Jupiter II

6 Month Interim Data

EuroPCR - Paris 2005

TRIAL DESIGN

JUPITER II is a randomized, double blind trial designed to evaluate safety and effectiveness of JANUS Tacrolimus eluting Carbostent for the treatment of coronary lesion in Direct Stenting as compared to TECNIC Carbostent coronary stent system. A total of 332 patients were enrolled in the study and randomized to either Janus stent (n=166) or TECNIC Carbostent (n=166).

TRIAL ENDPOINTS

The key endpoints of the study are:

- Assessment of in-stent and in-segment Late Lumen Loss (LLL) at 6 months follow-up by Quantitative Coronary Angiography (QCA)
- Assessment of binary angiographic restenosis at 6 months
- Clinically driven TLR within 6, 12 and 24 month follow-up
- MACE at discharge, 30 days, 6, 12 and 24 months
- Incidence of stent thrombosis within discharge, 30 days, 6, 12 and 24 months

PARTICIPATING CENTERS

[redacted] Massy (France)
[redacted] Dresden (Germany)
[redacted] Zürich (Switzerland)
[redacted] Berlin (Germany)
[redacted] Toulouse (France)
[redacted] Madrid (Spain)
[redacted] Cotignola (Italy)
[redacted] Nijmegen (Holland)

[redacted] Aalst (Belgium)
[redacted] Bad Krozingen (Germany)
[redacted] London (U.K)
[redacted] Innsbruck (Austria)
[redacted] Amsterdam (Holland)
[redacted] Rotterdam (Holland)
[redacted] Leuven (Belgium)
[redacted] Antwerp (Belgium)

JANUS
Tacrolimus eluting Carbostent

SORIN GROUP
AT THE HEART OF MEDICAL TECHNOLOGY

Jupiter II

6 Month Interim Data

EuroPCR - Paris 2005

INTERIM CLINICAL DATA (data adjudicated by Critical Event Committee-CEC)

	GROUP A	GROUP B
Number of patients	164	165
Mean age	63.9 ± 9.9	63.9 ± 9.6
Male gender	75.6%	74.6%

A total of 399 stents (193 in group A, 206 in group B) were implanted for the treatment of 376 lesions (187 group A, 189 group B). There are no significant differences between the 2 groups with respect to clinical characteristics and outcomes.

Clinical characteristics:

	GROUP A	GROUP B
Stable angina	65.6%	61.8%
Unstable angina	15.2%	18.8%
Silent Ischemia	9.2%	6.7%
MI	5.5%	8.5%
Asymptomatic	5.5%	4.2%
Diabetics	20.1%	17.6%

Lesions characteristics: (based on angiographic visual estimation)

	GROUP A	GROUP B
Lesion Length (mm)	11.83 ± 3.75	12.33 ± 3.88
Reference Vessel Diameter (RVD) (mm)	3.03 ± 0.37	2.97 ± 0.40
Minimal Lumen Diameter (MLD) (mm)	1.03 ± 0.65	1.01 ± 0.57

One month clinical data:

	GROUP A	GROUP B
MACE	0.6% (1 non Q wave MI* out of 164 patients)	0%

**Due to a stent thrombosis occurred after the procedure*

Six month interim data:

	GROUP A	GROUP B**
	102 pts	88 pts
MACE	11.8% (12 TLR out of 102 pts)	3.4% (3 TLR out of 88 pts)
Sub-acute and long term thrombosis	0%	0%

***1 death and 1 CABG occurred in group B and were adjudicated by CEC non stent related*

CONCLUSION

One month clinical data demonstrate in both groups excellent clinical outcomes.
Preliminary six month clinical data highlight the safety profile of both groups and lower MACE and TLR rates in group B together with no subacute and long term thrombosis case.
Further 6 month data will be presented at the ESC congress in Stockholm and the complete clinical and angiographic outcomes will be presented during the TCT congress in Washington in October.

SORIN GROUP
AT THE HEART OF MEDICAL TECHNOLOGY
janus@sorin.com