Medtronic News

Medtronic's Resolute(R) Drug-Eluting Stent Matches Market-Leading Rival in Large Head-to-Head Study

One-Year Clinical Results from Innovative RESOLUTE All Comers Trial Show Excellent Performance for Resolute DES in Challenging Patient Population

PARIS, May 25, 2010 (BUSINESS WIRE) --The highly anticipated first results of the RESOLUTE All Comers study were presented today during the late-breaking clinical trial session of the 2010 EuroPCR meeting. In this novel 2,292-patient randomized trial, the Resolute zotarolimus-eluting stent from Medtronic, Inc. (NYSE: MDT) was found to be as safe and effective as the Xience(R) V everolimus-eluting stent from Abbott Laboratories (NYSE: ABT).

This is the first major device study to directly compare Medtronic's Resolute drug-eluting stent (DES) to the current market-leading platform. The design of the RESOLUTE All Comers study included patients that are not typically enrolled in comparative clinical studies, making the results highly representative of real-world clinical practice.

At one year, the Resolute DES was shown to be as effective as the Xience DES in reducing the need for repeat procedures, and both second-generation stents were associated with low and similar rates of death from cardiac causes and heart attacks attributed to the treated vessel.

Available in many countries outside the United States and Japan, the Resolute drug-eluting stent is indicated for improving coronary luminal diameter and reducing restenosis in patients with symptomatic ischemic heart disease in de novo coronary artery lesions in native coronary arteries with a reference vessel diameter of 2.25 mm to 4.0 mm. In the United States, the Resolute DES is not available for sale and is limited by federal law to investigational use only.

The primary endpoint of the study was target lesion failure (TLF) - a composite of cardiac death, target vessel myocardial infarction and clinically driven target lesion revascularization. The Resolute DES posted TLF rates of 8.2 percent versus 8.3 percent for the Xience DES (non-inferiority p=<0.001).The manuscript of the trial's results has been accepted for publication by a major medical journal and is expected to be published soon.

"These compelling results were achieved in a challenging patient population that is representative of every day clinical practice," said Prof. Patrick Serruys, M.D., Ph.D., director of the Thoraxcenter at Erasmus University in Rotterdam, the Netherlands, and one of three principal investigators for RESOLUTE All Comers. "Given the rigorous design and conduct of this novel, multicenter randomized clinical trial, it is clear that the Resolute drug-eluting stent has distinguished itself as an important treatment option for a wide range of patients undergoing percutaneous coronary intervention."

RESOLUTE All Comers is one part of the comprehensive Resolute clinical program, which will enroll a total of more than 6,000 patients worldwide across a series of single-arm and randomized controlled trials, including RESOLUTE, RESOLUTE US, RESOLUTE International and RESOLUTE Japan. The Resolute clinical program is a collaborative effort involving hundreds of medical centers in more than 25 countries across Europe, Asia, the Pacific Rim, the Middle East, Africa, Latin America and North America.

Medtronic is committed to advancing the treatment of cardiovascular disease through collaboration with leading clinicians, researchers and scientists worldwide.

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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