Medtronic News

Medtronic's Resolute Drug-Eluting Stent Shows Strong Performance in Second 'All Comers' Study

Consistent Results in More Than 3,600 Patients from Complex Daily Practice of Interventional Cardiology Strengthen Evidence on Implantable Heart Device

WASHINGTON, Sep 22, 2010 (BUSINESS WIRE) --

Coronary artery disease, a leading cause of death and poor quality of life worldwide, runs the gamut from simple to complex, which complicates the daily practice of interventional cardiology. New clinical data from a second, large international study that enrolled "all comers," regardless of disease complexity and comorbidities, again demonstrated the strong performance of the Resolute drug-eluting stent (DES) from Medtronic, Inc. (NYSE: MDT), for patients across this continuum.

The latest findings from the company's Resolute clinical program were released at the start of the 2010 Transcatheter Cardiovascular Therapeutics (TCT) conference, which runs through Saturday. The findings include one-year results for RESOLUTE International, two subsets from RESOLUTE All Comers, and four-year results for the RESOLUTE feasibility study, which supported the CE (Conformité Européenne) mark of the Resolute DES.

"Medtronic is rapidly amassing a compelling body of high-quality evidence to demonstrate the safety and efficacy of the Resolute drug-eluting stent as a treatment for coronary artery disease in all its complexity," said interventional cardiologist Dr. Alan Yeung, chief of cardiovascular medicine at Stanford University in Palo Alto, Calif., and a principal investigator of RESOLUTE US, which will complete Medtronic's FDA submission for the Resolute DES. "These new data from RESOLUTE International in particular reinforce the strong results that the device showed in RESOLUTE All Comers. We hope to have the opportunity to present the one-year data from RESOLUTE US in March at the annual meeting of the American College of Cardiology."

RESOLUTE International

A key component of Medtronic's FDA submission for the Resolute DES, RESOLUTE International is a prospective, multicenter single-arm study with a composite primary endpoint of cardiac death (CD) and target vessel myocardial infarction (TVMI) at one year post-implant. Important secondary endpoints include ischemia driven repeat procedures at the site of the initial stent placement (target lesion revascularization, or TLR) and clotting of the stent (defined as definite or probable stent thrombosis by the Academic Research Consortium, or ARC).

The study enrolled 2,349 patients at 88 sites from 17 countries in Europe, Asia, Africa and Latin America, allowing patient types and lesion characteristics that are typically underrepresented in clinical trials - in short, all comers. To promote diversity in the study population, no single site was allowed to enroll more than 60 patients.

On the primary endpoint, just 4.1 percent of patients experienced CD or TVMI through one year of follow-up. On the secondary endpoints, clinically-indicated TLR occurred in 3.4 percent of patients and fewer than one (0.9) percent experienced stent thrombosis (ST). These event rates are low in comparison to other similar clinical trials, especially for an all-comers population that consists of a relatively high number of patients with complex disease. They are also consistent with event rates for patients who received the Resolute DES in the RESOLUTE All Comers pivotal trial, which was recently published in the New England Journal of Medicine.

Strengthening the validity of this study's results, RESOLUTE International includes design features and enhanced study methodologies more common in controlled trials. For example, the study required 100 percent

remote electronic data surveillance for all patients, including 100 percent review of possible triggers for event reporting. In addition, all events were adjudicated by an independent clinical events committee. Also, 25 percent of patients in RESOLUTE International were randomly assigned to 100 percent data monitoring throughout 12 month follow-up, unlike registry studies, which typically have less rigorous monitoring requirements. These design features and study methodologies enabled a pre-specified sub-analysis of monitored compared to unmonitored patients, which demonstrated nearly identical outcomes.

"What's really striking about the Resolute stent in this well-run single-arm study is how low the clinical event rates were across all lesion and patient subgroups, even in this real-world population," said Dr. Jorge Belardi, director of cardiology at the Cardiovascular Institute of Buenos Aires and principal investigator of RESOLUTE International. "The consistencies with RESOLUTE All Comers are equally striking."

RESOLUTE All Comers

RESOLUTE All Comers is the first randomized controlled trial to compare two second-generation drug-eluting stents head-to-head: Medtronic's Resolute DES and the Xience(R) V DES from Abbott Laboratories. The study enrolled 2,292 patients at 17 sites across Europe and, like RESOLUTE International, accepted all comers, making the results highly representative of real-world clinical practice. By meeting the composite primary endpoint of target lesion failure (TLF) - a combination of CD, TVMI and clinically driven TLR - at one year, the Resolute DES was shown to match the Xience V DES on important measures of both safety and efficacy.

Results for two patient subsets from RESOLUTE All Comers were released today at TCT: acute myocardial infarction (AMI) and multi-vessel intervention (MVI). In the AMI subset, defined by ST segment elevation myocardial infarction (STEMI) within 12 hours of the procedure, there was a statistically equivalent but numerically lower rate of TLF in the Resolute arm versus the Xience arm (3.3 percent vs. 7.1 percent, p=0.17). In the MVI subset, there was also a statistically equivalent but numerically lower rate of TLF in the Resolute arm versus the Xience arm (9.6 percent vs. 11.3 percent, p=0.55). Results in RESOLUTE International for these subsets were similar.

RESOLUTE Feasibility Study

The original RESOLUTE feasibility study is the first-in-man clinical trial of the Resolute DES. It enrolled 130 patients who received a Resolute DES at 12 centers in Australia and New Zealand. At four years of patient follow-up, the results show stable clinical efficacy with a low TLR rate of 2.3 percent and no stent thrombosis.

Medtronic's Resolute clinical program will enroll a total of more than 6,000 patients worldwide across a series of single-arm and randomized controlled trials, including RESOLUTE (n=130), RESOLUTE US (n=1,400), RESOLUTE All Comers (n=2,300), RESOLUTE International (n=2,200) and RESOLUTE Japan (n=100). It 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. Data from the entire program will support Medtronic's application to the FDA for approval of the Resolute DES.

The Resolute DES is not yet commercially available in Japan, Canada or the United States, where it is under investigational device evaluation in the 1,400-patient RESOLUTE US clinical study, which completed enrollment in December 2009. The device has been available internationally since October 2007, when it received CE Mark.

Medtronic offers a portfolio of stents to address the spectrum of clinical needs for patients with coronary artery disease. The company's stent portfolio includes the Driver and Integrity bare-metal stents and the Endeavor, Resolute and Resolute Integrity drug-eluting stents. Product availability varies by country. Based on FDA

approval, the Integrity Coronary Stent System became available this week in the United States; and based on CE mark, the Resolute Integrity Coronary Stent System became available outside the United States earlier this month.

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

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