Medtronic News

Study of Medtronic Endeavor(R) Drug-Eluting Stent Demonstrates Long-Term Advantages over Taxus(R) DES

Final Five-Year Follow-up of Randomized ENDEAVOR IV Trial Shows Durable Safety and Efficacy of Endeavor DES, with Comparatively Lower Rates of Cardiac Death/Myocardial Infarction and Very Late Stent Thrombosis

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

New research findings released at TCT 2011 show that the Endeavor(R) zotarolimus-eluting stent (DES) from Medtronic, Inc. (NYSE: MDT) outperformed Boston Scientific Corp.'s Taxus(R) paclitaxel-eluting stent on standard measures of safety and efficacy through five years of clinical follow-up.

The findings come from ENDEAVOR IV, a randomized trial involving nearly 1,550 patients with coronary artery disease that compared the two drug-eluting stents head-to-head.

A separate analysis released at the same meeting of interventional cardiovascular specialists also affirmed the strong, long-term safety profile of Medtronic's Endeavor DES, which elutes the drug zotarolimus from a highly biocompatible polymer that mimics the surface of a red blood cell.

The final five-year results of ENDEAVOR IV, presented today by co-principal investigator Dr. David Kandzari of Piedmont Heart Institute in Atlanta during the Cardiovascular Research Foundation's annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium, show statistically significant differences favoring the Endeavor DES on cardiac death/myocardial infarction (CD/MI) and very late stent thrombosis (VLST). The data also show a trend toward lower rates of target vessel failure (TVF) with the Endeavor DES in long-term follow-up.

"The five-year results from ENDEAVOR IV confirm that long-term clinical outcomes should be an essential consideration when making decisions related to stent selection," said Dr. Kandzari. "Interventionalists treating patients with coronary artery disease now have ample data to distinguish the important differences between the performance of these two drug-eluting stents."

5-YEAR RESULTS

ENDEAVOR IV
N=1,548

Endeavor vs. Taxus

Endpoint*	Endeavor *n=773*	Taxus *n=775*	*p* Value
TVF	17.2%	21.1%	*p*=0.061
TLR	7.7%	8.6%	*p*=0.70
CD/MI	6.4%	9.1%	*p*=0.048
Def/Prob ST	1.3%	2.0%	*p=0.42*
VLST	0.4%	1.8%	*p*=0.012

* *Endpoint Key*

TVF = target vessel failure (a composite of TVR, myocardial infarction and cardiac death)

TLR = target lesion revascularization

CD = cardiac death

MI = myocardial infarction

Def/Prob ST = definite and probable stent thrombosis as defined by the Academic Research Consortium (ARC)

VLST = very late stent thrombosis

ENDEAVOR Pooled Safety

Dr. Kandzari also presented a five-year update to a pooled analysis of safety data from the Endeavor clinical program at TCT 2011. The analysis, called ENDEAVOR Pooled Safety, involved 2,132 patients who received an Endeavor DES as participants in one of six studies, including ENDEAVOR IV.

ENDEAVOR Pooled Safety shows that at five years of follow-up, treatment with the Endeavor DES resulted in a significant reduction in TLR andCD/MI, and was associated with no increased risk of stent thrombosis in comparison to a bare-metal stent (BMS) control group including 596 patients from ENDEAVOR II.

5-YEAR RESULTS

ENDEAVOR Pooled Safety

Endeavor DES vs. Driver BMS

Endpoint*	Endeavor *n=1,879*	Driver *n=538*	*p* Value
TLR	7.4%	16.5%	*p*<0.001
CD/MI	5.7%	8.4%	*p*=0.016
Def/Prob ST	0.9%	1.7%	*p=0.10*
VLST	0.3%	0.4%	*p*=0.85

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

"These findings are even more relevant because most patients in both groups were off dual-antiplatelet therapy by one year after stent implantation," explained Dr. Kandzari, whose paper titled "Dual antiplatelet therapy duration and clinical outcomes following treatment with zotarolimus-eluting stents" appeared in the October 2011 edition of *JACC: Cardiovascular Intervention*. "The Endeavor DES exhibits a safety profile that not only is durable through late-term follow-up but that also distinguishes it from comparative devices."

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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