Medtronic News

# Medtronic issues statement on the FDA Circulatory Systems Devices Advisory Panel vote for the Symplicity Spyral Renal Denervation System

DUBLIN, Aug. 23, 2023 /PRNewswire/ -- Today, Medtronic announced the outcome of the U.S. Food & Drug Administration (FDA) Circulatory System Devices Panel (CSDP) meeting to review data presented in support of the Medtronic Symplicity Spyral™ Renal Denervation (RDN) System. The panel Committee voted unanimously (13-0) on safety and in favor (7-6) of the effectiveness of the Symplicity blood pressure procedure. The Committee's vote was closely divided on the benefit/risk profile of the device (tied at 6-6 and one abstention), with the panel chair breaking the tie, resulting in a final 6-7 vote.

"We appreciate the robust conversation that occurred prior to the vote," said Jason Weidman, senior vice president and president of the Coronary and Renal Denervation business, which is part of the Cardiovascular Portfolio at Medtronic. "We will continue to collaborate with the FDA on bringing a new option to the millions of people living with high blood pressure."

The CSDP is designed to review and evaluate data regarding the safety and effectiveness of devices for use in the circulatory and vascular systems and make appropriate recommendations to the FDA Commissioner. The panel recommendation will be considered by the FDA as it continues to review the Medtronic Symplicity Spyral RDN System for U.S. market approval.

"The Symplicity Blood Pressure Procedure has the potential to fill a significant unmet need in hypertension care, and we know patients are looking for options in addition to medication and lifestyle modifications to manage their blood pressure," said David Kandzari, M.D., chief, Piedmont Heart Institute and Cardiovascular Services and lead principal investigator of the SPYRAL HTN-ON MED clinical trial. "The totality of evidence demonstrated that there is a benefit with the Spyral RDN catheter, and there is no question about the safety of the procedure."

The Medtronic SPYRAL HTN Global Clinical Program is the most comprehensive clinical program studying RDN for more than 10 years in more than 4,000 patients in the presence and absence of medication, and with high baseline cardiovascular risk. The Symplicity blood pressure procedure has demonstrated sustained and durable drops in blood pressure out to three years in randomized control and real-world registry trials.[1],[2],[3],[4]

**About Hypertension**

Hypertension, or high blood pressure, impacts nearly 1 billion adults worldwide[1], and is the leading modifiable cause of heart attack, stroke, and death. Despite available treatment with medications and lifestyle changes, blood pressure remains uncontrolled for many patients. Nearly 80% of adults with hypertension do not have it under control[1] and half of hypertension patients become non-adherent to medication within one year.[2]

**About RDN**

The Medtronic Symplicity Spyral™ renal denervation (RDN) system uses a minimally invasive procedure that delivers radiofrequency (RF) energy to specific nerves near the kidneys that can become overactive and cause high blood pressure. Approved for commercial use in 70 countries around the world, the Symplicity Spyral Renal Denervation System is currently limited to investigational use in the U.S., Japan, and Canada.

**About Medtronic**

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Dublin,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 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] Bhatt, D. et al, Long-term outcomes after catheter-based renal artery denervation for resistant hypertension: final follow-up of the randomised SYMPLICITY HTN-3 Trial. The Lancet. September 18, 2022. DOI:https://doi.org/10.1016/S0140-6736(22)01787-1.

[2] Mahfoud, F. et al. Outcomes Following Radiofrequency Renal Denervation According to Antihypertensive Medications: Subgroup Analysis of the Global SYMPLICITY Registry DEFINE. Hypertension. August 2023; DOI: 10.1161/HYPERTENSIONAHA.123.21283.

[3] Mahfoud, F. 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. April 2022. https://doi.org/10.1016/S0140-6736(22)00455-X

[4] Mahfoud, F. et al. Cardiovascular Risk Reduction After Renal Denervation According to Time in Therapeutic Systolic Blood Pressure Range. Journal of the American College of Cardiology. November 2022. https://doi.org/10.1016/j.jacc.2022.08.802

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