Medtronic News

Medtronic Resolute(R) Drug-Eluting Stent Shows Superiority to Taxus(R) DES in Study of Patients with Coronary Artery Disease

Presented at CVIT by Principal Investigator Shigeru Saito, One-Year Data from RESOLUTE Japan Support Company's PMDA Submission for Product Approval

MINNEAPOLIS, Jul 25, 2011 (BUSINESS WIRE) --

TheResolute(R) drug-eluting stent (DES) from Medtronic, Inc. (NYSE: MDT), showed superiority to Boston Scientific Corp.'s Taxus(R) DES on the primary endpoint of the RESOLUTE Japan clinical study: in-stent late lumen loss at eight months.

The primary endpoint of RESOLUTE Japan compared 100 patients treated with the Resolute DES to a historical control - specifically, eight-month in-stent late lumen loss for 135 patients in the ENDEAVOR IV clinical trial who received a Taxus DES. Assessed at 12 months, clinical endpoints for RESOLUTE Japan included target lesion failure (TLF) - a composite endpoint of cardiac death, target vessel myocardial infarction (MI) and clinically driven target lesion revascularization (TLR) - and stent thrombosis.

RESOLUTE Japan was designed to evaluate the non-inferiority of the primary endpoint; if the non-inferiority threshold was met, then superiority was to be tested. With an in-stent late lumen loss at eight months of 0.13 mm ± 0.22 mm for RESOLUTE Japan patients (compared to 0.42 mm ± 0.50 mm for patients in the Taxus arm of ENDEAVOR IV), both non-inferiority and superiority were demonstrated ($p<0.0001$).

In addition, RESOLUTE Japan featured an exceptionally low rate of TLF (4.0%) and no instances of stent thrombosis.

RESOLUTE Japan results were presented on Saturday at CVIT 2011 - the 20th Annual Meeting of the Japanese Association of Cardiovascular Intervention and Therapeutics in Osaka - by the study's principal investigator, Dr. Shigeru Saito, director of Cardiology and Catheterization Laboratories at Shonan Kamakura General Hospital in Kamakura, Japan. They will be used to support Medtronic's submission to Japan's Pharmaceuticals and Medical Devices Agency (PMDA) for regulatory approval of the Resolute DES in Japan, the world's second largest market for medical devices (after the United States).

"Results from RESOLUTE Japan show that the Resolute drug-eluting stent will be a welcome addition to the treatment options already available to Japanese patients with coronary artery disease," Dr. Saito said. "They will be evaluated with interest by my fellow interventional cardiologists while we await the Japan launch of this next-generation DES."

The Resolute DES is not yet approved by Japan's PMDA or the U.S. Food and Drug Administration (FDA). The device received the CE (Conformité Européene) mark in October 2007 and is currently available in approximately 100 countries worldwide.

Part of the global clinical trial program for the Resolute DES, RESOLUTE Japan is a prospective, single-arm, open-label study that enrolled 100 patients at 14 Japanese medical centers between March 2009 and October 2009. To meet the study's inclusion criteria, all patients were required to have no more than two *de novo* native coronary lesions (in different vessels) with from 50% to less than 100% diameter stenosis, reference vessel diameters of 2.5-3.5 mm and lesion lengths no greater than 27 mm.

Exclusion criteria included myocardial infarction within 72 hours of the index procedure, a percutaneous coronary intervention (PCI) of a target vessel within nine months pre-procedure, and planned PCI of any vessel within 30 days post-procedure.

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.

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