Medtronic News

Medtronic announces FDA approval of minimally invasive device to treat hypertension

The Symplicity™ blood pressure procedure offers patients a new adjunct approach to lowering blood pressure

Approval is the culmination of ten years of clinical research and development of the Medtronic renal denervation technology

DUBLIN, Nov. 17, 2023 /PRNewswire/ -- Medtronic plc (NYSE: MDT), a global leader in healthcare technology, today announced that the United States Food and Drug Administration (FDA) has approved the Symplicity Spyral™ renal denervation (RDN) system, also known as the Symplicity™ blood pressure procedure, for the treatment of hypertension. With this approval, Medtronic will immediately begin commercialization.

Hypertension, or high blood pressure, is the leading modifiable cause of heart attack, stroke, and death, and its prevalence is notably worse in underserved U.S. populations. Despite available medications and lifestyle interventions, control rates remain low. These challenges speak to the possibility that patients may benefit from an adjunctive treatment option to better manage their blood pressure.

"Medtronic has always believed in the potential of this therapy. We partnered closely with leading experts in our clinical community who could help us in our journey to get this technology to the people who need it most," said Jason Weidman, senior vice president and president of the Coronary and Renal Denervation business within the Cardiovascular Portfolio at Medtronic. "It was the promise of this therapy that enabled Medtronic to keep going, even when others exited the renal denervation space. High blood pressure is a global health issue, and patients need more options to manage their blood pressure. The approval of the Symplicity blood pressure procedure represents a significant milestone for physicians and patients in the treatment of hypertension."

The Medtronic Symplicity blood pressure procedure is an innovative, minimally invasive procedure that delivers radiofrequency energy to nerves near the kidneys that can become overactive and contribute to high blood pressure. After sedation, the doctor inserts a single thin tube (known as a catheter) into the artery leading to the kidney. Once the tube is in place, the doctor administers energy to the system to calm the excessive activity of the nerves connected to the kidney. The tube is removed, leaving no implant behind.

"The Symplicity blood pressure procedure is safe and effective, providing significant 'always on' blood pressure reductions for patients," said David Kandzari, M.D., chief, Piedmont Heart Institute and Cardiovascular Service and co-principal investigator of the SPYRAL clinical program. "This landmark approval is the culmination of rigorous scientific study and clinical trials, including long-term, sham-controlled studies in the presence and absence of medication, and the largest real-world study."

Patient preference and shared decision making have been identified as critical components of developing a hypertension care plan including the Symplicity blood pressure procedure. According to results from a Medtronic-led patient preference study, when presented with an interventional treatment with blood pressure reduction and potential risks in line with those of the Symplicity blood pressure procedure, approximately one third of patients were likely to choose the interventional treatment.

"This approval paves the way for a transformation in hypertension treatment, offering a solution that complements medication and lifestyle changes," said Raymond Townsend, M.D., from the Hypertension Section, Department of Internal Medicine / Renal, University of Pennsylvania School of Medicine and co-principal investigator of the SPYRAL clinical program. "The Symplicity blood pressure procedure is a promising treatment option for clinicians and patients alike and offers opportunity to fulfill a significant unmet need in hypertension care, especially for those patients who are desperately seeking additional

approaches to get their blood pressure down."

The Medtronic SPYRAL HTN Global Clinical Program is the most comprehensive clinical program studying RDN and is backed by experience in more than 25,000 patients treated globally, studied in the presence and absence of medication, and in patients with high baseline cardiovascular risk. Although currently limited for investigational use in Japan, China and Canada, the Symplicity Spyral Renal Denervation System is approved for commercial use in more than 70 countries around the world.

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 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.

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