Medtronic News

ACC.22: Medtronic renal denervation system demonstrates significant blood pressure reduction through three years

- Medtronic adds to its robust clinical program with long-term data demonstrating the continued blood pressure lowering effect of the Symplicity renal denervation procedure
- Medtronic also completes enrollment in the SPYRAL HTN-ON MED trial

DUBLIN and WASHINGTON, April 4, 2022 /PRNewswire/ -- Medtronic plc (NYSE:MDT), a global leader in healthcare technology, today announced long-term data from the first 80 patients in the SPYRAL HTN-ON MED trial, which were presented today at the American College of Cardiology's 71st Annual Scientific Session (ACC.22) late-breaking featured clinical research sessions. The data were also simultaneously published in *The Lancet*.[1]

In the first 80 patients of the SPYRAL HTN-ON MED trial, the data demonstrated that patients who were prescribed anti-hypertensive medications and treated with the Medtronic Symplicity Spyral™ Renal Denervation (RDN) System continued to show durable, clinically significant blood pressure reductions through three years. At three years:

- 18.7 mmHg reduction in RDN patients versus 8.6 mmHg in sham for 24-hour systolic ambulatory blood pressure (ABPM)
- 20.9 mmHg reduction in RDN patients versus 12.5 mmHg in the sham arm for office systolic blood pressure (OSBP)

"Across the latest trials, consistent blood pressure reductions have been observed in patients with uncontrolled hypertension treated with the Medtronic Symplicity Spyral RDN system," said Felix Mahfoud, M.D., cardiologist at Saarland University Hospital in Homburg, Germany, and member of the SPYRAL HTN executive committee. "For the first time, we now have randomized data that demonstrates that in a typical patient population – hypertension patients who are on anti-hypertensive medications and treated with RDN – we are seeing the continued, long-term blood pressure lowering effect. Lowering blood pressure can have meaningful clinical results for patients, including a decrease in the risk of cardiovascular events."

The trial also demonstrated procedural and long-term safety with the Symplicity Spyral renal denervation catheter, with zero major device or procedural safety events through three years.[1]

"With the ON MED randomized data presented and published today, Medtronic has now demonstrated the long-term benefit of renal denervation against a backdrop of an anti-hypertensive medication, with continued demonstration of a safe procedure," said Jeffrey Popma, M.D., chief medical officer for the Coronary & Renal Denervation business and the Structural Heart & Aortic business, which are part of the Cardiovascular Portfolio at Medtronic. "This highlights the importance of additional treatment options such as renal denervation."

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 United States, Japan, and Canada.

SPYRAL HTN-ON MED is a global, randomized, sham-controlled trial investigating the blood pressure lowering effect and safety of RDN with the radiofrequency-based Medtronic Symplicity Spyral system in hypertensive patients prescribed one to three anti-hypertensive medications. The long-term ON MED data presented at ACC.22 studied the same cohort of patients as the six-month primary endpoint analysis that was previously published in *The Lancet* in 2018.[2]

Medtronic completes randomization in the full cohort of its SPYRAL HTN-ON MED Trial

Medtronic also announced it recently completed randomization for the full cohort of its SPYRAL HTN-ON MED trial and closed enrollment. The full analysis cohort targets up to 340 randomized patients. Medtronic expects the six-month post procedure follow-up for the full cohort will be complete in the second half of calendar year 2022.

"The data presented at ACC underscores Medtronic's confidence in RDN as a solution for the millions of people who suffer from uncontrolled high blood pressure. These new data will be important to regulatory officials, clinicians and payers as we look to bring a new treatment option to market for patients with uncontrolled hypertension," said Jason Weidman, senior vice president and president of the Coronary & Renal Denervation business unit, which is part of the Cardiovascular Portfolio at Medtronic. "Looking ahead, we remain focused on the anticipated six-month follow up for the full cohort of the ON MED trial in the second half of this calendar year."

The SPYRAL HTN-ON MED trial is part of the SPYRAL HTN Global Clinical Program, adding to the safety and efficacy data for RDN. Along with the real-world data from the Global Symplicity Registry, when combined with commercial experience, there have been more than 20,000 procedures performed with Medtronic RDN technology. The clinical program is backed by the most rigorous and extensive patient experience studied in the presence[2] and absence[3] of medication and in patients with high baseline cardiovascular risk.[4]

About the Medtronic Symplicity Spyral™ Renal Denervation System

The Medtronic RDN procedure uses a minimally invasive procedure that delivers radiofrequency energy to specific nerves near the kidneys that can become overactive and cause high blood pressure.

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered inDublin, Ireland, is the leading global healthcare technology company that boldly attacks the most challenging health problems facing humanity by searching out and finding solutions. Our Mission — to alleviate pain, restore health, and extend life — unites a global team of 90,000+ passionate people across 150 countries. Our technologies and therapies treat 70 health conditions and include cardiac devices, surgical robotics, insulin pumps, surgical tools, patient monitoring systems, and more. Powered by our diverse knowledge, insatiable curiosity, and desire to help all those who need it, we deliver innovative technologies that transform the lives of two people every second, every hour, every day. Expect more from us as we empower insight-driven care, experiences that put people first, and better outcomes for our world. In everything we do, we are engineering the extraordinary. For more information on Medtronic (NYSE:MDT), visit www.Medtronic.com and follow @Medtronic on Twitter and LinkedIn.

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] Mahfoud F, Kandzari D, Kario K, et al. Long-term efficacy and safety of renal denervation in the presence of antihypertensive drugs (SPYRAL HTN-ON MED): a randomised, sham-controlled trial. *Lancet*. 2022; https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(22)00455-X/fulltext

[2] Kandzari D, Böhm M, Mahfoud F, et al. Effect of renal denervation on blood pressure in the presence of antihypertensive drugs: 6-month efficacy and safety results from the SPYRAL HTN-ON MED proof-of-concept randomised trial. *Lancet* 2018; 391: 2346-55.

[3] Böhm M, Kario K, Kandzari D et al. Efficacy of catheter-based renal denervation in the absence of antihypertensive medications (SPYRAL HTN-OFF MED Pivotal): a multicentre, randomised, sham-controlled trial. *Lancet* 2020; 395:1444–51.

[4] Mahfoud F, Mancia G, Schmieder R, et al. Renal denervation in high-risk patients with hypertension.*J Am Coll Cardiol 2020*; 75: 2879-88.

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