Medtronic News

Independent Study Finds Biodegradable Polymer Stents Provide No Clinical Benefit Over Resolute Integrity(TM) DES

BIO-RESORT Demonstrates Excellent Clinical Outcomes for Medtronic Resolute(TM) Integrity(TM) DES, a Gold Standard for Percutaneous Coronary Intervention

DUBLIN and WASHINGTON, DC - Oct. 30, 2016 - Investigators today unveiled clinical data from the independent BIO-RESORT study, representing the first all-comers analysis to compare the safety and efficacy of biodegradable polymer stents (BP-DES) to durable polymer Resolute(TM) Integrity(TM) drug-eluting stent (DP-DES) from Medtronic plc (NYSE: MDT). At one year, patients with coronary artery disease who were treated with a biodegradable polymer stent showed no clinical benefits over patients treated with Resolute Integrity. The highly-anticipated results were presented today during a Late-Breaking Clinical Trial session at the Transcatheter Cardiovascular Therapeutics (TCT) Annual Meeting and simultaneously published in *The Lancet*.

As sdzauthors write in *The Lancet* manuscript, "Neither of these [biodegradable] stents have [previously] been compared with the new-generation thin-strut durable polymer zotarolimus-eluting stent (Resolute Integrity, Medtronic, Santa Rosa, CA, USA) - an established device with excellent clinical outcomes."1

In the BIO-RESORT study, the primary composite endpoint of target vessel failure at one-year showed no statistically significant difference in outcomes for the Resolute Integrity DP-DES treated group (N=1173) at 5.4 percent compared to 4.7 percent with the Synergy BP-DES (N=1172) arm and 4.7 percent with the Orsiro (N=1169) BP-DES am (difference of 0.7 percent; p=0.45 for Synergy and p=0.46 for Orsiro). The one year outcomes also found no statistically significant difference in stent thrombosis between Resolute Integrity and the BP-DES groups (difference of 0.1 percent; p=0.77).

"The BIO-RESORT trial demonstrates the continued value of high-quality randomized DES trials in true all-comers, reflecting real world clinical practice. BIO-RESORT included the greatest proportion of patients with STEMI - more than 30 percent - of all previous randomized stent trial in all-comers and one of the greatest proportions of patients with acute coronary syndromes at almost 70 percent," said Professor 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 the Netherlands, principal investigator of the trial and presenter of the data at TCT. "As in our previous randomized study - the DUTCH PEERS trial - patients treated with the Resolute Integrity stent showed low and favorable one-year clinical event rates. The stent was an excellent challenge for the two novel very-thin strut biodegradable polymer drug eluting stents to compare with, and the results showed no significant difference in the 12-month incidence of the composite primary endpoint. The long-term results of the BIO-RESORT trial will be of great interest, too."

The Resolute Integrity DES features proven Continuous Sinusoid Technology, which provides excellent deliverability and conformability to the vessel wall. The durable polymer used with the Resolute Integrity DES - called BioLinx(TM) - was specifically designed for DES use. BioLinx is non-inflammatory and non-thrombogenic, which allows for rapid and complete endothelial healing, while minimizing the risk of stent thrombosis. Long-term performance of BioLinx in over 16,000 patients studied in the RESOLUTE clinical program, demonstrated low stent thrombosis in real-world patients through five years, as well as a low risk for stent thrombosis with interruption or discontinuation of DAPT after one month. The Resolute Integrity stent offers a treatment option with a proven long term safety and efficacy profile that is yet to be established for new DES designs with biodegradable polymers.

"The findings of the BIO-RESORT trial reinforce the optimal design and proven, long-term performance of Resolute Integrity, which continues to meet both the current and future needs of our customers even when compared to the benefits of

biodegradable technologies," said Martin Rothman, M.D., vice president, medical affairs for the Coronary and Structural Heart division at Medtronic.

The BIO-RESORT study was supported by Boston Scientific, Biotronik, and Medtronic.

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 88,000 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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1 http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(16)31920-1/fulltext

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