Medtronic News

# New Medtronic Data Show Significant Blood Pressure Lowering Effect of Renal Denervation in Patients Taking Anti-Hypertensive Medication

*Late-Breaking SPYRAL HTN-ON MED Study at EuroPCR Indicates RDN Lowers Blood Pressure in Hypertensive Patients in Presence of BP Medication*

DUBLIN and PARIS - May 23, 2018 - Medtronic plc (NYSE:MDT) today announced first-ever-data from the SPYRAL HTN-ON MED Study. Initial study results found statistically significant and clinically important blood pressure reductions in hypertensive patients prescribed anti-hypertension medications treated with the Symplicity Spyral renal denervation (RDN) system with no major adverse safety events out to six months. The Late-Breaking Trial data, presented at the 2018 EuroPCR Annual Meeting in Paris, was published simultaneously in The Lancet. The Symplicity Spyral system is investigational in the United States and Japan.

At six months, patients randomized to the renal denervation procedure experienced an average 9 mm Hg drop in 24-hour mean systolic ambulatory blood pressure (ABPM), resulting in a 7.4 mm Hg difference compared to patients in the sham control arm (p=0.005). For RDN patients, 24-hour mean diastolic ABPM also declined 6 mm Hg, which is 4.1 mm Hg lower than the sham control arm (p=0.029).

Likewise, average office systolic blood pressure (OBP) in patients in the RDN arm declined 9.4 mm Hg - a 6.8 mm Hg difference from the sham control arm (p=0.021), and the diastolic OBP declined 5.2 mm Hg, a 3.5 mm Hg difference from the sham control arm (p=0.048).

"Data from the SPYRAL HTN-ON MED study is important for the clinical community and for patients with hypertension as it represents a typical scenario of managing uncontrolled hypertension patients, prescribed up to three blood pressure medications," said David Kandzari, M.D., director of interventional cardiology and chief scientific officer at Piedmont Heart Institute in Atlanta, Ga., co-principal investigator in the SPYRAL HTN-ON MED study, and member of the Medtronic Executive Committee that designed and oversees the SPYRAL HTN Global Clinical Program. "With these new results, mirroring those of the parallel SPYRAL HTN-OFF MED trial, we have convincing evidence at six months showing the continued safety and efficacy of RDN in both the presence and absence of blood pressure medication."

Renal denervation is a minimally invasive procedure intended to regulate over activity of nerves that lead to and from the kidney, which plays an important role in managing blood pressure.

The SPYRAL HTN-ON MED Study subjects were prescribed a stable regimen of up to three anti-hypertensive medications, including diuretics, calcium channel blockers, ACE /ARB inhibitors or beta blockers. Similar to recent studies of uncontrolled hypertension, drug testing indicated that adherence to prescribed anti-hypertensive medication was inadequate as only about 60 percent of patients were found to be taking medications as prescribed. Medication adherence remains a challenge in controlling hypertension in patients resulting in intermittent blood pressure control that can lead to an increased risk for cardiovascular events.

Additional analysis of the cyclical hourly changes in blood pressure demonstrated that the blood pressure lowering effects of renal denervation were distributed throughout the day and, importantly, throughout the nighttime period when blood pressure control is even more critical due to higher risks of adverse events like heart attack and stroke caused by hypertension. Blood pressure during sleep is the most significant predictive marker of cardiovascular disease morbidity and mortality, and reduction in asleep blood pressure is associated with highly significant reduction of cardiovascular disease risk.1

"We are encouraged by these data showing the procedure may enable a blood pressure lowering effect 24 hours a day. RDN is

essentially 'always on' even when the effect of medications may be subsiding between doses," said Raymond Townsend, M.D., director of the Hypertension Program at the Hospital of the University of Pennsylvania, a professor of Medicine in the Perelman School of Medicine at the University of Pennsylvania, and co-principal investigator in the trial. Townsend is a member of the Medtronic Executive Committee that designed and oversees the SPYRAL HTN Global Clinical Program. "These data also show that treatment with RDN in the main renal artery and branches with the Spyral System can help reduce blood pressure."

Propelled by the momentum of the "ON" and "OFF MED" trials, the global SPYRAL HTN clinical program has now moved into its final pivotal phase.

"These positive outcomes, taken together with the already presented OFF MED data, and the recent initiation of our SPYRAL HTN Pivotal Trial, are strong indicators that RDN may one day play a significant role in helping to address the hypertension epidemic that more than one billion patients face around the world," 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.

The clinical program utilizes the Medtronic next-generation renal denervation technology, composed of the flexible, 6 Fr guide catheter compatible, Symplicity Spyral Multi-Electrode Renal Denervation Catheter and Symplicity G3(TM) Renal Denervation RF (radiofrequency) Generator.

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 84,000 people worldwide, serving physicians, hospitals and patients in approximately 160 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.

-end-

1 Hermida RC, Ayala DE, Fernández JR, Mojón A, Smolensky MH. Hypertension: New perspective on its definition and clinical management by bedtime therapy substantially reduces cardiovascular disease risk. Eur J Clin Invest. 2018;48:e12909.

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

Ryan Weispfenning
Investor Relations
+1-763-505-4626

---

https://news.medtronic.com/2018-05-23-New-Medtronic-Data-Show-Significant-Blood-Pressure-Lowering-Effect-of-Renal-Denervation-in-Patients-Taking-Anti-Hypertensive-Medication