Medtronic News

Medtronic Begins New Pilot Study as Part of SPYRAL HTN Clinical Program for Renal Denervation in Hypertension Patients

SPYRAL DYSTAL Study to Evaluate the Effects of RDN Using Fewer, Targeted Ablations to Achieve Meaningful Blood Pressure Reductions

DUBLIN, Feb. 04, 2020 (GLOBE NEWSWIRE) -- Medtronic plc (NYSE:MDT) today announced it will begin enrollment in a pilot study evaluating the safety and efficacy of the Symplicity™ Spyral renal denervation (RDN) system using a targeted procedural approach with a reduced number of radio frequency (RF) ablations. Set to enroll 50 patients at up to 15 sites in the U.S. and Europe, the single-arm study is designed to focus on ablating the distal main renal artery and primary branches to lower blood pressure utilizing a simplified procedural approach.

“In depth anatomical study indicates the renal nerves are closer to the renal artery in the distal renal artery and branches. Focusing the procedure on these targeted locations may help us understand if we can achieve meaningful blood pressure reductions more efficiently,” said Andrew Sharp, M.D., interventional cardiologist at the University Hospital of Wales, in Cardiff, United Kingdom, and co-principal investigator of the SPYRAL DYSTAL study. “Early evidence using this modified approach has been encouraging and we intend to build on that data with the DYSTAL study.”

Renal denervation is a minimally invasive procedure intended to regulate overactivity of nerves that lead to and from the kidney, which play an important role in controlling blood pressure.

“As we strive to build upon the rigorous renal denervation studies within the SPYRAL HTN Clinical Program, the DYSTAL study will help inform how we can fine-tune the procedure and continue to address the unmet need in hypertension management,” said Dave Moeller, vice president and general manager of the Coronary and Renal Denervation business, which is part of the Cardiac and Vascular Group at Medtronic.

SPYRAL HTN-OFF MED Pivotal Trial Data at ACC.20
Results from the SPYRAL HTN OFF MED Pivotal Trial will be presented as a Late-Breaking Clinical Trial at the American College of Cardiology 69th Annual Scientific Sessions on March 29, 2020, in Chicago. The prospective, international, randomized, sham-controlled study is investigating the blood pressure lowering effect and safety of renal denervation with the Symplicity Spyral system in the absence of medication.

"Medtronic is committed to realizing the full potential of renal denervation, and we look forward to the highly anticipated results of the SPYRAL HTN-OFF MED Pivotal Trial to be unveiled at ACC in March,” said Moeller.

Hypertension is the single largest contributor to cardiovascular death; it dramatically increases risk of heart attack, stroke, heart failure, and kidney failure. The annual direct costs of hypertension are estimated at $500 billion worldwide. More than 40 percent of hypertension patients are not fully adherent to prescribed pharmacological therapy, which may lead to inadequate blood pressure control and greatly increased cardiovascular risk – thus, highlighting the need for alternative treatment options.

In addition to the SPYRAL DYSTAL Study, the Medtronic SPYRAL HTN Global Clinical Program 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. The program also includes the real-world GLOBAL SYMPLICITY REGISTRY that has enrolled over 2,700 patients with the Medtronic Symplicity RDN system, including 600 patients with the Symplicity Spyral catheter.

Approved for commercial use in more than 50 countries around the world, the Symplicity Spyral system is limited to

investigational use in the United States, 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.

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Joey Lomicky
Public Relations
+1-763-526-2494

Ryan Weispfenning
Investor Relations
+1-763-505-4626

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