JANUS: 6-month real life experience from e-Janus

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Summit TCT Asia Pacific

CARBOSTENT™ coating: Carbofilm™

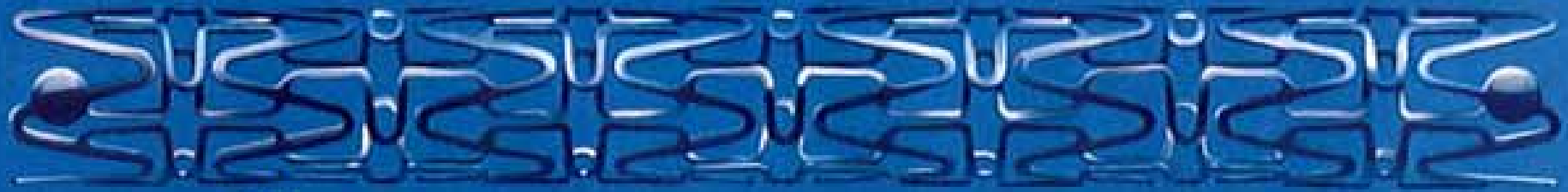
Uncoated

The stent is coated with CARBOFILM™

an integral and permanent thin film

of *TURBOSTRATIC CARBON*

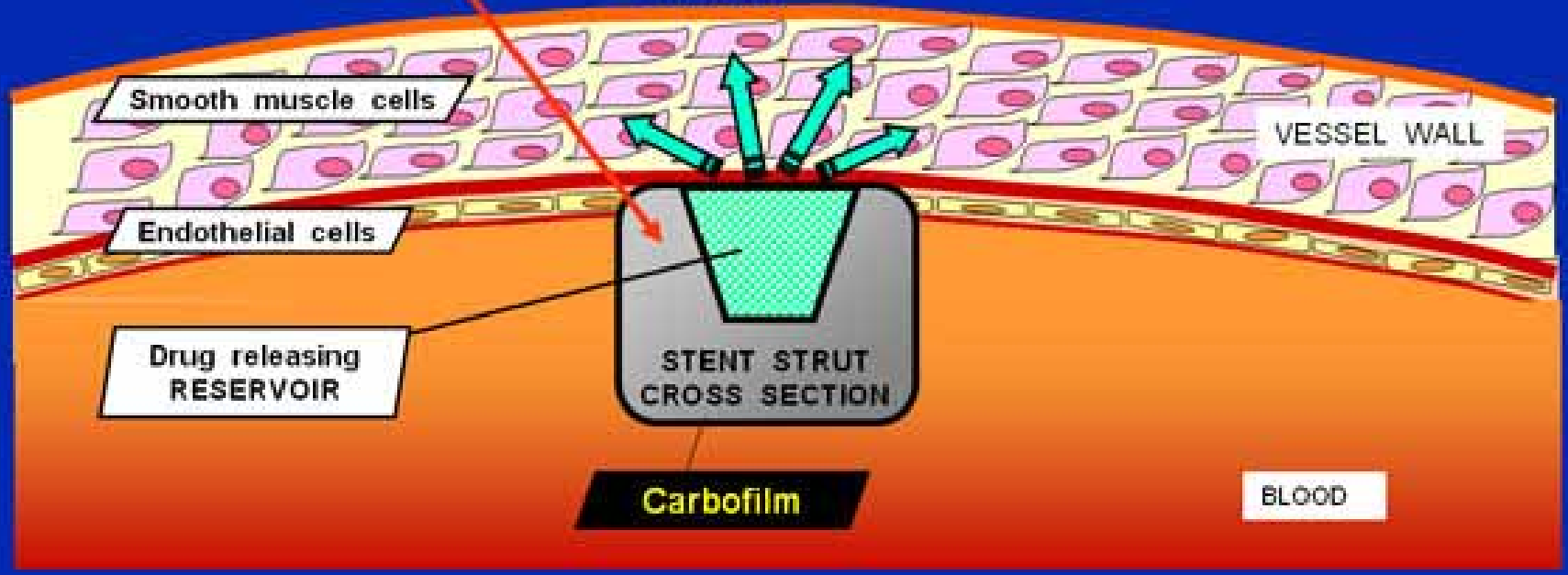
obtained from PYROLYTIC CARBON



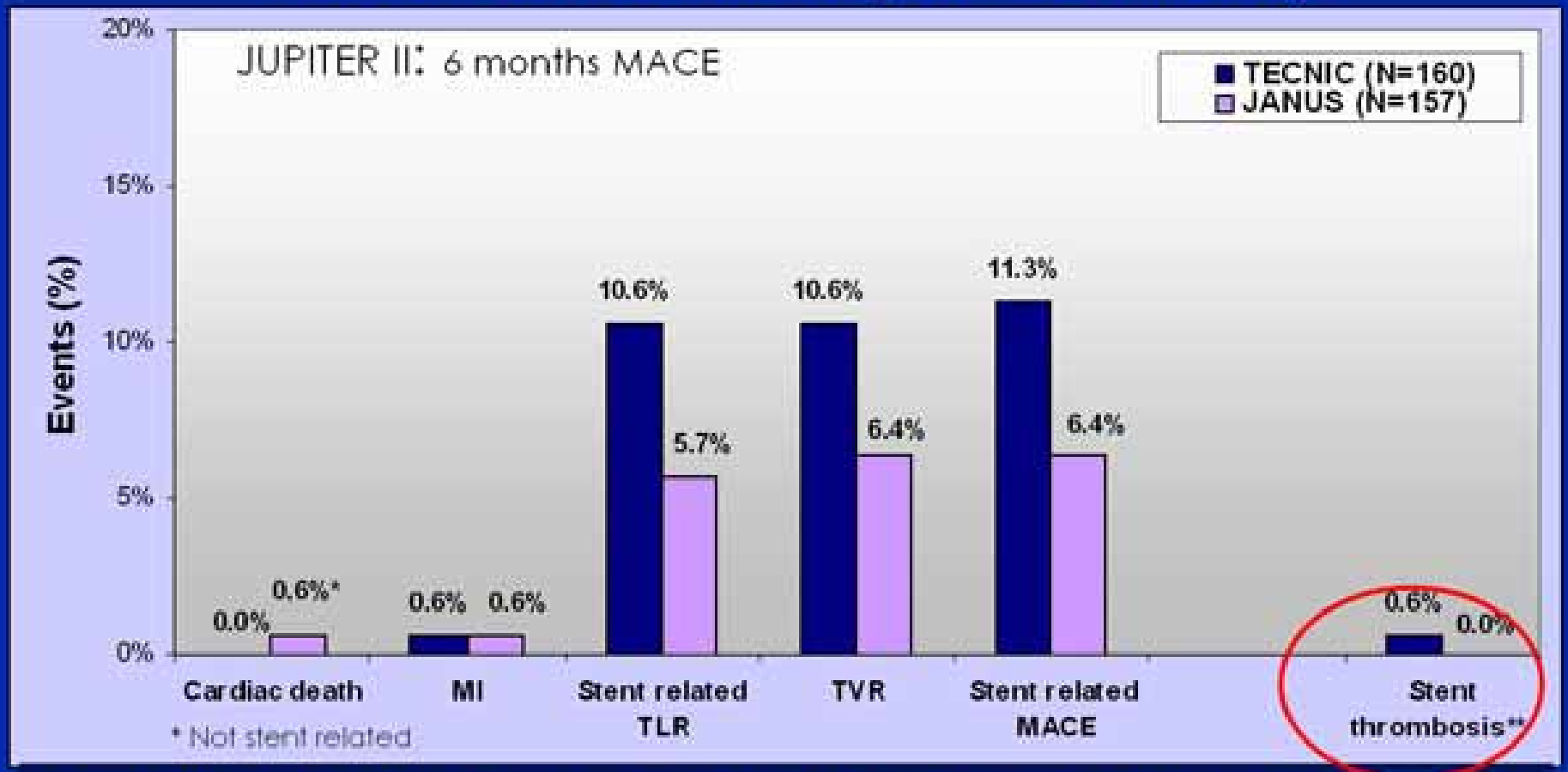
Carbofilm™ coated

JANUS Tacrolimus Eluting Carbostent

- Deep reservoirs on the outer stent surface contain and release the drug only towards the vessel wall
- Integral thromboresistant Carbofilm coating on the whole stent surface
- No drug released from the blood contacting surface



Jupiter II randomized trial: Proven clinical safety and efficacy



**Over 40% of the patients received less than 3 months dual antiplatelet regimen

e-Janus

- **AIM OF THE STUDY**

Assessment of clinical performance of Janus Tacrolimus eluting Carbostent in the treatment of de novo or restenotic lesions in "real world" population.

- **STUDY DESIGN**
  - Over 2.500 patients in 100 centers worldwide (except U.S. & Japan)
  - Based on electronic CRFs
  - Independent CEC (Clinical Events Committee)
  - 3% site monitoring

- **PRIMARY ENDPOINTS**
  - Incidence of MACE within discharge, 30 days, 6,12 & 24 months
  - Thrombosis rate within discharge, 30 days, 6, 12 & 24 months (acute, sub-acute and late thrombosis)
  - Clinical performance of Janus Carbostent, during implant procedure
- **SECONDARY ENDPOINT**
  - Clinically driven TLR at 6 months

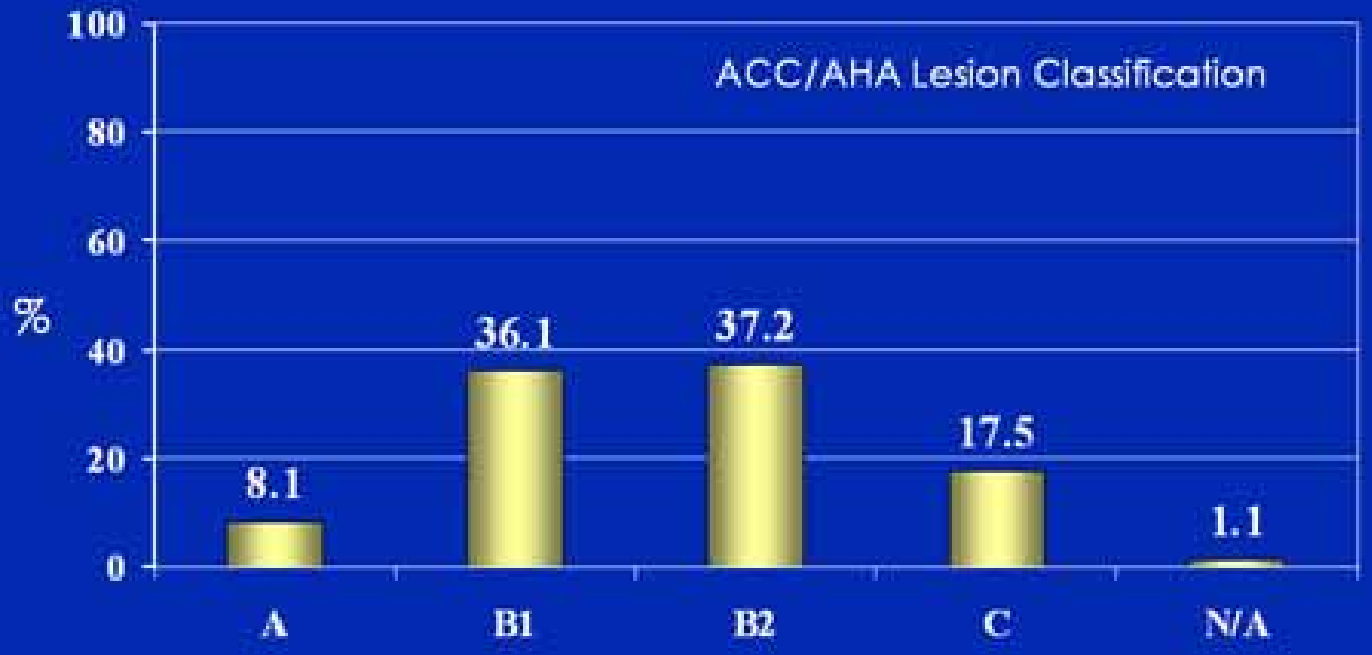
* Selected angiographic follow-up also performed

Baseline Clinical Characteristics

N° of enrolled pts	**2490**
Interim Analysis on	**587 pts**
Male	**73.9%**
Age (yrs)	**63.5 ± 11.0**
Diabetes	**30.8% (181 pts)**
ID Diabetes	8.7% (51 pts)
NID Diabetes	22.1% (130 pts)
AMI	**22.7% (133 pts)**
Multivessel disease	**50.4% (296 pts)**

Target Lesion Characteristics

N° of lesions	670
Bifurcation	14.5% (97/670)
Ostial Lesion	17.3% (116/670)
Total Chronic Occlusion	6.7% (45/670)



e-Janus Interim Analysis on 587 pts

Procedural Characteristics

Direct stenting technique	**42.8 %**
# Stent/patient	**1.25 ± 0.55**
# Stent/lesion	**1.1 ± 0.37**
Mean Stent Length (mm)	**17.8 ± 5.15**
Stent max pressure (atm)	**14.3 ± 2.95**

Procedure Success*	**98.8% (662/670 les)**

***Residual diameter stenosis <20% (by visual estimate) after stenting procedure**

e-Janus Interim Analysis on 587 pts

Cumulative Clinical Events at 1 month follow-up

	Total (stent and not stent related)
MACE (n)	**3.3% (19)**
Death (n)	**2.1% (12)**
Cardiac Death	2.1% (12)
MI (n)	**1.0% (6)**
Q-Wave	0.9% (5)
Non Q-Wave	0.2% (1)
TLR (n)	**0.2% (1)**
CABG	0%
Re-PTCA	0.2% (1)
Re-PTCA + stent	0%
TVR (n)	0.2% (1)

e-Janus Interim Analysis on 587 pts

Clinical Events at 6-month follow-up

	Total (stent and not stent related)
MACE (n)	**4.3% (25)**
Death (n)	**0.7% (4)**
Cardiac Death	0.7% (4)
MI (n)	**0.5% (3)**
Q-Wave	0.3% (2)
Non Q-Wave	0.2% (1)
TLR (n)	**3.1% (18)**

e-Janus Interim Analysis on 587 pts

Revascularization at 6-month follow-up

	Total
TLR (n)	**3.1% (18)**
CABG	0.7% (4)
Re-PTCA	0.5% (3)
Re-PTCA + stent	1.9% (11)
TVR (n)	0.2% (1)

e-Janus Interim Analysis on 587 pts

Stent Thrombosis (subacute & late)

Sub-acute Thrombosis	**5/587 (3 pts with suboptimal procedure*)**
Late Thrombosis	**1/587 (pt stopped dual antiplatelet therapy)**

Low incidence of late stent thrombosis in "real world" population

*1 pt: incomplete stent apposition to the vessel wall on target lesion 1&2,
stent did not cover the entire target lesion 3;
1 pt: stent length inadequate for the lesion length;
1 pt: lesion not completely covered by the stent and stent diameter inadequate for the lesion.

e-Janus Interim Analysis on 587 pts

AMI Subgroup

Baseline Clinical Characteristics

N° of analyzed pts	**133 out of 587**
Male	**73.7%**
Age (yrs)	**61.9 ± 12.5**
Diabetes	**33.8% (45 pts)**
ID Diabetes	10.5% (14 pts)
NID Diabetes	23.3% (31 pts)
Multivessel disease	**45.9% (61 pts)**

e-Janus Interim Analysis on 133 AMI pts

Cumulative Clinical Events at 1 month follow-up
AMI subgroup

	Total (stent and not stent related)
MACE (n)	**6.8% (9)**
Cardiac Death (n)	**5.3% (7)**
MI (n)	**0.7% (1)**
Q-Wave	0.7% (1)
Non Q-Wave	0%
TLR (n)	**0.7% (1)**
CABG	0%
Re-PTCA	0.7% (1)
Re-PTCA + stent	0%
TVR (n)	0%

e-Janus Interim Analysis on 133 AMI pts

Clinical Events at 6-month follow-up
AMI subgroup

	Total (stent and not stent related)
MACE (n)	3.0% (4)
Cardiac Death (n)	0.7% (1)
MI (n)	0%
Q-Wave	0%
Non Q-Wave	0%
TLR (n)	2.2% (3)

e-Janus Interim Analysis on 133 AMI pts

Revascularization at 6-month follow-up
AMI subgroup

	Total
TLR (n)	**2.2% (3)**
CABG	0%
Re-PTCA	0.7% (1)
Re-PTCA + stent	1.5% (2)
TVR (n)	0.7% (1)

e-Janus Interim Analysis on 133 AMI pts

Stent Thrombosis (subacute & late)
AMI subgroup

Sub-acute Thrombosis	**2/133 (1 pt with suboptimal procedure*)**
Late Thrombosis	**0/133**

No incidence of late stent thrombosis in AMI subgroup population

*1 pt: incomplete stent apposition to the vessel wall on target lesion 1&2, stent did not cover the entire target lesion 3.

Conclusions:

e-Janus "real-world" interim data demonstrated:

- Low Stent Thrombosis in the first 587 patients
- Low MACE events at 6-month
- Clinical efficacy with low TLR rates at 6-month in both the overall population (3.1%) and the AMI subgroup (2.2%)
- Good safety profile in the high-risk AMI patients

The absence of late thrombosis in the AMI subgroup clearly reinforces the strong benefits of the Janus platform.