Medtronic News

Medtronic Resolute(R) Drug-Eluting Stent Shows Strong Results, Even in Challenging Diabetes Patients with Coronary Disease

Pooled Data Analyses to Be Presented at TCT 2011 Demonstrate Heart Device's Consistently Positive Performance Across Multiple Clinical Studies

SAN FRANCISCO, Nov 08, 2011 (BUSINESS WIRE) --

Currently under review by the U.S. Food and Drug Administration (FDA), the Resolute(R) drug-eluting stent (DES) from Medtronic, Inc. (NYSE: MDT) continues to demonstrate consistently positive performance across a variety of studies, according to two new data analyses being presented this week at TCT 2011.

The first analysis, RESOLUTE Pooled Diabetics, focuses on outcomes in patients with both coronary artery disease and diabetes, two common comorbidities; the second, RESOLUTE Pooled Safety, focuses on safety outcomes across all patient types.

For the more than 1,500 patients with diabetes mellitus who participated in the global Resolute clinical program to evaluate the implantable medical device's performance in the treatment of coronary artery disease, the Resolute DES showed strong results through one-year of follow-up. Prof. Sigmund Silber, M.D., FACC, FESC, director of the Heart Centre at the Isar in Munich, Germany, will present the results of this analysis for the first time today at the Cardiovascular Research Foundation's annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium for interventional cardiovascular specialists.

"People with diabetes and heart disease constitute about one-third of the patients that receive percutaneous coronary interventions worldwide," explained Prof. Silber. "They are an especially challenging group of patients to treat because of their increased risk of subsequent cardiovascular events, including heart attack and cardiac death, as well as repeat procedures in the target vessel."

RESOLUTE Pooled Diabetics

This post-hoc pooled analysis of the Resolute clinical program presents the outcomes of all 1,535 diabetes patients treated with a Resolute DES in five studies to those without diabetes. For contemporary context, it compares these outcomes to those of patients who received a Xience V DES from Abbott Laboratories in the randomized RESOLUTE All Comers trial.

Called RESOLUTE Pooled Diabetics, the analysis also presents the outcomes in insulin-dependent, non-insulin-dependent and patients without diabetes treated with a Resolute DES.

RESOLUTE Pooled Diabetes shows very similar and low rates of events across these patient subsets. No differences were observed between the Resolute and Xience arms after propensity adjustment in this post-hoc analysis, which will be presented at the session titled "Intersection of Diabetes and PCI."

"This pooled data analysis found low event rates for the Resolute DES through one-year of follow-up among patients with or without diabetes, and even among patients with insulin-dependent diabetes, although we need more data in this special subgroup," Prof. Silber concluded.

12-MONTH RESULTS

Diabetes and Non-Diabetes Patients

Resolute vs. Xience V

*Endpoint**	*Diabetes Patients N=1,805*		*Non-Diabetes Patients N=4,477*	
	Resolute N=1,535	*Xience V N=270*	*Resolute N=3,595*	*Xience V N=882*
TLF	7.8%	9.0%	6.1%	8.3%
TLR	4.0%	5.0%	2.9%	3.0%
CD/TVMI	4.7%	4.9%	3.6%	5.7%
Def/Prob ST	1.0%	0.8%	0.7%	0.7%

NOTE: Data in this table are from post-hoc analysis; event rates are unadjusted.

Insulin-Dependent Diabetes,
Non-Insulin Dependent Diabetes and
Non-Diabetes Patients

Resolute Only

*Endpoint**	*Insulin-Dependent Diabetes Patients N=455*	*Non-Insulin Dependent Diabetes Patients N=1,080*	*Non-Diabetes Patients N=3,595*
TLR	6.3%	3.1%	2.9%
CD/TVMI	6.6%	3.8%	3.6%
Def/Prob ST	1.5%	0.8%	0.7%

NOTE: Data in this table are from post-hoc analysis; event rates are unadjusted.

RESOLUTE Pooled Safety

Following Prof. Silber's presentation, Dr. Martin Leon of NewYork-Presbyterian Hospital/Columbia University Medical Center will present the two-year safety data from the global Resolute clinical program, which enrolled more than 5,000 patients treated with the Resolute DES. His presentation will occur during the session titled "Predictors and Prevention of Stent Thrombosis."

The results of this post-hoc analysis, termed RESOLUTE Pooled Safety, were compared to those patients who received a Xience V DES in the RESOLUTE All Comers trial. No differences were observed between the Resolute and Xience arms after propensity adjustment.

2-YEAR RESULTS

All Patients
N=6,282

Resolute vs. Xience V

*Endpoint**	*Resolute N=5,130*	*Xience V N=1,152*
TLF	9.4%	10.7%
TLR	4.8%	5.2%
CD/TVMI	5.5%	6.2%
Def/Prob ST	0.96%	0.98%

NOTE: Data in this table are from post-hoc analysis; event rates are unadjusted.

**Endpoint Key*

TLF = target lesion failure (a composite endpoint combining CD, TVMI and TLR)

TLR = target lesion revascularization

CD = cardiac death

TVMI = target vessel myocardial infarction

D*ef/Prob ST = definite/probable stent thrombosis as defined by the Academic Research Consortium (ARC)*

RESOLUTE (First-in-Human Study)

Also presented at TCT 2011 will be the final, five-year follow-up from the original feasibility study of the Resolute DES, which includes zero ARC def/prob ST and a TLR rate of 3.1 percent in 130 patients. This presentation of long-term results from RESOLUTE, as the study is called, will be made on Tuesday by Prof. Ian Meredith of Monash Medical Centre in Melbourne, Australia during the session titled "Drug-Eluting Stents II."

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 FDA. Medtronic continues to anticipate FDA approval of the Resolute DES in the first half of 2012.

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.

ABOUT MEDTRONIC

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