Medtronic News

Independent Study Shows New Data on Shortened DAPT in STEMI Patients with Medtronic Resolute Integrity Drug-Eluting Stent

DAPT-STEMI Late-Breaker at TCT Reveals Results of Shortened DAPT Duration in Higher-Risk Patients

DUBLIN and DENVER - November 1, 2017 - Investigators today unveiled clinical data from the independently run DAPT-STEMI trial, which found no difference in patient outcomes between six-and 12-month dual anti-platelet therapy (DAPT) duration in ST-Elevation Myocardial Infarction (STEMI) patients implanted with the Resolute(TM) Integrity(TM) Drug-Eluting Stent (DES). The results help inform physician decision making around the use of newer-generation DES in high-risk patients who typically receive a longer DAPT regimen after percutaneous coronary intervention (PCI). The DAPT-STEMI trial was presented today during a Late-Breaking Clinical Trial session at the Transcatheter Cardiovascular Therapeutics (TCT) Annual Meeting.

The DAPT-STEMI trial evaluated 1,100 STEMI patients who were treated with the Resolute Integrity DES. Event-free patients (N=870) at six months were randomized 1:1 to either stop dual antiplatelet therapy (and receive aspirin only) or continue DAPT (receive aspirin plus a second anti-platelet medicine) to 12-months. The primary non-inferiority endpoint - composite of all-cause mortality, myocardial infarction, revascularization, stroke, or TIMI major bleeding - was met at two years showing no difference between the six-month and 12-month DAPT arms (P=0.004 for non-inferiority).

"These data help expand the growing body of clinical evidence that may support physicians in tailoring DAPT regimens for patients," said Dr. Elvin Kedhi, M.D., Ph.D., interventional cardiologist at Isala Hartcentrum in Zwolle, the Netherlands, principal investigator of the trial and presenter of the data at TCT. "We believe the results from DAPT-STEMI, in addition to the future outcomes from the RESOLUTE ONYX ONE study, will help to inform DAPT guidelines for newer-generation DES."

STEMI results from the blockage (thrombosis) of a major coronary artery. Consequently, these patients remain at higher risk following PCI due to this high thrombotic risk. Contemporary guidelines suggest STEMI patients receive 12-months of DAPT after PCI. After PCI, approximately 20 percent of patients interrupted or discontinued DAPT early for a variety of reasons within one year as shown in the RESOLUTE Pooled Analysis.1

"Physicians are the ultimate DAPT decision-makers, therefore it's critical that we invest in providing relevant and clinically meaningful evidence around DAPT duration," 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. "We look forward to continuing this important research with the upcoming enrollment initiation of our ONYX ONE study that will evaluate one-month DAPT with the Resolute Onyx DES in patients at a high bleeding risk."

Stents from the Resolute DES family have been implanted in approximately seven 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. The Resolute Integrity and Resolute Onyx stents are not indicated for the treatment of STEMI patients in the United States. However, the Resolute family of stents received CE Mark to treat patients with Acute Coronary Syndrome (ACS), which includes STEMI.

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 84,000 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 Kandzari D. Pharmacodynamic considerations and clinical impact of dual antiplatelet therapy interruption after Resolute zotarolimus-eluting stent implantation. ACC 2014.

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