Medtronic News

Medtronic Resolute® Drug-Eluting Stent Delivers Durable Clinical Outcomes Through Two Years in Major Studies

Recently FDA-Approved, Novel Heart Device Shows Consistently Low Event Rates Across Broad Spectrum of Coronary Artery Disease Patients, Including Those with Diabetes

CHICAGO--(BUSINESS WIRE)--Mar. 24, 2012-- According to new clinical data presented today at ACC.12 — the 61st Annual Scientific Session & Expo of the American College of Cardiology (ACC) — the Resolute drug-eluting stent (DES) from Medtronic, Inc. (NYSE: MDT) maintains a powerful and persistent treatment effect for a wide variety of patients with coronary artery disease, including those with diabetes mellitus, through two years of follow-up.

The latest data on this novel heart stent, which received approval from the U.S. Food and Drug Administration (FDA) last month with a first-of-its-kind indication for the treatment of coronary artery disease in patients with diabetes mellitus, come from the RESOLUTE US clinical study and two pooled analyses of the entire Resolute clinical program — one on safety measures for all patients (RESOLUTE Pooled Safety), the other for all patients with diabetes (RESOLUTE Pooled Diabetes).

Highlights of the two-year data include low rates of target lesion failure (TLF), target lesion revascularization (TLR) and definite/probable stent thrombosis (def/prob ST).

Laura Mauri, M.D., of Harvard Clinical Research Institute and Brigham and Women's Hospital in Boston, presented the two-year results from RESOLUTE US; Jorge Belardi, M.D., of the Cardiovascular Institute of Buenos Aires in Argentina, the two-year update for RESOLUTE Pooled Safety; and Alan Yeung, M.D., of the Stanford University School of Medicine in Palo Alto, the two-year update for RESOLUTE Pooled Diabetes.

"What's particularly striking about the two-year outcomes from the Resolute clinical program is the device's consistently strong performance and low event rates in such a wide variety and high number of patients," explained Dr. Mauri, a national co-principal investigator of RESOLUTE US like Dr. Yeung and Martin Leon, M.D., of the Cardiovascular Research Foundation and NewYork-Presbyterian Hospital/Columbia University Medical Center in New York. "The Resolute DES yields excellent outcomes in patients with and without diabetes mellitus, and that's a factor of significant clinical relevance given the large number of diabetes patients that undergo percutaneous coronary intervention each year. Its safety and efficacy data at two years of patient follow-up continue to impress."

RESOLUTE US

RESOLUTE US enrolled 1,402 patients across 128 U.S.-based clinical trial sites. The two-year results among 1,359 patients include low rates of TLF (7.3%), clinically-driven TLR (4.3%), and def/prob ST (0.2%).

These powerful clinical results were achieved despite 34 percent of the patients having diabetes mellitus, which typically drives higher event rates. Among the 474 patients with diabetes in RESOLUTE US, the Resolute DES showed consistently low two-year rates of TLF (8.9%) and clinically-driven TLR (5.7%) and no def/prob ST (0.0%).

Pooled Analyses

The global RESOLUTE clinical program consisted of a large randomized controlled trial and a series of confirmatory single-arm studies involving nearly 250 sites in 32 countries. In total, the program enrolled 5,130 patients who received a Resolute DES; about one third (n=1,535) of these patients had diabetes, a proportion that mirrors the U.S. patient mix for percutaneous coronary intervention (PCI).

For the pooled analyses related to safety and diabetes presented today at ACC.12, two-year data on more than 5,000 patients

from the RESOLUTE program who received a Resolute DES were included. Individual trials, while powered for many composite endpoints, are often underpowered to show real differences for low-frequency but clinically important adverse events such as ST.

The two-year update to RESOLUTE Pooled Safety showed very low rates of clinically-driven TLR (4.7%) and def/prob ST (0.9%), despite 46 percent of the patients in the RESOLUTE program being considered complex1.

The two-year update to RESOLUTE Pooled Diabetes, which presents clinical outcomes in patients with and without diabetes who received a Resolute DES, shows consistently low event rates out to two years despite the higher-risk nature of the diabetes patient population. For example, the update presents clinically-driven TLR and def/prob ST rates for the standard-risk diabetes patients, a cohort pre-specified for analysis by the FDA in order to obtain the device's diabetes indication.

Dataset	Patients *with* Diabetes	Patients *without* Diabetes
RESOLUTE Pooled Standard-Risk Cohort (N=2,781)	(N=878)	(N=1,903)
-- clinically-driven TLR	4.8%	3.4%
-- def/prob ST	0.3%	0.4%

In collaboration with leading clinicians, researchers and scientists, 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 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.

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1 *Complex patient definition: bifurcation, bypass grafts, ISR, AMI <72 hr, LVEF <30%, unprotected LM, >2 vessels stented, renal insufficiency or failure (creatinine >140 µmol/L), lesion length >27 mm, >1 lesion per vessel, lesion with thrombus or TO (preprocedure TIMI = 0). Only R-AC and R-INT included complex patients.*

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