deliver a controlled, low-power radio-frequency (RF) energy routine according to a proprietary algorithm 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 Symplicity HTN-3 study in August 2011. More information about Symplicity HTN-3, which is currently enrolling patients, 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.

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

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