Medtronic News

Landmark SPYRAL HTN-OFF MED Pivotal Trial Shows Superiority for Renal Denervation in Patients with High Blood Pressure Compared to Sham Procedure

ACC.20/WCC: Study Finds Significant Blood Pressure Reductions Achieved with RDN in Absence of Anti-Hypertensive Medication
Medtronic Receives FDA "Breakthrough Device Designation" for Symplicity Spyral™ Renal Denervation System

DUBLIN, March 29, 2020 (GLOBE NEWSWIRE) -- Medtronic plc (NYSE:MDT), the global leader in medical technology, today announced first-ever clinical data from the SPYRAL HTN-OFF MED Pivotal Trial. The prospectively powered study of patients with uncontrolled high blood pressure (BP) not taking anti-hypertensive medications met its primary and secondary effectiveness endpoints, with a >99.9% probability of superiority for both versus those who received a sham control procedure. Additionally, there were no major device or procedural safety events through three months. The study was presented today as part of the American College of Cardiology together with the World Congress of Cardiology Scientific Sessions (ACC.20/WCC) and published simultaneously in *The Lancet*.

The global, sham-controlled study evaluated 331 patients—166 of whom were randomized to renal denervation (RDN), a minimally invasive procedure intended to regulate overactivity of nerves that lead to and from the kidney. Results showed a statistically significant 9.2 mm Hg reduction in patients' office systolic blood pressure (OSBP) and 4.7 mm Hg reduction in 24-hour systolic ambulatory blood pressure (ABPM) at three months in those treated with the Symplicity Spyral RDN system. Blood pressure reductions were sustained consistently throughout the day and nighttime periods, which may offer an important benefit as cardiovascular risk is higher during the nighttime period. Anti-hypertensive medications (if prescribed) were discontinued for at least three weeks prior to randomization.

"These exciting results definitively demonstrate that RDN lowers blood pressure, including over the 24-hour period," said Prof. Michael Böhm, M.D., Ph.D., chief of cardiology at the University Hospital Homburg/Saar in Germany. "These new findings complement the broader SPYRAL Program further reinforcing RDN as a treatment option for patients with uncontrolled hypertension."

At three months, the study showed:

- RDN was superior to sham in all BP measures (24-hour ABPM and Office BP, systolic and diastolic).
- RDN had significantly greater BP reductions vs. sham control in both 24-hour systolic ABPM (4.0 mmHg, $p<0.001$), and office systolic BP (6.6 mmHg, $p<0.001$).

"As many patients with uncontrolled hypertension struggle to adhere to lifelong drug therapy for a variety of reasons and may look to other options that complement traditional treatments, we believe this advance could help clinicians work with patients to better manage their high blood pressure," 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. "Medtronic is committed to the field of renal denervation and in addressing the unmet need in hypertension management globally, and we look forward to seeing more insights from our industry-leading SPYRAL HTN clinical program as we realize the full potential of the therapy."

Medtronic also recently received Breakthrough Device Designation by the FDA for the Symplicity Spyral renal denervation system. The FDA Breakthrough Device Program is intended to help patients receive more timely access to certain technologies, such as renal denervation, that have the potential to provide more effective treatment or diagnosis for life-threatening or irreversibly debilitating diseases or conditions.

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 approximately $400 billion worldwide. It is estimated that almost 20% of patients with uncontrolled hypertension are completely non-adherent to oral medications, while nearly half are partially non-adherent, highlighting the need for alternative treatment options.

The SPYRAL HTN-OFF MED Pivotal Trial is part of the SPYRAL HTN Global Clinical Trial Program and accompanies the SPYRAL HTN-ON MED Trial and the SPYRAL DYSTAL Study. Along with the Global Symplicity Registry, conducted outside the United States, Medtronic's renal denervation program includes more than 4,000 patients, studied in the presence and absence of medication, and in patients with high baseline cardiovascular risk. Approved for commercial use in more than 60 countries around the world, the Symplicity Spyral system is limited to investigational use in the United States, Japan and Canada.

Analyst and Investor Briefing

Medtronic will host a webcast on Sunday, March 29, 2020, from 4:00 p.m. to 5:00 p.m. Central Daylight Time. The webcast will feature remarks on the company and recent clinical data announcements from the Medtronic Cardiac and Vascular Group management team. The live audio webcast can be accessed by clicking on the Investor Events link at http://investorrelations.medtronic.com on March 29. Within 24 hours of the webcast, a replay will be available on the same page. This event is not part of the official ACC.20/WCC program.

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 90,000 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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