Medtronic News

Medtronic Begins Renal Denervation Study for High Blood Pressure Patients Prescribed Anti-Hypertensive Medication

FDA-Approved Study Furthers Medtronic Commitment to Generate Meaningful Clinical Evidence for Use of Renal Denervation to Treat Uncontrolled Hypertension

DUBLIN - November 8, 2018 - Medtronic plc (NYSE:MDT) today announced U.S. Food and Drug Administration (FDA) approval to begin a clinical trial to evaluate the Symplicity Spyral(TM) renal denervation system in patients with high blood pressure (hypertension) who are already prescribed anti-hypertension medications. The SPYRAL HTN-ON MED Trial is the latest prospectively powered, randomized, sham-controlled study within the broader Medtronic SPYRAL HTN Global Clinical Program, and will evaluate a patient population comparable to what physicians typically encounter in daily practice - patients with uncontrolled blood pressure taking multiple anti-hypertensive medications.

"A broad range of patients suffer with hypertension today, many of whom remain uncontrolled despite being prescribed a variety of medications; the consequences of uncontrolled hypertension represent both a substantial impact to public health and a large unmet need in medicine for new approaches," said David Kandzari, M.D., director of interventional cardiology and chief scientific officer at Piedmont Heart Institute in Atlanta, Ga., principal investigator and member of the SPYRAL HTN Global Clinical Program Executive Committee. "This trial will add yet another critical piece to the RDN evidence basis and is designed to build on the success of our pilot study, which showed a benefit for RDN in an on-med patient population."

The design of the ON MED Trial announced today builds on the randomized sham-controlled SPYRAL HTN-ON MED pilot study that was published in The Lancet last May, showing renal denervation with the Symplicity Spyral renal denervation system - a minimally invasive, radio frequency (RF)-based procedure intended to regulate the activity of nerves that lead to and from the kidney - can play an important role in managing blood pressure for patients taking anti-hypertensive medications. The 80-patient pilot study demonstrated statistically significant and clinically relevant reductions in both office and 24-hour systolic blood pressure. Notably, those blood pressure lowering effects were observed not only throughout the daytime, but also during the nighttime and early morning periods when heart attack and stroke risk due to hypertension are highest, resulting in the observation that RDN is "always on."

The ON MED Trial is a 2:1 randomized, sham-controlled study and will randomize up to 340 patients at 55 centers in the U.S., Japan, Europe, Australia and Canada. Patients will be followed out to three years. Primary safety endpoints will include major adverse events at one month and new renal artery stenosis at six months. The primary efficacy endpoint is 24-hour ambulatory blood pressure at six months. Subjects will be prescribed a stable regimen of up to three anti-hypertensive medications, including diuretics, calcium channel blockers, ACE/ARB inhibitors or beta blockers.

"Medtronic is committed to building a robust global renal denervation clinical program with results from several randomized, sham-controlled, prospectively-powered, blinded clinical studies, in both the absence and presence of prescribed medications," 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. "Results from the ON MED Trial will add to the growing body of evidence supporting renal denervation and is intended to support clinicians in making treatment decisions for patients who might benefit from this procedure."

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. It is estimated that almost 20 percent of patients are completely non-adherent to oral medications while nearly half are partially non-adherent, highlighting the need for alternative treatment options.

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.

In addition to the ON MED trial announced today, the SPYRAL HTN Global Clinical Program also includes the SPYRAL HTN Pivotal Trial, which was announced in April and is evaluating patients in the absence of medication. For more information on the SPYRAL HTN Clinical Trial Program, visit www.spyralhtntrials.com.

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 86,000 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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