

Clinical Trial: SPIRIT III - A Clinical Evaluation of the XIENCE™ V Everolimus Eluting Coronary Stent System (CSS) in the Treatment of Subjects with De Novo Native Coronary Artery Lesions

CT00370

(Cardiovascular Therapeutics)

Sponsoring Company:

- Abbott Vascular Devices
- Boston Scientific Corporation
- Guidant Corporation

Product:

- XIENCE™ V everolimus-eluting coronary artery stent system
- TAXUS® Express² paclitaxel-eluting coronary stent system

Objective:

- To demonstrate the safety and efficacy of the XIENCE V everolimus eluting coronary stent system as compared to the TAXUS paclitaxel eluting coronary stent system in patients with coronary artery disease in a large-scale pivotal study

Inclusion Criteria:

- Target lesion(s) in a major artery or branch with visually estimated stenosis of $\geq 50\%$ and $< 100\%$ with a TIMI flow of ≤ 1

Exclusion Criteria:

- Lesion located within an arterial or saphenous vein graft or distal to a diseased arterial or saphenous vein graft
- Lesion involving a bifurcation ≥ 2 mm in diameter, ostial lesion $> 50\%$ stenosed by visual estimation, or a side branch requiring predilatation
- Located in a major epicardial vessel that has been previously treated with brachytherapy or PCI < 9 months prior to index procedure
- Total occlusion (TIMI flow 0)
- Target vessel contains thrombus
- A significant lesion ($> 40\%$ DS) located in the same epicardial vessel as the target lesion

Primary Endpoints:

- In-segment LLL at 240 days

- Assume LL = 0.24 ± 0.47 mm in both arms
- Non-inferiority margin = 0.195 mm, one-sided $\alpha = 0.025$
- 564 total pts \rightarrow 99% power (assuming 10% dropout)
- Pre-specified sequential non-inferiority and superiority tests
- In pts with 2 lesions, primary endpoint analysis based on a randomly assigned "analysis lesion"

Secondary Endpoints:

- Major adverse cardiac events (cardiac death, MI, TLR)
- Death (cardiac and non cardiac)
- MI (Q-wave and non Q-wave)
- Stent thrombosis (ACS + angiographic thrombus, or unexplained death or STEMI/Q-wave MI in target lesion distribution within 30 days)
- Endpoints measured at 30 days, 6 months, 9 months, and yearly through 5 years
- Major secondary endpoint: Ischemia-driven TVF at 270 days

PI:

- Stone, Gregg W., MD; and Rogers, Campbell D.K., MD

PI Study Site:

- Columbia University Medical Center, New York, NY; and Brigham and Women's Hospital, Boston, MA

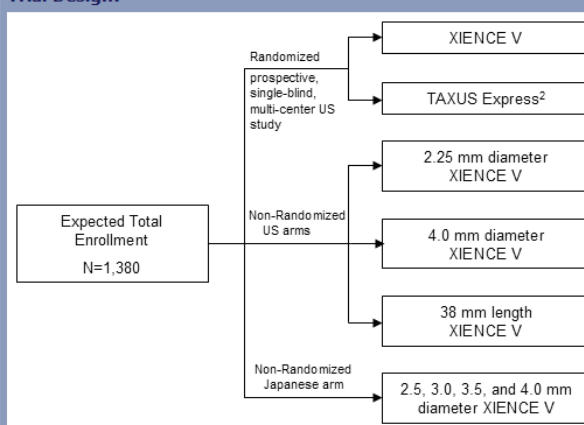
Enrollment:

- 1,002

Trial Start Date:

- June 2005

Trial Design:



Patient Demographics:

Demographics at Enrollment			
Patients	XIENCE V n=669	TAXUS n=333	P Value
Age (in years)	63.2 \pm 10.5	62.8 \pm 10.2	0.54
Male (%)	70.1	65.7	0.17
Hypercholesterolemia (%)	74.2	71.5	0.36
Diabetes-mellitus (%)	29.6	27.9	0.60
Insulin requiring (%)	7.8	5.5	0.19
Current smoker (%)	23.4	22.5	0.81
Prior MI (%)	19.9	18.0	0.49
Unstable angina (%)	18.7	25.1	0.02

Angiography at Enrollment			
Patients	XIENCE V lesions=767	TAXUS lesions=382	P Value
Lesion location	--	--	--
LAD	41.3%	42.9%	0.61
LCX	27.6%	28.3%	0.83
RCA	31.0%	28.5%	0.41
LMCA	0.1%	0.3%	0.55
QCA	--	--	--
RVD (mm)	2.77 \pm 0.45	2.76 \pm 0.46	0.87
MLD (mm)	0.82 \pm 0.41	0.83 \pm 0.40	0.79
%DS	70.0 \pm 13.3	69.4 \pm 13.6	0.54
Lsn length (mm)	14.7 \pm 5.6	14.7 \pm 5.7	0.92

Primary Endpoint: 8 Mo In-segment LL

Patients	XIENCE V	TAXUS
Total at Randomization (n=564)	376	188
Lost to f/u	3	3
Patient Withdrawal	2	3
Death	2	1
No Qualifying Angio	67	37
Total at 8 month angioF/U* (N=446; 79%)	302	144

Results:

Antiplatelet Agent Utilization			
Patients	XIENCE V n=669	TAXUS n=333	P Value
Aspirin	--	--	--
180 Days	96.6%	96.1%	0.72
270 Days	96.1%	94.6%	0.26
365 Days	94.9%	92.4%	0.15
Thienopyridine	--	--	--
180 Days	94.5%	94.0%	0.77
270 Days	74.4%	76.7%	0.44
365 Days	71.2%	70.4%	0.82

Patient Flow Through Clinical		
Patients	XIENCE V	TAXUS
Total at Randomization (n=1002)	669	333
Lost to f/u	9	8
Patient Withdrawal	5	4
Total at 12 Month Follow-Up (n=976; 97.4%)	655	321

1-Year Results			
Events, (Patients if different)	XIENCE V n=655	TAXUS n=321	P Value
Death, all cause	1.2%	1.2%	1.0
Cardiac	0.8%	0.9%	0.72
Non cardiac	0.5%	0.3%	1.0
MI, all	2.8%	4.1%	0.33
Q-wave	0.3%	0.3%	1.0
Non Q-wave	2.5%	3.8%	0.31
TVR	6.1%	7.5%	0.41
TLR	3.4%	5.6%	0.12
TVR remote	3.1%	4.4%	0.35
Stent Thrombosis, All	5/647 (0.8%)	2/317 (0.6%)	1.0
0 - 30 Days	3/667 (0.4%)	0/330 (0%)	0.55
30-365 Days	2/646 (0.3%)	2/317 (0.6%)	0.60
ARC definite/probable	7/652 (1.1%)	2/319 (0.6%)	0.73
Definite	5/652 (0.8%)	0/319 (0%)	0.18
Probable	2/652 (0.3%)	2/319 (0.6%)	0.60
0 - 30 Days	4/667 (0.6%)	0/330 (0%)	0.31
30-365 Days	3/651 (0.5%)	2/319 (0.6%)	0.67

Conclusion:

- The everolimus-eluting XIENCE V stent was both noninferior and superior to the TAXUS stent in reducing in-segment late loss (primary endpoint).
- The XIENCE V stent significantly reduced in-stent late loss at 8 months and reduced angiographic follow-up diameter stenosis with a strong trend toward lower binary restenosis
- The XIENCE V stent demonstrated noninferior rates of target vessel failure at 9 months, with a significant 44% reduction in major adverse cardiovascular events. It also showed a strong trend toward reduced ischemia-driven target lesion revascularization, with a significant reduction in any target lesion revascularization.
- Post hoc: Stent thrombosis defined by ARC definitions

Top 20 PI Sites

(PI Site, PI, Patients Enrolled)

- California**
 - Good Samaritan Hosp., Los Angeles, CA, R. Matthews, 16 Patients
 - Scripps Memorial Hospital, La Jolla, CA, R. Fortuna, 20 Patients
- Indiana**
 - The Heart Center of IN, Indianapolis, IN, J. Hermillier, 48 Patients
- Kentucky**
 - Jewish Hospital, Louisville, KY, N. Xenopoulos, 29 Patients
- Massachusetts**
 - Brigham & Women's Hospital, Boston, MA, L. Mauri, 18 Patients
- Maryland**
 - St. Joseph Medical Center, Towson, MD, M. Midei, 107 Patients
- Michigan**
 - Borgess Medical Center, Kalamazoo, MI, A. Carter, 24 Patients
 - Northern Michigan Hospital, Petoskey, MI, L. Cannon, 18 Patients
- Montana**
 - St. Patrick Hospital, Missoula, MT, M. Sanz, 60 Patients
- North Carolina**
 - N. Carolina Baptist Hosp., NC, R. Applegate, 29 Patients
 - Presbyterian Hospital, Charlotte, NC, J. Williams, 41 Patients
- Wake Medical Center, Raleigh, NC, W. Newman, 90 Patients**
- Nebraska**
 - Nebraska Heart Hospital, Lincoln, NE, D. Netz, 14 Patients
- New York**
 - Columbia Univ. Med. Ctr., New York, NY, M. Collins, 19 Patients
 - St. Joseph's Hospital, Syracuse, NY, R. Caputo, 32 Patients
- Ohio**
 - The Christ Hospital, Cincinnati, OH, J. Young, 27 Patients
 - EMH Regional Medical Center, Elyria, N. Farhat, OH, 39 Patients
- Rhode Island**
 - The Miriam Hospital, Providence, RI, P. Gordon, 29 Patients
 - Rhode Island Hospital, Providence, RI, D. Williams, 23 Patients
- Vermont**
 - Fletcher Allen Healthcare, Burlington, VT, H. Dauerman, 16 Patients

- Trial enrollment will be updated when SPIRIT III has been published.

Last Update: January 31, 2008

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