Medtronic News

Medtronic Completes Enrollment in Landmark U.S. Study of Symplicity(TM) Renal Denervation System for Treatment-Resistant Hypertension

Milestone Marks a Critical Step Forward in Bringing Renal Denervation to Patients in the U.S.

MINNEAPOLIS - May 23, 2013 - Medtronic, Inc. (NYSE: MDT), today announced it has finished randomizing Symplicity HTN-3, the company's pivotal U.S. clinical trial of the Symplicity(TM) renal denervation system for treatment-resistant hypertension. Renal denervation is a minimally invasive, catheter-based procedure to reduce activity of the renal (kidney) nerves, which are part of the sympathetic nervous system and help regulate blood pressure. The Symplicity renal denervation system is available in more than 70 countries worldwide; it is only available for investigational use in the U.S. and Japan.

The Symplicity renal denervation system is also one of the first medical devices to participate in the U.S. Food and Drug Administration (FDA) and the Centers for Medicare & Medicaid Services (CMS) parallel review program, which will allow the CMS to begin national coverage determination while the FDA completes its review of safety and efficacy. Data from the Symplicity HTN-3 clinical trial will be a significant component of the parallel review.

"Paralleling the increased prevalence of obesity, treatment-resistant hypertension has emerged as a major health problem in the Western world. The results of this study will provide the medical community with data that will not only further our understanding of the impact of renal denervation on treatment-resistant hypertension, but also potentially help bring a new treatment option to people in the U.S. affected by this condition," said George Bakris, M.D., professor of medicine and director of the ASH Comprehensive Hypertension Center at the University of Chicago Medicine and past-president of the American Society of Hypertension, and co-principal investigator of Symplicity HTN-3.

Symplicity HTN-3 is Medtronic's first blinded, 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 in the U.S. The trial randomized 530 patients across nearly 90 medical centers in the U.S. to receive either renal denervation and treatment with anti-hypertensive medications or treatment with anti-hypertensive medications alone. The primary endpoints of the study are the change in blood pressure from baseline to six months following randomization and the incidence of major adverse events one month following randomization and renal artery stenosis to six months.

"Because patients had to meet the most strict inclusion criteria of any renal denervation clinical trial to date, enrollment in Symplicity HTN-3 was at first challenging," said Deepak L. Bhatt M.D., M.P.H., chief of cardiology, VA Boston Healthcare System, director, Integrated Interventional Cardiovascular Program, Brigham and Women's Hospital and VA Boston Healthcare System, professor of medicine, Harvard Medical School, and co-principal investigator of Symplicity HTN-3. "The Symplicity HTN-3 study investigators and research coordinators should be recognized for their leadership in addressing initial recruiting challenges to complete this seminal clinical trial."

ABOUT THE SYMPLICITY CLINICAL PROGRAM

Medtronic is committed to advancing the research and development of renal denervation worldwide, as demonstrated by the rigorous Symplicity clinical program. The program is comprised of a series of trials, including the Symplicity HTN-1 and Symplicity HTN-2 studies, both complete, and the Global SYMPLICITY Registry, which is currently enrolling. The robust SYMPLICITY global dataset with planned follow-up to 5 years will evaluate blood pressure reduction as well as long-term cardiovascular outcomes from hypertension such as stroke, myocardial infarction, heart failure and cardiovascular death. In total, Medtronic's global Symplicity clinical program will involve more than 8,000 patients worldwide. It is through these studies that Medtronic will continue to grow the substantial body of evidence to support the use of renal denervation in conditions associated with hyperactive sympathetic nervous system drive, including treatment-resistant hypertension.

"The completion of enrollment in the Symplicity HTN-3 trial brings physicians and treatment-resistant hypertension patients in the U.S. one step closer to having access to this innovative technology," said Nina Goodheart, vice president, general manager, Renal Denervation, Medtronic. "This important milestone reinforces Medtronic's strong commitment to increasing the collective understanding of renal denervation through our global clinical development program for our Symplicity renal denervation portfolio."

ABOUT THE SYMPLICITY(TM) RENAL DENERVATION SYSTEM

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 both renal arteries in turn. 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 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 Symplicity system's catheter and proprietary generator and algorithms were carefully and specifically developed through years of clinical experience to treat renal denervation. The Symplicity renal denervation system has been used for nearly six years to successfully treat more than 5,000 patients with treatment-resistant hypertension worldwide.

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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