Medtronic News

Medtronic Resolute(R) Drug-Eluting Stent Delivers Compelling Clinical Outcomes in Major Studies

Across Spectrum of Patients with Coronary Artery Disease, Novel Heart Device Shows Strong Results at One Year in RESOLUTE US and Two Years in RESOLUTE All Comers

NEW ORLEANS, Apr 04, 2011 (BUSINESS WIRE) --

Results of two major clinical studies presented at ACC.11 - the 60th Annual Scientific Session & Expo of the American College of Cardiology (ACC) - demonstrate that the Resolute(R) drug-eluting stent (DES) from Medtronic, Inc. (NYSE: MDT), provides a positive and persistent treatment effect for a wide variety of patients with coronary artery disease.

One-year results of RESOLUTE US were presented today in the late-breaking clinical trials session for interventional cardiology and published by the *Journal of the American College of Cardiology (JACC)* Two-year results of RESOLUTE All Comers were presented yesterday as a featured interventional clinical study and published by *TheLancet*. These studies are key components of the comprehensive RESOLUTE clinical program, which has enrolled more than 5,000 patients across a combination of randomized controlled and single-arm trials conducted around the world.

These new data from RESOLUTE US complete Medtronic's submission to the U.S. Food and Drug Administration (FDA) for pre-market approval (PMA) of the Resolute DES, which remains an investigational device in the United States, where its use is limited to this FDA-approved clinical trial. The FDA's decision is expected in the first half of 2012. "The latest findings from the uniquely designed RESOLUTE clinical program, with the broad spectrum of patients enrolled, support this novel drug-eluting stent as a new alternative in the treatment of coronary artery disease," said Martin B. Leon, M.D., director of the Center for Interventional Vascular Therapy at NewYork-Presbyterian Hospital/Columbia University Medical Center and a RESOLUTE US principal investigator (PI). "Based on the growing body of clinical evidence on the device, the Resolute DES has distinguished itself as a viable choice for a wide variety of patients."

The other PIs for RESOLUTE US are Laura Mauri, M.D., chief scientific officer of the Harvard Clinical Research Institute and an interventional cardiologist at Brigham and Women's Hospital in Boston, andAlan Yeung, M.D., director of interventional cardiology at Stanford University School of Medicine in Palo Alto, Calif.

RESOLUTE US

One-year results of the 1,402-patient RESOLUTE US study include low rates of target lesion failure (TLF, 4.7%), clinically-driven target lesion revascularization (TLR, 2.8%) and definite/probable stent thrombosis (ST, 0.1%) through 12 months of follow-up. These powerful clinical results were achieved despite 34% of the patients in the study having diabetes, which typically correlates with higher event rates and represents an underserved patient population.

RESOLUTE US is a prospective single-arm study evaluating the safety and efficacy of the Resolute DES in a U.S. patient population. It consists of four substudies based on stent diameter and length: 2.25-3.5 mm Clinical, 2.25-3.5 mm Angio/IVUS, 4.0 mm Angio and 38 mm Clinical. The first three substudies of RESOLUTE US comprise a clinical cohort of 1,242 patients and an angiographic cohort of 160 patients. All three have completed enrollment and have met their prespecified primary endpoints. The 38 mm substudy is still enrolling patients.

The design of RESOLUTE US, with its four substudies, will enable the FDA to evaluate the safety and efficacy of the entire size matrix of the Resolute DES, from diameters of 2.25-4.0 mm and lengths of 8-38 mm. Total enrollment in RESOLUTE US will exceed 1,500 patients. The RESOLUTE clinical program will enroll a total of more than 5,000 patients worldwide.

RESOLUTE All Comers

Two-year results of the 2,292-patient RESOLUTE All Comers study indicate that the Resolute DES continues to match the Xience V DES at two years of follow-up. On the primary endpoint of TLF, originally assessed at one-year, the rates at two years remain statistically equivalent for the two devices: 11.2% TLF for Resolute, 10.7% TLF for Xience (p=0.736). In addition, the rates of definite/probable very late stent thrombosis between one and two years were identical and low for each stent at 0.3%, with no statistical difference between the two stents in cumulative ST through two years.

RESOLUTE All Comers is the first randomized controlled trial to compare two second-generation drug-eluting stents head-to-head: the Resolute DES and the Xience V DES. (The Promus DES from Boston Scientific Corp. is identical to the Xience V DES.) With very few exclusion criteria, the study accepted virtually "all comers," making the results highly representative of routine clinical practice. Nearly 70% of the patients in RESOLUTE All Comers were considered complex. By meeting the study's primary non-inferiority endpoint of TLF at one year, the Resolute DES was shown to match the Xience V DES on an important clinical outcome.

In collaboration with leading clinicians, researchers and scientists worldwide, Medtronic offers the broadest range of innovative medical technology for the interventional treatment of cardiovascular disease and cardiac arrhythmias.

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