Medtronic News

Medtronic Gets Go-Ahead from FDA for Study of Novel Treatment for High Blood Pressure

Patient Enrollment in U.S. Clinical Trial of Renal Denervation with Symplicity(R) Catheter System(TM) for Treating Resistant Hypertension to Start Soon

MINNEAPOLIS, Jul 11, 2011 (BUSINESS WIRE) --

Medtronic, Inc. (NYSE: MDT), announced today that the U.S. Food and Drug Administration (FDA) has conditionally approved the protocol for SYMPLICITY HTN-3, the company's U.S. clinical trial of renal denervation with the Symplicity(R) Catheter System(TM)for the treatment of resistant hypertension (high blood pressure in the presence of three or more medications), an especially dangerous disease affecting hundreds of millions of people worldwide. Patient enrollment in the landmark study is expected to start soon.

Medtronic is leading the development of renal denervation therapy. Having received Europe's CE (Conformité Européene) mark and a listing with Australia's Therapeutic Goods Administration (TGA), Medtronic's Symplicity Catheter System is commercially available in Europe and Australia.

FDA approval of the SYMPLICITY HTN-3 protocol enables Medtronic to become the first company to conduct a randomized, controlled trial of renal denervation in the United States. The Symplicity Catheter System is not approved by the FDA for U.S. commercial distribution.

The principal investigators of SYMPLICITY HTN-3 are George Bakris, M.D., professor of medicine and director of the Hypertension Center at the University of Chicago Medical Center; and Deepak L. Bhatt, M.D., M.P.H., 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 imminent start of this clinical trial marks a pivotal point in the study of hypertension treatments," said Dr. Bakris, who also serves as president of the American Society of Hypertension. "SYMPLICITY HTN-3 will assess the efficacy and safety of renal denervation with the Symplicity Catheter System - a treatment approach that represents a first in our field: a catheter-based intervention for patients with resistant hypertension who have been unable to achieve target blood pressure levels despite multiple medications."

Dr. Bhatt added: "There is already a great deal of excitement about this trial in the medical community because of its potential to shed light on novel treatments for hypertension."

SYMPLICITY HTN-3 is a single-blind, randomized, controlled trial designed to evaluate the safety and effectiveness of renal denervation with the Symplicity Catheter System in patients with resistant hypertension. Across 60 U.S. medical centers, the study will enroll approximately 500 patients who will be randomized 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 incidence of major adverse events one month following randomization.

The Symplicity Catheter System accomplishes renal denervation, a minimally invasive procedure that modulates the output of the sympathetic nerves located outside the renal artery walls. The system consists of a proprietary generator and a flexible catheter. The catheter is introduced through the femoral artery in the upper

thigh and is threaded up into the renal artery near each kidney. Once in place, the tip of the catheter delivers low-power radio-frequency (RF) energy according to a proprietary algorithm, or pattern, to modulate the surrounding sympathetic nerves. Renal denervation does not involve a permanent implant.

Clinical research to date shows that renal denervation with the Symplicity Catheter System may provide a significant and sustained reduction in blood pressure levels for many patients with uncontrolled blood pressure despite multiple medications. Results from SYMPLICITY HTN-2, a randomized, controlled trial of 106 patients in Europe, Australia and New Zealand, showed that patients with resistant hypertension randomized to renal denervation achieved a mean blood pressure reduction of 32/12 mm Hg at 6 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 mm Hg). The overall occurrence of adverse events did not differ between groups.

Hypertension is the leading attributable cause of death worldwide. It is a significant, 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. 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 sometimes 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 resistant.1

More information about the SYMPLICITY HTN-3 trial is available online 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.

1 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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