Medtronic News

With Medtronic Resolute Stent, Interrupting Dual Antiplatelet Therapy After One Month Showed No Increased Safety Risk in Robust Analysis

ACC.13 Presentation Features Unprecedented Data on Nearly 5,000 Patients, Including "All Comers," from Global RESOLUTE Clinical Program

SAN FRANCISCO -- March 11, 2013 -- Cardiologists at ACC.13 learned today that patients with coronary artery disease who received a Resolute drug-eluting stent from Medtronic, Inc. (NYSE: MDT) as participants in one of several clinical studies and interrupted or discontinued their dual antiplatelet therapy after one month of the implant procedure showed no increased safety risk through one year of follow-up.

This finding comes from a new analysis of nearly 5,000 patients from the global RESOLUTE clinical program, which included two large studies that enrolled "all comers."

Ajay Kirtane, M.D., chief academic officer and director of the interventional cardiology fellowship program at NewYork-Presbyterian Hospital/Columbia University Medical Center, presented the analysis at the 62nd Annual Scientific Session & Expo of the American College of Cardiology (ACC).

"While most physicians would expect patients who interrupted their dual antiplatelet therapy after as few as 30 days following drug-eluting stent implantation to be at a much greater risk for stent thrombosis, this was not observed with the Resolute stent," Dr. Kirtane said. "These data should be very reassuring to physicians as well as to patients in whom this newer generation stent is implanted."

As part of the new analysis, the investigators also examined patients who interrupted their dual antiplatelet therapy after at least one month following the implant procedure for a period of more than 14 days, by which time normal platelet function typically resumes. Interestingly, these patients -- who constituted the vast majority of those who interrupted their dual antiplatelet therapy after one month -- experienced no instances of stent thrombosis (0.0%) through one year of follow-up.

Based on this analysis, Medtronic recently received approval from European regulators to update the CE *(Conformité Européenne)* mark labeling for the Resolute Integrity drug-eluting stent with new language related to one-month duration of dual antiplatelet therapy. This labeling update applies to product distributed in countries that accept the CE mark. It does not apply to product distributed outside this region, including the United States.

Dual antiplatelet therapy guidelines for patients who receive a drug-eluting stent differ by geographic region, but generally recommend daily compliance for six to 12 months.
The applicable guidelines are referenced in the country-specific labeling for each device.

In other data presented at ACC.13, the RESOLUTE Pooled Safety update, which includes data on all 5,130 patients who received a Resolute stent as participants in the program, showed a consistently low rate of stent thrombosis of 1.1 percent out to three years after implant; and in the RESOLUTE US study, which enrolled 1,402 U.S. patients, the stent thrombosis rate out to three years was a low 0.37 percent.

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, Inc. (www.medtronic.com), headquartered in Minneapolis, is the global leader in medical technology -- alleviating pain, restoring health and extending life for millions of people around the world.

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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