ENDEAVOR II Pivotal Clinical Trial

Fact Sheet & Clinical Data Summary

Caution: The Endeavor™ Drug Eluting Coronary Stent is an investigational device with an investigational drug (ABT-578) and is exclusively for clinical investigation.

Trial Name: ENDEAVOR II Pivotal Clinical Trial

Start Date: July 2003
Enrollment Completion: January 2004

Purpose: ENDEAVOR II was a randomized (1 to 1), double-blind pivotal clinical trial to assess the safety and efficacy of the investigational Endeavor™ Drug Eluting Coronary Stent compared to the Medtronic Driver™ Cobalt Alloy Coronary Stent in the treatment of restenosis in single de novo native coronary artery lesions.

Size / Location:

- 1,197 patients at 72 sites in Europe, Asia Pacific, Israel, New Zealand and Australia.
- First and largest DES pivotal trial ever conducted outside the United States comparing a drug eluting stent to a bare metal stent.

Stent Diameters: 2.25 mm – 3.5 mm
Stent Lengths: 18 – 30 mm
Lesion Lengths: 14 – 27 mm / Pre Dilatation Required
Randomization: 1 to 1 – Endeavor Stent (600); Driver Stent Control (600)

Primary Endpoint: Target Vessel Failure (TVF; defined as a composite of cardiac death, myocardial infarction and Target Vessel Revascularization) at 9 months.)

Key Secondary Endpoints:

- MACE at 30 days
- Late Lumen Loss at 8 months
- In-Stent / In-Segment Angiographic Binary Restenosis (ABR) at 8 months
- Target Lesion Revascularization (TLR) at 9 months
- Target Vessel Revascularization (TVR) at 9 months

Follow Up: 600 patient angiographic follow up
300 patient Intravascular Ultrasound (IVUS)
IVUS for overlapping stents

ENDEAVOR II Key Clinical and Angiographic Results Summary

Parameter	**Endeavor Stent** (598 patients)	**Driver Stent Control** (599 patients)
MACE	7.4%	14.7%
TLR	4.6%	12.1%
TVR	5.7%	12.8%
TVF	8.1%	15.4%
%DS In-Segment	32.6%	44.3%
%DS In-Stent	27.9%	42.1%
ABR In-Segment	13.3%	34.2%
ABR In-Stent	9.5%	32.7%
LL In-Segment	0.36	0.71
LL In-Stent	0.62	1.03
LL Index In-Stent	0.34	0.54

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