

SPYRAL HTN-ON MED study shows significant, consistent, long-term blood pressure lowering effect at two years

Company commits to advancing clinical data for Symplicity™ with the SPYRAL Gemini clinical trial and expansion of the GSR-DEFINE clinical trial

GALWAY, Ireland and WASHINGTON, Oct. 28, 2024 /PRNewswire/ -- Medtronic plc (NYSE: MDT), a global leader in healthcare technology, today announced new, long-term data from its SPYRAL HTN-ON MED clinical trial that showed subjects who underwent radiofrequency renal denervation with the Symplicity™ Spyral renal denervation (RDN) system had significantly greater reductions in 24-hr ambulatory systolic blood pressure (ABPM), and office-based systolic blood pressure (OSBP) compared to sham patients at two years. The data were presented as a part of the 2024 Transcatheter Cardiovascular Therapeutics Conference (TCT).

"These findings are a key step toward informing the medical community of the long-term effectiveness with radiofrequency renal denervation as a treatment for uncontrolled hypertension," stated Dr. David Kandzari, Chief of Piedmont Heart Institute and Cardiovascular Services and lead principal investigator of the SPYRAL HTN-ON MED trial. "Importantly, at two years, we continue to see Symplicity is safe and consistent with clinically meaningful and significant blood pressure reductions. These data further substantiate sustained blood pressure reductions consistently observed in across the SPYRAL and Global Symplicity clinical programs."

The two-year data is consistent with other long-term data for Symplicity RDN, demonstrating clinically meaningful, consistent and sustained blood pressure reductions.^{1,2} At two years, the data showed:

- Significant group differences in 24-hr ABPM and OSBP in favor of RDN, despite significantly more medications detected in the sham group
 - 24 months ABPM: -12.1 mmHg in RDN group vs. -7.0 mmHg in sham group (treatment difference: -5.7 mmHg; p=0.039)
 - OSBP: -17.4 mmHg in the RDN group vs. -9.0 mmHg in the sham group (treatment difference: -8.7 mmHg; p=0.0034)
- Long-term safety with no confirmed renal artery stenosis greater than 70% in the Spyral group at two years

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 Symplicity Spyral RDN system in hypertensive patients who have been prescribed up to three anti-hypertensive medications. After the six-month primary endpoint assessment, the study continued to assess 24-hr ABPM and OSBP from baseline through yearly follow ups.

SPYRAL GEMINI Clinical Program

Medtronic intends to investigate multi-organ (hepatic artery and renal artery)denervation with the Symplicity Spyral catheter. The planned **G**lobal Pilot study of **r**Enal and hepatic co**M**bi**N**ed denervation (SPYRAL GEMINI pilot study) will investigate the safety and efficacy of the multi-organ ablation approach in uncontrolled hypertension patients who are both on and off medications.

"Medtronic is uniquely positioned to explore the blood pressure lowering potential of multi-organ denervation. This is supported by both its intellectual property and the Symplicity Spyral catheter design, which enables access and treatment of the Common Hepatic Artery - a vascular target rich with sympathetic innervation - with the same single catheter," said Jason Weidman, senior vice president and president of the Coronary and Renal Denervation business within the Cardiovascular Portfolio at Medtronic. "The promising preclinical data highlight the potential for interventional denervation in the liver to support additional

blood pressure lowering effects of the procedure.³ This approach underscores our dedication to innovation for both patients and physicians."

The utilization of Symplicity Spyral in the hepatic artery is investigational and not approved for use.

GSR-DEFINE Expands to the United States

Medtronic will also expand the GSR-DEFINE clinical trial to sites in the United States. The GSR-DEFINE trial is an extension of the Global SYMPPLICITY Registry, and is a prospective, all-comer observational study in 251 sites across 55 countries, including 3,000 patients from the GSR study and enrolling up to an additional 2,000 patients globally.

"This year at TCT, we are not only reinforcing the consistent, long-term effects of radiofrequency denervation, but we're further demonstrating our commitment to evidence generation and innovation," said Jason Fontana, PhD, general manager Renal Denervation, and vice president of Global Marketing for the Coronary and Renal Denervation business. "As the leader in interventional hypertension treatments, we are excited to extend the largest evidence platform available to U.S. physicians and their patients."

Approved for commercial use in over 75 countries around the world, the Symplicity Spyral renal denervation system is currently limited to investigational use in Japan.

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Galway, 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 95,000+ passionate people across more than 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 [LinkedIn](https://www.linkedin.com/company/medtronic).

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 DE, 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. The Lancet. 2022; 399:1401-1410.

² GSR 2024 update: Mahfoud et al. EuroPCR. 2024

³ Tzafiri, A.R., et al Morphometric analysis of the human common hepatic artery reveals a rich and accessible target for sympathetic liver denervation. Sci Rep 12, 1413 (2022). <https://doi.org/10.1038/s41598-022-05475-6>

Contacts:

Krystin Hayward Leong

Public Relations

+1-508-261-6512

Ryan Weispfenning

Investor Relations

+1-763-505-4626

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