Medtronic News

Medtronic Announces CE Mark and TGA Listing for the Symplicity Spyral(TM) Multi-Electrode Catheter and Symplicity G3(TM) Generator

Thomson Reuters ONE via COMTEX) --Multi-Electrode System Built Upon Clinical Success and Strong Safety Profile of Single-Electrode Symplicity(TM) Renal Denervation System

MINNEAPOLIS -- December 5, 2013 -- Medtronic, Inc. (NYSE: MDT), announced today CE Mark (Conformite Europeenne) in Europe and Therapeutic Goods Administration (TGA) listing in Australia for its highly flexible 4 Fr multi-electrode Symplicity Spyral(TM) catheter and Symplicity G3(TM) radio frequency (RF) generator. This new system is designed to significantly reduce ablation time and provide ease of deliverability during renal denervation procedures for patients with uncontrolled hypertension. The multi-electrode Spyral system leverages the proprietary Symplicity treatment algorithm and Symplicity helical ablation pattern responsible for the clinical success and unmatched safety profile of the single-electrode Symplicity renal denervation system. The Symplicity renal denervation system is available for investigational use only in the United States.

The Symplicity Spyral catheter features four electrodes that are able to deliver simultaneous or selective RF energy into the renal artery wall to disrupt the output of overactive sympathetic nerves. The new 4 Fr catheter is compatible with a 6 Fr guide catheter and is delivered over a 0.014 inch guide wire via a rapid exchange system. The Symplicity Spyral catheter is highly conformable to artery shape and size and accommodates vessel diameters of 3-8 mm. Its non-occlusive design ensures the catheter will not obstruct renal blood flow during the procedure.

"The multi-electrode Symplicity system builds upon the single-electrode Symplicity system by helping significantly reduce ablation time," said Michael Bohm, MD, PhD, Chairman, Department of Internal Medicine, University of Saarland, Homburg/Saar, Germany. "Further, the ease of use and exceptional deliverability help simplify the procedure."

The Symplicity Spyral catheter is powered by a new RF generator that leverages the benefits of Medtronic's proprietary Symplicity(TM) treatment algorithm with its built-in safety features. The system uniquely offers physicians control and flexibility with the ability to turn specific electrodes on and off to accommodate different anatomies. The G3 generator includes a new touch screen user interface compatible with the single-electrode Symplicity catheter.

"As we continue to drive the future of renal denervation as a treatment for uncontrolled hypertension, we are excited to deliver our fast and efficient multi-electrode Symplicity Spyral system, inspired by years of clinical experience and collaboration with top thought leaders in the field," said Nina Goodheart, Vice President, General Manager, Renal Denervation, Medtronic. "We have significantly enhanced our technology with sophisticated features designed to meet specific unmet needs and we believe these improvements, coupled with our strong safety and efficacy profile, will provide unprecedented benefit to both patients and physicians."

About Uncontrolled Hypertension

Approximately 120 million people with high blood pressure worldwide are considered to have uncontrolled hypertension, with systolic blood pressures at or above 140 mm Hg, despite all efforts to control blood pressure with both lifestyle and medical management strategies.[1],[2],[3] Uncontrolled hypertension is associated with a hyperactive sympathetic nervous system and is directly linked with a high risk of heart attacks, stroke, heart failure, kidney disease and death. Most patients living with uncontrolled hypertension are prescribed three to five classes of anti-hypertensive medications, which can equate to taking four or more pills each day and are subsequently subjected to numerous side effects that may negatively impact quality of life.

About the Symplicity Clinical Trial Program

Medtronic continues to lead the advancement of research and development in renal denervation worldwide with more clinical studies ongoing than any other manufacturer with the longest follow-up data out to three years. Medtronic's rigorous clinical evaluation program of the Symplicity renal denervation system will involve more than 8,000 patients worldwide, including the U.S., Europe and Japan, with more than 1,200 of these patients participating in randomized clinical trials.

- SYMPLICITY HTN-1: A series of pilot studies at 19 centers in Australia, Europe and the United States with 153 patients with systolic blood pressure >=160 mm Hg enrolled. SYMPLICITY HTN-1 is the longest running clinical trial investigating the safety and efficacy of renal denervation.

- SYMPLICITY HTN-2: A randomized, controlled clinical trial of 106 patients at 24 centers in Europe, Australia and New Zealand to investigate renal denervation in patients with treatment-resistant hypertension randomly allocated in a one-to-one ratio to undergo renal denervation with previous treatment or to maintain previous treatment alone.

- SYMPLICITY HTN-3: First and only pivotal U.S. clinical trial of the Symplicity renal denervation system for uncontrolled hypertension completed enrollment of 535 patients across nearly 90 U.S. medical centers in May 2013. The results are expected to be available during the first half of 2014.

- SYMPLICITY HTN-4: First randomized, controlled trial to investigate renal denervation for moderate uncontrolled hypertension in U.S. patients with systolic blood pressure greater than or equal to 140 and less than 160 mm Hg. Enrollment began in November 2013.

- Global SYMPLICITY Registry: Prospective, multi-center, open-label registry of 5,000 patients in 200+ centers, designed to document the long-term safety and effectiveness of renal denervation in real-world patient populations, as well as gather data for other diseases characterized by elevated sympathetic drive.

- SYMPLICITY-HF: Clinical study designed to evaluate the safety and physiologic response to renal denervation with the Symplicity system in patients with chronic heart failure and renal impairment. The study will enroll approximately 40 adult subjects with chronic heart failure and renal impairment in Europe and Australia.

- Symplicity Spyral(TM) Catheter Feasibility Study: Prospective, single-arm, non-randomized clinical study of Medtronic's multi-electrode catheter, which completed enrollment of 50 patients in Australia and New Zealand designed to evaluate acute procedure safety and change in office blood pressure from baseline at six months.

- HTN-Japan: Open-label study being conducted in approximately 100 patients across up to 18 centers in Japan, designed to randomize subjects 1:1 to renal denervation versus no denervation with both groups receiving fully-tolerated doses of antihypertensive medications.

- SYMPLICITY HTN-India: Open-label study being conducted in approximately 40 patients across several centers in India, designed to evaluate the safety and efficacy of renal denervation in the local population.

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.

[1] Egan, Brent M., et al. "Uncontrolled and Apparent Treatment resistant Hypertension in the United States, 1988-2008." Circulation 124. 9 (2011): 1046-1058.

[2] Chobanian AV, Bakris GL, Black HR, Cushman WC, Green LA, Izzo JL, Jr., Jones DW, Materson BJ, Oparil S, Wright JT, Jr., Roccella E, Joint National Committee on Prevention DE, Treatment of High Blood Pressure. National Heart L, Blood I, National High Blood Pressure Education Program Coordinating C. Seventh report of the joint national committee on prevention, detection, evaluation, and treatment of high blood pressure. Hypertension. 2003;42:1206----1252.

[3] Staessen JA, Li Y, Thijs L, Wang JG. Blood pressure reduction and cardiovascular prevention: An update including the 2003----2004 secondary prevention trials. Hypertension research: official journal of the Japanese Society of Hypertension. 2005;28:385----407

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Source: Medtronic, Inc. via Globenewswire

HUG#1747802

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