Medtronic News

Medtronic's Endeavor Stent Continues to Demonstrate Compelling and Consistent Long-Term Clinical Results

Independent Analysis of Large and Comprehensive ENDEAVOR Program Shows Remarkably Durable Safety and Efficacy at Five Years of Follow Up in Coronary Artery Disease Patients

MINNEAPOLIS & ALTANTA, Mar 14, 2010 (BUSINESS WIRE) -- The consistency and quality of the long-term clinical results for the Endeavor(R) drug-eluting stent (DES) from Medtronic, Inc. (NYSE: MDT), continue to distinguish it as a treatment for coronary artery disease, according to newly released data.

Five-year findings from the comprehensive ENDEAVOR program were released today at ACC.10, the American College of Cardiology's 59th Scientific Session. The E-Pooled analysis - which now includes five-year data from the ENDEAVOR I (E-I), ENDEAVOR II (E-II), E-II Continued Access (CA), and ENDEAVOR III (E-III) clinical studies, and three-year data from the ENDEAVOR IV (E-IV) and ENDEAVOR Pharmacokinetics (E-PK) clinical studies - demonstrates striking consistency in clinical results across multiple studies. Notable findings include a very low rate of late repeat revascularization events and a paucity of very late stent thrombotic events with 8,799 patient-years of follow up.

"The consistency of results across these well conducted clinical trials is remarkable," said Dr. David Kandzari, director of interventional cardiology research at Scripps Clinic in La Jolla, Calif., and co-principal investigator of E-III and E-IV. "The Endeavor stent has demonstrated a very compelling safety and efficacy profile wherein there is a very low likelihood that patients treated with the Endeavor stent will experience late stent clotting or the need for a repeat procedure beyond the first year of follow up."

The E-Pooled analysis includes patients who were treated with the Endeavor DES in E-I, E-PK, E-II, E-II CA, E-III and E-IV; it uses the Medtronic Driver(R) bare-metal stent (BMS) control arm of E-II as a comparator. The following table shows rates of major adverse cardiac events (MACE), all-cause mortality, cardiac death/myocardial infarction (CD/MI), target lesion revascularization (TLR), and definite and probable stent thrombosis (ST) as defined by the Academic Research Consortium (ARC).

E-Pooled Analysis at Five Years of Patient Follow Up

Event	Endeavor DES n=2,132	Driver BMS n=596	P-value
MACE*	14.3%	24.4%	<0.001
All-cause mortality	6.1%	7.6%	0.206
CD/MI	5.2%	8.4%	0.003
TLR	7.0%	16.5%	<0.001
ST (ARC def/prob)	0.8%	1.7%	0.051
Very Late (>1 yr) ST	0.2%	0.4%	0.460

* MACE is a composite endpoint comprised of all-cause mortality, MI, emergent CABG and TLR

Of particular relevance are the longitudinal safety results, including the low rates of CD/MI and ST, which are achieved against a background of only 39 percent and 8 percent of Endeavor patients being maintained on dual-antiplatelet therapy at one year and five years of follow-up, respectively.

The E-Pooled analysis includes clinical data on more than 2,100 Endeavor patients from six rigorously conducted clinical trials distinguished by 100 percent patient monitoring, 100 percent source data verification and independent, blinded event adjudication performed at the Harvard Clinical Research Institute.

Included in this analysis - and also released today at ACC.10 - are the final five-year results from the ENDEAVOR III randomized controlled trial comparing the Endeavor DES to the Cypher(R) DES (from Johnson & Johnson's Cordis Corp.) with a primary angiographic endpoint of late lumen loss at eight months.

E-III five-year results show low rates of MACE, TLR and ST for Endeavor patients which are consistent with the E-Pooled analysis. They also reveal statistically significant difference in rates of CD/MI as well as a trend toward lower MACE in favor of the Endeavor DES.

- MACE - Endeavor 13.6% v. Cypher 21.8% (p=0.054)
- CD/MI - Endeavor 1.3% v. Cypher 6.5% (p=0.003)
- ST (ARC Def/Prob/Poss) Endeavor 1.0% vs. Cypher 3.7% (p=0.079)
- TLR - Endeavor 8.0 v. Cypher 6.5% (p=0.547)

Importantly, E-III five-year outcomes confirm the phenomena of late catch-up in TLR with the Cypher DES: From years 1-5 of follow up, the data show a TLR increase of 86 percent with the Cypher DES compared to 21 percent with the Endeavor stent. This difference in TLR rates after the first year of patient follow up in E-III drives similar overall TLR rates at five years. Additionally, MACE increased in the Cypher patients by 173 percent compared to 74 percent in the Endeavor patients.

While the observed increase in late clinical events with the Cypher DES are intriguing and consistent with other recent trials, E-III is not designed or powered to detect differences in clinical events. The definitive study comparing the Endeavor DES to the Cypher DES is PROTECT, the largest randomized stent trial of its kind, with independent and blinded clinical events adjudication and data safety monitoring committees. With 8,800 patients, PROTECT is designed to evaluate whether the Endeavor stent protects against late stent thrombosis and results in fewer deaths and MIs at three years of follow-up. Enrollment in the PROTECT study was completed in December 2008.

Medtronic CardioVascular is committed to advancing the treatment of coronary, peripheral, aortic and structural heart disease through collaboration with leading clinicians, researchers and scientists worldwide.

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