

PERSEUS Clinical Program – Workhorse Trial

OBJECTIVE:	Evaluation of TAXUS® Element™ Paclitaxel Eluting Coronary Stent System compared to TAXUS® Express® Paclitaxel-Eluting Coronary Stent System for the treatment of <i>de novo</i> lesions
STENT:	TAXUS Element Stent
PURPOSE:	Safety and Efficacy (Pivotal Study)
DESIGN:	Global multicenter, prospective, 3:1 randomized, single-blind, non-inferiority
LESION:	Single <i>de novo</i> lesion
CONTROL:	TAXUS Express Stent
RELEASE KINETICS:	Slow Release
PRIMARY ENDPOINT:	12 month TLF (TLF is comprised of any ischemia-driven target lesion revascularization, myocardial infarction (Q-wave and non Q-wave) related to the target vessel or cardiac death related to target vessel
LOCATION & SITES:	US, Australia, New Zealand, Singapore: 90 sites
ENROLLMENT:	July 16, 2007 - October 1, 2008 (complete)
PATIENTS:	1,262
INVESTIGATOR:	Dean J. Kereiakes, MD. Louis A Cannon, MD, USA

Patient Characteristics	TAXUS® Element Stent (N=942)	TAXUS® Express Control (N=320)	p-Value
Age (years)	62.2 ± 9.6	63.5 ± 9.5	0.03
Male	70.8%	68.8%	0.49
Diabetes	24.6%	25.0%	0.89
Insulin	7.3%	7.5%	0.92
Current Smoker	24.3%	23.5%	0.76
Unstable Angina	20.7%	21.3%	0.84

Baseline Lesion Characteristics (Determined by QCA)			
Lesion Length (mm)	14.2 ± 6.1	14.1 ± 5.8	0.68
RVD (mm)	2.8 ± 0.5	2.8 ± 0.5	0.37
B2/C Lesions	66.9	64.7	0.47
%DS (mm)	72.1 ± 10.9	71.7 ± 10.9	0.58

PERSEUS WH Post-Procedure Outcomes			
MLD			
In-Stent (mm)	2.68 ± 0.39	2.54 ± 0.36	0.01
In-Segment	2.25 ± 0.49	2.16 ± 0.37	0.17
Acute Gain			
In-Stent	1.93 ± 0.41	1.83 ± 0.40	0.09
In-Segment	1.51 ± 0.48	1.45 ± 0.40	0.41
PERSEUS WH 9-Month QCA Outcomes			
Late Loss			
In-Stent	0.34 ± 0.55	0.26 ± 0.52	0.33
In-Segment	0.17 ± 0.48	0.16 ± 0.45	0.86
Diameter Stenosis			
In-Stent	16.37 ± 20.86	16.02 ± 20.61	0.91
In-Segment	26.10 ± 17.71	26.37 ± 17.47	0.92

PERSEUS WH 12 -Month Clinical Outcomes			
TLF	5.6%	6.1%	0.78
Primary Non-Inferiority Endpoint	Difference: -0.57%; 95% CI** 1.85% (prespecified Δ 4.1%). 99.96% probability of non-inferiority.		
MACE	7.4%	7.7%	0.86
TLR	3.8%	4.5%	0.60
Cardiac Death	0.5%	0.3%	>0.99
All-Cause death	0.6%	0.7%	>0.99
MI	2.2%	2.9%	0.48
Q-Wave MI	0.5%	0.0%	0.34
Non-Q –Wave MI	1.6%	2.9%	0.17
TVR	5.6%	5.8%	0.94
ARC Definite/Probable Stent Thrombosis	0.4%	0.3%	>0.99

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*Control is the TAXUS Express Stent.

**CI is "Credible Interval"

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