Medtronic News

Medtronic Announces Randomized Global Resolute Onyx(TM) DES One-Month Dual Antiplatelet Therapy Study to Address Critical Unanswered Question in Interventional Cardiology

First-of-its-Kind Randomized Clinical Trial Will Evaluate One-Month DAPT in Patients Following PCI Procedures with the Newer-Generation Durable Polymer Resolute Onyx DES

DUBLIN- August 14, 2017 - Medtronic plc (NYSE: MDT) today announced a global randomized clinical trial that will evaluate one-month dual antiplatelet therapy (DAPT) - the combination of aspirin and an anti-clotting medication - in patients implanted with the Resolute Onyx(TM) Drug-Eluting Stent (DES) during percutaneous coronary intervention (PCI). Designed to evaluate clinical DAPT outcomes between two DES for the first time ever, the RESOLUTE ONYX ONE-MONTH DAPT Study intends to help inform DAPT guidelines for newer-generation DES that currently favor bare-metal stents (BMS) for patients with stable ischemic heart disease who might require a shorter dual antiplatelet regimen.

Guidelines regarding DAPT therapies vary geographically and by patient presentation. Decisions about duration of DAPT are best made on an individual basis and should integrate clinical judgment, assessment of the benefit/risk ratio, product labeling, and patient preference. The RESOLUTE ONYX ONE-MONTH DAPT Study will enroll up to approximately 2,000 patients at approximately 70 sites worldwide.

The study further demonstrates the significant clinical investment from Medtronic to provide relevant DAPT evidence to physicians for both current and previous generation DES, including the Zotarolimus-eluting Endeavor Sprint Stent in Uncertain DES Candidates (ZEUS) Study that showed significant safety benefits with a previous generation DES vs. BMS in patients who would typically not receive a DES, such as those at a high risk for bleeding.

"The ZEUS trial and subsequently, the LEADERS-FREE trial (which evaluated a different DCS vs. BMS), showed that other DES systems could be a better alternative to BMS in patients with a high risk of bleeding," said Stephan Windecker, M.D., of Bern University Hospital in Switzerland, and principal investigator in the study." The study addresses the critical question whether newer generation durable-polymer DES, like Resolute Onyx, that have demonstrated excellent procedural success in addition to sustained long-term safety and efficacy, could potentially improve results even further among these patients."

Results from the RESOLUTE ONYX ONE-MONTH DAPT Study will also build on the RESOLUTE Pooled DAPT Interruption analysis that showed no increased risk of stent thrombosis with DAPT interruption or discontinuation after one-month.

The Resolute Onyx DES is the first and only DES to feature Core Wire Technology, an evolution of Continuous Sinusoid Technology (CST). CST is a unique Medtronic method of stent manufacturing, which involves forming a single strand of cobalt alloy wire into a sinusoidal wave to construct a stent. This enables greater deliverability and conformability to the vessel wall. With Core Wire Technology, a radiopaque inner core is incorporated within the cobalt alloy wire to enhance visibility for accurate stent placement. Core Wire Technology also enables thinner struts while maintaining structural strength.

"We're continuously looking at ways to invest in clinical evidence and expand our product portfolio to help address the most important unanswered questions and unmet needs in interventional cardiology," said Martin Rothman, M.D., vice president, medical affairs for the Coronary and Structural Heart division, which is part of the Cardiac and Vascular Group at Medtronic. "In addition to generating new, meaningful evidence to help guide clinical practice, we are also looking to develop next-generation technologies that will build on the exceptional deliverability that physicians have come to expect with our stent platforms. Along with DES, our pipeline includes a cadre of other tools that will help interventional cardiologists improve patient outcomes and address unmet clinical needs around the world."

Stents from the Resolute DES family have been implanted in more than six million patients around the world, one million of

whom have been implanted with the latest generation Resolute Onyx DES. The Resolute Onyx DES received CE (*Conformité Européene*) Mark in September 2014 and FDA approval in April 2017.

In collaboration with leading clinicians, researchers, and scientists worldwide, Medtronic offers the broadest range of innovative medical technology for the interventional and surgical treatment of cardiovascular disease and cardiac arrhythmias. The company strives to offer products and services that deliver clinical and economic value to healthcare consumers and providers around the world.

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 91,000 people worldwide, serving physicians, hospitals and patients in more than 160 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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