Results Announced from Two Renal Denervation Studies at EuroPCR Show Positive Outcomes in High-Risk Hypertensive Patients

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(GLOBE NEWSWIRE via COMTEX) --Late-Breaking Clinical Trial Results and Updated Global SYMPLICITY Registry Data Demonstrate Long-Term Results of RDN for Uncontrolled Hypertension

DUBLIN and PARIS - May 22, 2019 - Investigators today unveiled late-breaking clinical data from a first-of-its-kind physician sponsored clinical trial. The data indicate that renal denervation (RDN) with the Medtronic Symplicity(TM) renal denervation system was associated with reduced occurrence of subclinical atrial fibrillation (AF) in a small subset of high-risk patients with hypertensive heart disease over a median follow-up period of more than two years. Results from the single-center, randomized, sham-controlled study were presented today during a Late-Breaking Clinical Trial session at the 2019 EuroPCR Annual Meeting in Paris.

The investigator-led study funded by Medtronic randomized 80 patients to either the renal denervation procedure with the Symplicity renal denervation system or a fake "sham" procedure. Renal denervation is a minimally invasive, catheter-based procedure intended to deliver energy to overactive nerves in the kidney, decreasing their activity which is thought to be a cause of both hypertension and arrhythmias. AF occurrence was monitored by Medtronic implantable diagnostic technology. The results from the study demonstrate subclinical AF developed at a lower rate in the group of patients who received RDN than those receiving the sham procedure (19 percent versus 47 percent).

"In this high-risk cohort of patients with hypertensive heart disease, who are at risk for atrial fibrillation and cardiovascular death, this study suggests there may be an important benefit provided by renal denervation," said Marshall J Heradien, M.D., cardiologist and specialist physician at Stellenbosch University in Cape Town, South Africa, and principal investigator in the study. "Consistent with previous studies, these data show that the RDN procedure offers a lasting, positive effect that may translate into improved clinical outcomes."

New Data from the Global SYMPLICITY Registry

Investigators also reported new, three-year data from the Global SYMPLICITY Registry (GSR), which is the largest registry documenting the long-term safety and effectiveness of the Medtronic renal denervation systems in a real-world setting in patients with uncontrolled hypertension. To date, the registry has enrolled more than 2,600 patients treated with RDN and includes three-year follow-up for more than 2,300 patients.

The latest outcomes from the Registry presented at EuroPCR showed renal denervation led to significant and clinically meaningful reductions in both office and ambulatory blood pressure that were sustained out to three years post-procedure (16.5 mm Hg OSBP and 8.9 mm Hg 24H systolic ABPM). The Registry findings showed blood pressure reductions were consistent and sustained across various high-risk patient subgroups, including those with diabetes, isolated systolic hypertension (ISH), chronic kidney disease (CKD), resistant hypertension and those aged 65 years and older.

"As demonstrated by these studies presented at EuroPCR, new data continue to demonstrate that renal denervation is a safe and useful complement to manage uncontrolled hypertension, with patients experiencing meaningful blood pressure reductions out to several years and in the setting of daily clinical practice," said Dave Moeller, vice president and general manager of the Coronary and Renal Denervation business, which is part of the Cardiac and Vascular Group at Medtronic. "Results from these studies will add to the robust growing body of evidence supporting renal denervation and may be important for consideration with patients suffering from uncontrolled hypertension."

Hypertension is the single largest contributor to cardiovascular death; it dramatically increases risk of heart attack, stroke, heart failure, and kidney failure. The annual direct costs of hypertension are estimated at $500 billion worldwide. It is estimated that almost 20 percent of patients are completely non-adherent to oral medications while nearly half are partially non-adherent, highlighting the need for alternative treatment options.

In addition to the Global SPYMPLICITY Registry, the Medtronic SPYRAL HTN Global Clinical Program includes the SPYRAL HTN PIVOTAL and SPYRAL HTN-ON MED Trials, both prospectively powered, randomized, sham-controlled studies evaluating patients with uncontrolled blood pressure in the absence and presence of prescribed anti-hypertensive medications respectively. Medtronic is also conducting a 70-patient SYMPLICITY AF study, evaluating renal denervation in patients with paroxysmal and persistent atrial fibrillation. Approved for commercial use in more than 50 countries around the world, the Symplicity Spyral(TM) system is limited to investigational use in the United States, Japan, and Canada.

About Medtronic

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies - alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 86,000 people worldwide, serving physicians, hospitals and patients in more than 150 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

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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