Medtronic News

Late Breaking Data at EuroPCR Demonstrates Long-Term Benefits of Medtronic Radiofrequency Renal Denervation in Real-World Hypertensive Patients

Medtronic Launches New GSR-DEFINE Study to Expand Real-World Data to 5,000 Patients

DUBLIN, May 18, 2021 /PRNewswire/ -- Medtronic plc (NYSE:MDT), the global leader in medical technology, today announced new clinical data from the Global SYMPLICITY Registry (GSR) indicating that renal denervation (RDN) with the Medtronic Symplicity™ Renal Denervation System was associated with clinically significant and sustained blood pressure reductions in a real-world hypertensive patient population through three years. Results from the prospective, single-arm, global, observational study are being presented as a Late-Breaking Clinical Trial session at the 2021 EuroPCR Annual Meeting.

The study analyzed nearly 3,000 patients with uncontrolled hypertension (HTN) and other comorbidities typical in HTN patients (chronic kidney disease, diabetes). Patients were treated with the Symplicity Renal Denervation System utilizing the single electrode Symplicity Catheter or the Symplicity Spyral Multi-Electrode Catheter, and their outcomes were analyzed up to three years post procedure. RDN with the radiofrequency based Symplicity Renal Denervation System is a minimally invasive procedure intended to regulate overactivity of nerves that lead to and from the kidney, which play an important role in blood pressure control.

The GSR study results demonstrated the Symplicity Renal Denervation System led to significant and clinically meaningful reductions in blood pressure that were sustained out to three years post-procedure. Patients experienced a mean reduction of 16.7 mmHg office systolic blood pressure (OSBP) at three years compared to baseline.

Investigators also evaluated the benefit of RDN within various patient subgroups using a clinical composite endpoint; a retrospective analysis comprised of both OSBP, 24-hour ambulatory blood pressure (ABPM) and medication burden. They found a consistent benefit of RDN in patients with versus without diabetes, chronic kidney disease, or patients who were 65 years and above. The similar clinical composite endpoint was used in a recent *EuroIntervention* publication that showed patients were nearly three times more likely to benefit from RDN compared to remaining on a regime of anti-hypertensive medications alone (Win Ratio = 2.78, $p<0.001$).[1]

"As we continue to expand our clinical data around renal denervation for uncontrolled hypertension management, we wanted to broaden our understanding of the long-term benefits for our patients who suffer from multiple chronic conditions and are typically prescribed multiple medications," said Felix Mahfoud, M.D., cardiologist at Saarland University Hospital in Homburg, Germany and principal investigator in the study. "With this new analysis, we can now help patients continue to see the real-world benefits of renal denervation."

EuroPCR: New Analysis on Estimated Risk Reduction from Symplicity RDN System

In addition to the Late Breaking Clinical Trial results at EuroPCR, investigators also reported a new analysis estimating the reduction in clinical events in patients treated with the Symplicity RDN system. The analysis used the clinical events observed at three years in the Global SYMPLICITY Registry and put these in perspective with a modeled control. The results showed a 26% relative risk reduction in major cardiovascular events (MACE) over three years for the full study cohort treated with RDN, and a 34% reduction for patients suffering from resistant hypertension over the same timeframe.

Medtronic Expands RDN Real-World Data Collection with the New GSR-DEFINE Study

Building on the success of GSR and continuing its commitment to providing real-world evidence for the Symplicity Spyral Renal Denervation System, Medtronic also announced today launch of the GSR-DEFINE Study. This new phase of patient data collection aims to enroll an additional 2,000 patients suffering from uncontrolled hypertension, who will be treated with the Medtronic Symplicity Spyral Multi-Electrode Renal Denervation Catheter. The study will collect data for a subgroup of patients out to five years.

"Medtronic's commitment to creating a minimally invasive solution to treat patients with uncontrolled high blood pressure is evident through our growing body of clinical evidence as part of our Symplicity Global Clinical Program," said Jason Weidman, senior vice president and president of the Coronary & Renal Denervation business unit, which is part of the Cardiovascular Portfolio at Medtronic. "The data presented today at EuroPCR not only add to our understanding of RDN's durability as a tool for hypertension treatment, but it also continues to propel Medtronic as a leader in this space."

About the Medtronic Symplicity Spyral Clinical Program

Along with the GSR and GSR-DEFINE studies, the Medtronic Symplicity Global Clinical Program also includes the SPYRAL HTN-OFF MED 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.[2]

Approved for commercial use in more than 60 countries around the world, the Symplicity Spyral Renal Denervation System is limited to investigational use in the U.S., 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 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.

[1] Kandzari et al, Prioritised endpoints for device-based hypertension trials: the win ratio methodology, *EuroIntervention* 2021; 16:e1496-e1502

[2] Böhm M, et al. Lancet. 2020;395(10234):1444-1451

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