Medtronic News

Medtronic Resolute(R) Drug-Eluting Stent Offers Strong Performance in Diabetic Patients with Heart Disease

Clinical Data from Multiple Studies Presented at EuroPCR Show Next-Generation Device Delivers Excellent Safety and Efficacy in Challenging Patient Population

PARIS, May 18, 2011 (BUSINESS WIRE) --

For patients with both heart disease and diabetes who took part in a pooled series of rigorous clinical trials, the Resolute drug-eluting stent (DES) from Medtronic, Inc. (NYSE: MDT), provided remarkably safe and effective outcomes, according to the results of several studies presented today at EuroPCR, a major international meeting for cardiac and vascular specialists. The findings, presented during a session titled "Which DES for diabetics?," are noteworthy because diabetes is a common and complicating co-morbidity in patients with coronary artery disease that poses significant treatment challenges.

RESOLUTE Pooled Diabetics

Prof. Sigmund Silber of the Heart Catheterization Centre in Munich, Germany, presented a pre-specified pooled analysis of clinical data on 867 "on-label" diabetic patients who received a Resolute DES as participants in Medtronic's global RESOLUTE clinical program. This analysis, called RESOLUTE Pooled Diabetics, showed exceptionally low rates of adverse events in this challenging patient population at one year of follow-up.

On-label diabetic patients: One-year follow-up*

- target lesion failure** (TLF), 6.6%
- clinically-driven target lesion revascularization (TLR), 3.4%
- definite/probable stent thrombosis*** (def/prob ST), 0.3%

* *On-label was defined as excluding the following characteristics: bifurcation, saphenous vein graft (SVG), in-stent restenosis (ISR), acute myocardial infarction (AMI) within 72 hours, left ventricular ejection fraction (LVEF) of less than 30%, unprotected left main disease, atherosclerosis in three or more vessels, renal impairment, total lesion length per vessel of greater than 27 mm, two or more lesions per vessel, lesion with thrombus, or lesion with total occlusion.*

** *TLF is a composite endpoint combining cardiac death, target vessel myocardial infarction and TLR.*

*** *90.1% of patients were on dual-antiplatelet therapy at one year.*

"Diabetic patients whose co-morbid heart disease is treated with percutaneous coronary intervention have an increased risk of repeat procedures and other major adverse cardiovascular events," explained Prof. Silber. "And yet our analysis of the 'on-label' diabetic patient cohort from the RESOLUTE clinical program suggests a homogeneous treatment effect across diabetic and non-diabetic patients that we find intriguing. Not surprisingly, a notable exception to this effect was seen in the insulin-dependent diabetic patient subset, which serves to underscore the challenges that persist in determining the ideal interventional treatment for these patients."

Of the 5,130 patients in the RESOLUTE clinical program who have been followed for at least one year, 1,535 (29.9%) had diabetes. Of these diabetic patients, 878 (57.2%) were considered "on-label." Insulin-dependence, which represents a more serious and advanced form of diabetes, characterized 250 (28.5%) of the on-label diabetic patients.

As part of RESOLUTE Pooled Diabetics, Prof. Silber also presented the differences in adverse event rates for on-label diabetic and non-diabetic patients, as well as for on-label insulin-dependent and non-insulin-dependent diabetic patients, at one year. None of the differences between these groups were statistically significant.

Diabetic patients vs. non-diabetic patients: One-year follow-up

- TLF, 6.6% vs. 4.9%
- TLR, 3.4% vs. 2.0%
- def/prob ST, 0.3% vs. 0.3%

Insulin-dependent diabetic patients vs. non-insulin-dependent diabetics: One-year follow-up

- TLF, 10.6% vs. 5.0%
- TLR, 5.4% vs. 2.7%
- def/prob ST, 0.8% vs. 0.2%

"While the outcomes in the on-label diabetic patient population are encouragingly low," Prof. Silber said, "it is of interest to determine how these event rates compare with those seen in non-diabetic patients as well as between insulin-dependent and non-insulin-dependent diabetics."

Italian Study of Resolute DES

Following Prof. Silber's presentation, Dr. Alfonso Ielasi at the San Raffaele Scientific Institute in Milan, Italy presented "Clinical Outcomes in Diabetic and Non-Diabetic Patients Treated with Resolute Zotarolimus-Eluting Stent: A Multicenter Italian Observational Report." This independent research, conducted by a network of Italian physicians, examined a total of 896 "all-comer" (in contrast to "on-label") patients: 293 (32.7%) with diabetes, 603 (67.3%) without diabetes. The results showed low rates of adverse events at 15 months of follow-up.

Diabetic patients vs. non-diabetic patients: 15-month follow-up

- TLF, 5.0% vs. 3.7%
- TLR, 3.5% vs. 2.3%
- def/prob ST, 1.4% vs. 0.6%

"While none of the differences found in our analyses were statistically significant, the results are certainly concordant with the one-year analysis of RESOLUTE Pooled Diabetics," said Prof. Antonio Colombo, also of the San Raffaele Scientific Institute. "They show that the Resolute DES appears to be highly efficacious even in challenging patients with diabetes, with a low incidence of stent thrombosis. Looking forward, the higher, though non-significant, TLR rate in the diabetic cohort compared to non-diabetics may provide insight into the appropriate sample size needed to study this significant subgroup of patients in future trials."

The Resolute DES is commercially available in more than 100 countries outside the United States, where its use is limited by U.S. law to clinical trials approved by the U.S. Food and Drug Administration (FDA). The RESOLUTE clinical program will ultimately enroll more than 6,000 patients worldwide and involves 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.

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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