Medtronic News

Medtronic's Multi-Electrode, Simultaneously Firing Renal Denervation Catheter Shows Reduced Procedure Times While Demonstrating Significant Blood Pressure Reduction

Initial Results from Feasibility Study of the Symplicity Spyral(TM) Catheter Show Safety and Efficacy While More than Halving Mean Procedure Time

MINNEAPOLIS and PARIS - MAY 21, 2013 - Medtronic, Inc. (NYSE: MDT) announced today preliminary results from the feasibility study of its Symplicity SpyralTM multi-electrode, 6 Fr renal denervation catheter, which showed safe, significant blood pressure reduction at one month in patients with treatment-resistant hypertension. Additionally, patients who had the renal denervation procedure with the Symplicity Spyral catheter (n=29) had a mean procedure time of 21 minutes, a decrease of 33 minutes from the mean procedure time for the Symplicity Flex(TM) single-electrode catheter shown in the Symplicity HTN-2 clinical. Nearly all of the patients in the one-month analysis had a radio frequency (RF) treatment time of 1 minute per artery; two of the 29 patients received more than one treatment in a single artery.

At one month, patients in this study experienced an average blood pressure reduction of -16/-7 mm Hg [p<.001] from baseline. These results are consistent with the efficacy data seen in the Symplicity HTN-1 feasibility trial for the Symplicity Flex single-electrode catheter, which showed an average blood pressure reduction of -19/-9 mm Hg [p<0.01] (n=143) after one month follow up. Further, average heart rate reduction for patients in the study was -4.3±11.0 beats per minute (BPM) from baseline [p=0.047] to one month; pulse pressure also improved significantly following treatment with a reduction of -8.8±14.9 mm Hg [p<0.004]. These data will be presented during an oral session at EuroPCR 2013 on Thursday, May 23, 2013.

"Early results of this trial are encouraging as they indicate that the clinical outcomes of this multi-electrode catheter are consistent with the well-established clinical data for the single-electrode Symplicity catheter. And, the possibility of reduced procedure times can have profound benefits for this patient population," said Robert Whitbourn, M.D., Director of the Cardiac Cath Labs & Coronary Intervention, St Vincent's Hospital, Melbourne, Australia and principal investigator of the study. "The data from this early analysis are not entirely unexpected given the single- and multi-electrode catheters use a consistent helical ablation pattern and both leverage the Symplicity renal denervation treatment algorithms."

Study investigators in this early experience with the Symplicity Spyral catheter reported no safety concerns. A total of 29 patients were treated with a 100 percent acute success rate in accessing the vessels and delivering therapy. During the study, three procedural events were observed with two pseudoaneurysms and one closure site complication, not related to RF energy delivery. There was one vessel irregularity on angiography due to the application of radio frequency energy to the vessel wall; no renal artery stenosis hypertensive crises or clinically meaningful changes in renal function were reported following the procedure.

The Symplicity Spyral catheter feasibility study is prospective, single-arm, non-randomized and will enroll approximately 50 patients at sites in Australia and New Zealand. The study's primary endpoint is acute procedure safety associated with the delivery and/or use of the Symplicity Spyral catheter. Its primary effectiveness endpoint is change in office blood pressure from baseline at six months.

The Symplicity Spyral catheter builds upon Medtronic's experience with the single-electrode Symplicity catheter for uncontrolled hypertension, demonstrating the company's commitment to the development and advancement of renal denervation technology based on critical physician and patient needs. The Symplicity

Spyral catheter features four electrodes that deliver RF energy simultaneously and is designed to significantly reduce ablation time during renal denervation procedures. The new catheter is 6 Fr guide-compatible, highly conformable to artery shape and size encompassing vessel diameters of 3-8 mm, and has a non-occlusive design. This new design is intended to provide ease of deliverability and consistency of RF energy application, while also enabling the treatment of a wide range of renal anatomies.

The Symplicity Spyral catheter will be powered by a new RF generator that will leverage the benefits of Medtronic's proven and proprietary Symplicity(TM) treatment algorithm with its built-in safety features. The new generator will include a new touch screen user interface that also will be compatible with the single-electrode Symplicity catheter.

"The Symplicity Spyral catheter is an exciting technology innovation that will enable Medtronic to take a substantial step forward in extending renal denervation options for physicians and their patients," said Nina Goodheart, Vice President, General Manager, Renal Denervation, Medtronic. "By combining important features of our single-electrode Symplicity catheter and learnings from our robust renal denervation clinical trial program, we are creating products designed to help meet physician needs, as well as safe, significant and sustained outcomes for their patients."

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.

Medtronic's Symplicity Flex single-electrode catheter has been used for more than five years to treat more than 5,000 patients with treatment-resistant hypertension worldwide. The Symplicity Flex single-electrode catheter and proprietary generator and algorithms were carefully and specifically developed through years of clinical experience to deliver the renal denervation procedure. The Symplicity Flex single-electrode catheter is only available in the United States and Japan for investigational use.

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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The Symplicity Spyral renal denervation catheter is pending CE Mark and not yet commercially available anywhere in the world.

Contacts:
Wendy Dougherty
Public Relations
+1-763-381-1204

Jeff Warren
Investor Relations
+1-763-505-2696

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