Medtronic News

Late-Breaking Clinical Study Results Demonstrate Exceptional Safety and Efficacy Outcomes for Resolute Onyx(TM) DES

TCT18: BIONYX Study Shows Strong Performance with Durable Polymer Resolute Onyx DES in Head-to-Head Comparison with Biodegradable Polymer DES

DUBLIN and SAN DIEGO - September 22, 2018 - Investigators today unveiled new clinical data from the physician-initiated BIONYX study, representing the first all-comers analysis in nearly 2,500 patients comparing the safety and efficacy of the durable polymer Resolute Onyx(TM) drug-eluting stent (DP-DES) from Medtronic plc (NYSE: MDT) to the Orsiro biodegradable polymer stent (BP-DES). At one year, the study showed patients with coronary artery disease who were treated with Orsiro BP-DES received no clinical advantage compared to patients treated with the Resolute Onyx DP-DES, and Orsiro BP-DES demonstrated a higher rate of stent thrombosis.1 Published simultaneously in *The Lancet*, the results were presented today during a Late-Breaking Clinical Trial session at the 30th Transcatheter Cardiovascular Therapeutics conference (TCT), the annual scientific symposium of the Cardiovascular Research Foundation.

Enrolling approximately 2,500 real-world patients (71 percent with acute coronary syndrome), the BIONYX study had a primary composite endpoint of target vessel failure (TVF) at one-year and showed no statistically significant difference in outcomes for the Resolute Onyx DP-DES treated group (N=1,243) at 4.5 percent compared to 4.7 percent with the Orsiro BP-DES. However, notable differences were observed in significantly lower rates of definite or probable stent thrombosis (0.1 percent for Resolute Onyx compared to 0.7 percent with Orsiro DES) at one year ($p = 0.01$).

"Never before has a head-to-head stent trial assessed the new-generation durable polymer zotarolimus-eluting stent - the Resolute Onyx DES - which has thinner struts and improved visibility compared to its predecessor, the Resolute Integrity DES," said Prof. Clemens von Birgelen, M.D. Ph.D., co-director of the Department of Cardiology at Thoraxcentrum Twente, Professor of Cardiology at University of Twente in Enscheded, the Netherlands, principal investigator of the trial and presenter of the data at TCT. "The Resolute Onyx demonstrated excellent safety and efficacy that matched at one-year the results of a biodegradable polymer sirolimus-eluting stent with ultra-thin struts that showed excellent outcomes in previous head-to-head stent studies. The stent thrombosis data are promising, but should not be overestimated as we cannot exclude a play of chance."

The Resolute Onyx DES is coated with the proprietary BioLinx(TM)polymer, a bio-compatible and non-thrombogenic coating specifically designed for use on DES. Low rates of stent thrombosis have been observed in more than 70,000 real-world clinical study patients, with additional studies underway, including the global Medtronic Onyx ONE Month DAPT Program comprised of two studies designed to investigate safety following one-month of dual anti-platelet therapy (DAPT) discontinuation post-PCI. The Resolute Onyx DES offers the broadest size matrix available and is the first-and-only DES to feature Core Wire Technology which enables thinner struts and greater deliverability while maintaining structural strength and enhanced visibility.

"We have yet to see any meaningful clinical benefit with the introduction of biodegradable stent technologies," 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. "The Resolute Onyx DES has been shown to deliver excellent outcomes for a wide range of patients, and we are pleased to see that the combination of visibility, thin struts, conformability, and biocompatibility resulted in a very low stent thrombosis rate in this study."

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 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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1 Stent thrombosis was not a powered endpoint in the BIONYX Study.

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