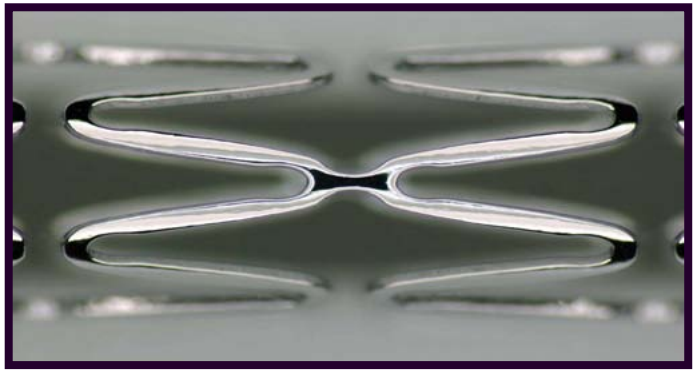
NOBORI 1 – Phase 1
Final 5 Years Results

Potential conflicts of interest

- **I have the following** potential conflicts of interest to report:
  - Research contracts
  - X Consulting
  - Employment in industry
  - Stockholder of a healthcare company
  - Owner of a healthcare company
  - Other(s)

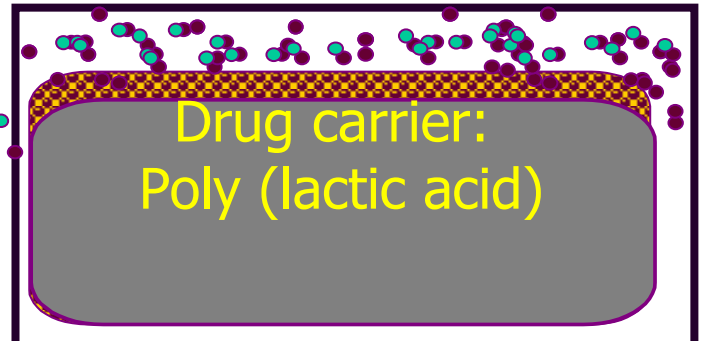
- **I do not have any potential conflict of interest**

Nobori DES Components



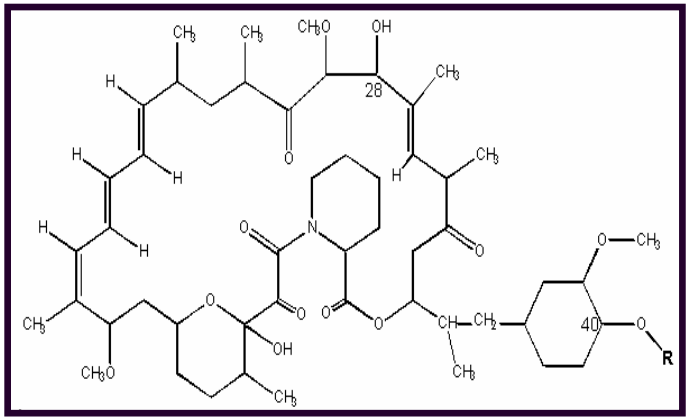
BMS Platform

- Excellent Flexibility and Scafolding
- Optimal Side Branch Access
- Innovative delivery system with hidrophilic M-coating



PLA Biodegradable Polymer

- Abluminal coating
- Controlled biodegradability
- Precise drug release kinetics
- Simultaneous release of drug and polymer degradation



Biolimus A9™ (rapamycin derivative)

- A potent new “Limus” designed for stent applications
- Powerful anti-proliferative, anti-inflammatory properties
- Prevents smooth muscle cell proliferation
- Highly lipophilic with optimal local tissue uptake

NOBORI 1 Study Design

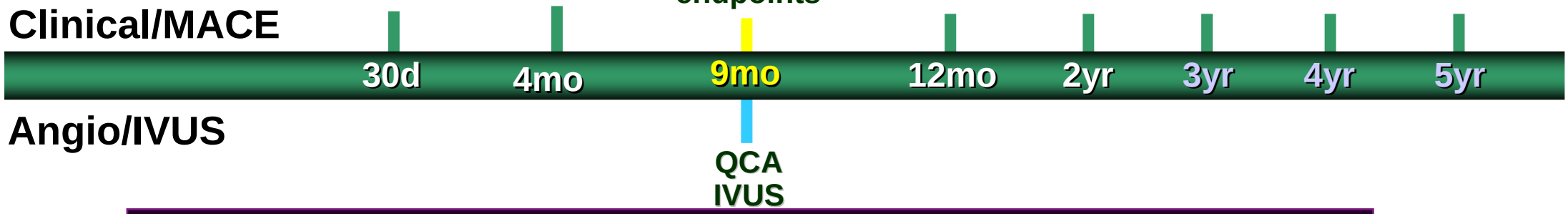
2:1 randomization
Single blind - two vessel – staging allowed

Up to two lesions in two epicardial vessels
Vessel diameter: 2.5-3.5 mm
Lesion length: <25 mm
Pre-dilatation required

Nobori Arm
Phase 1 (n=85)
Phase 2 (n=153)

PI: Dr B. Chevalier
N = 363 patients
29 sites
Europe, Asia, Australia

Control Taxus Arm
Phase 1 (n= 35)
Phase 2 (n= 90)



Primary endpoint: In-stent late lumen loss by QCA at 9 months
Secondary endpoints: In-segment late loss, BAR, Key IVUS Parameters
MACE (Death, MI, TVR) TLR, TVF at 9 months and ABR at 9 months, Procedure, Lesion success, Drug therapy: ASA and clopidogrel 6 months

NOBORI 1

Study Sites and Investigators

Australia:

- Adelaide — S. Worthley
- Melbourne — I. Meredith

Belgium:

- Liege — V. Legrand
- Aalst — W. Wijns
- Brussels — K. Erard

Denmark:

- Aarhus — L. Thuesen

France:

- St Denis — B. Chevalier
- Toulouse — J. Marco
- Paris — E. Teiger
- Massy — MC. Morice
- Quincy — P. Garot
- Caen — M. Hamon
- Toulouse — D. Carrie

Korea:

- Seoul — S-J Park

Germany:

- Bad Soden — N. Reifart
- Munich — S. Silber
- Bad Nauheim — C. Hamm
- Munich — T. Schiele
- Leipzig — G. Schuler
- Frankfurt — B. Nowak
- Trier — K. Hauptmann

The Netherlands:

- Rotterdam — P. Serruys
- Zwolle — H. Suryapranata
- Eindhoven — H. Bonnier

Spain:

- Madrid — E. Garcia
- Barcelona — A. Serra

UK:

- London — M. Thomas
- Manchester — F. Fath-Ordoubadi
- Brighton — D. Hildick-Smith

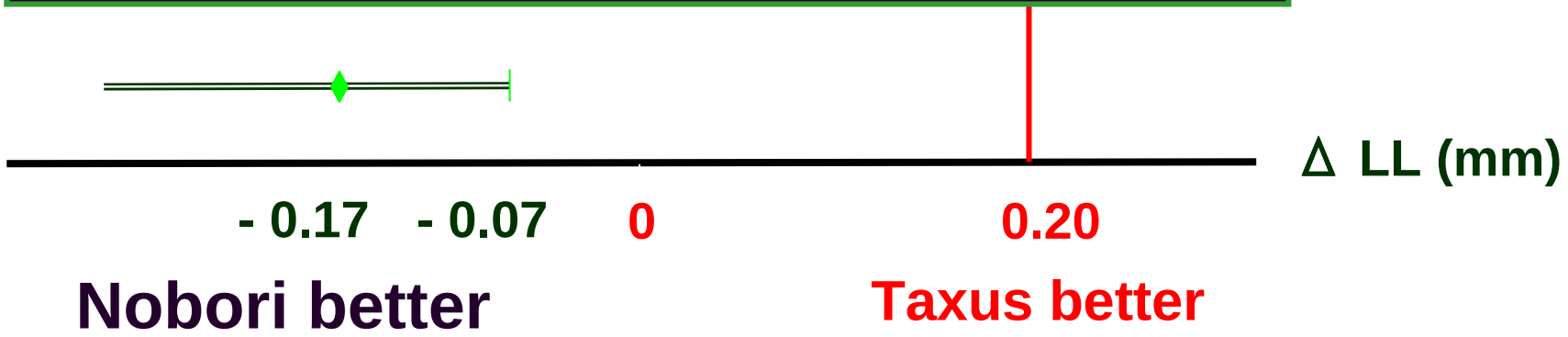
Baseline Patient Characteristics

Patient characteristic	Nobori Arm N=238	Taxus Arm N=125	P-value
Age (years)	63.2±10.6	62.9±10.0	0.78
Sex: male	72.7	68.0	0.39
Previous MI	23.5	28.0	0.37
Previous PTCA/CABG	24.7	20.6	0.67
Diabetes mellitus	16.8	27.2	0.03
insulin dependent	7.6	3.2	
non insulin dependent	9.2	24.0	
Hypertension	65.6	68.0	0.73
Hypercholesterolemia	69.8	74.4	0.39
Smoking history	59.5	52.8	0.22
Stable angina	71.8	71.6	0.96
Unstable angina	28.2	28.4	

Numbers are % or mean±SD

Primary Endpoint Result At 9-months

- Assumed in-stent Late Loss (LL)
  - ✓ 0.39 mm for Taxus® / 0.34 mm Nobori
  - ✓ Assumed SD: 0.50 mm
- Delta non-inferiority margin: 0.20mm



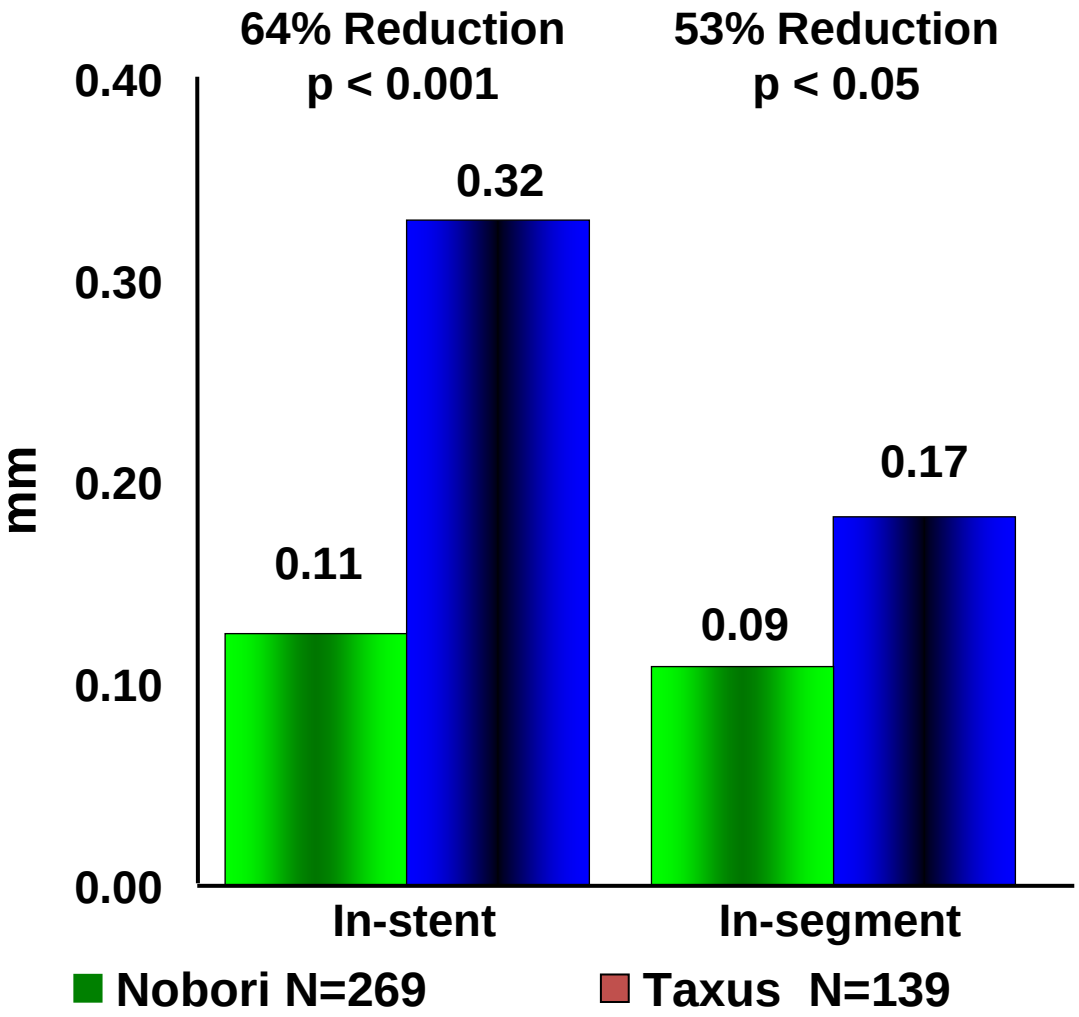
Late Loss result

- ✓ 0.32 ± 0.33 mm Taxus
- ✓ 0.15 ± 0.27 mm Nobori

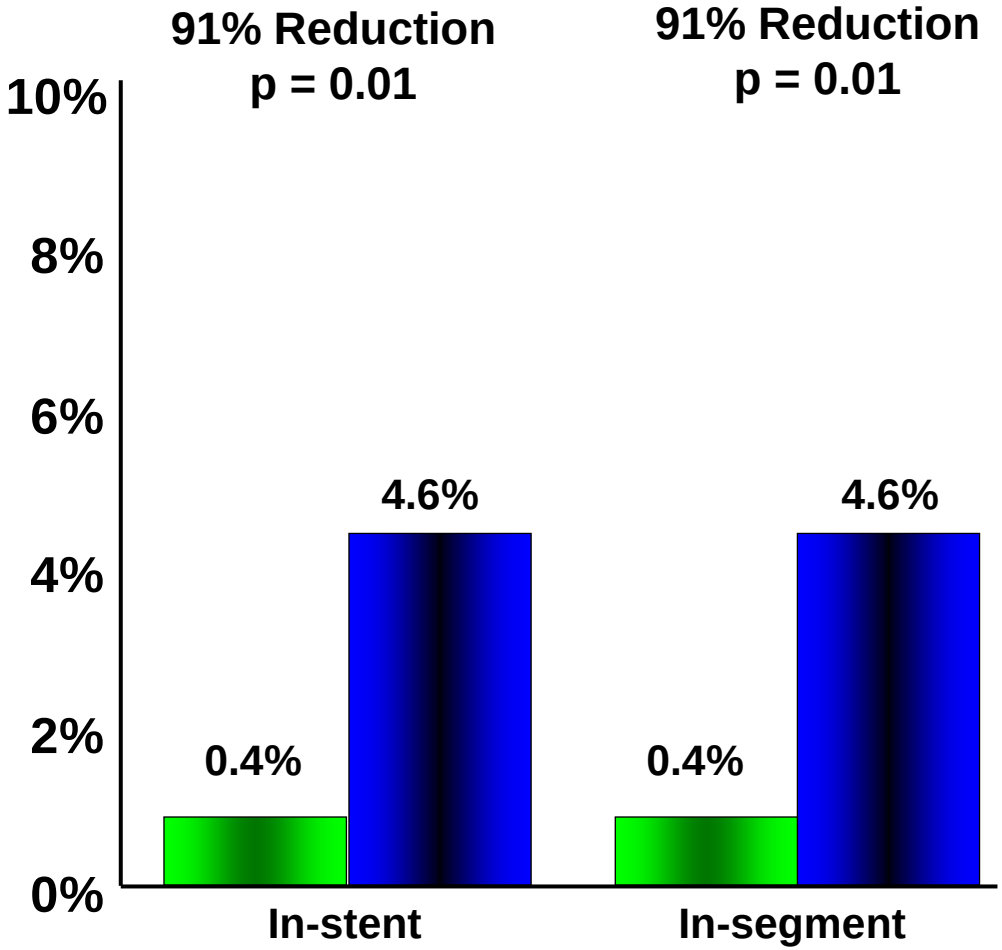
Result:
Nobori = NON-INFERIOR p<0.001

Key Angiographic Findings at 9 months

Late Loss



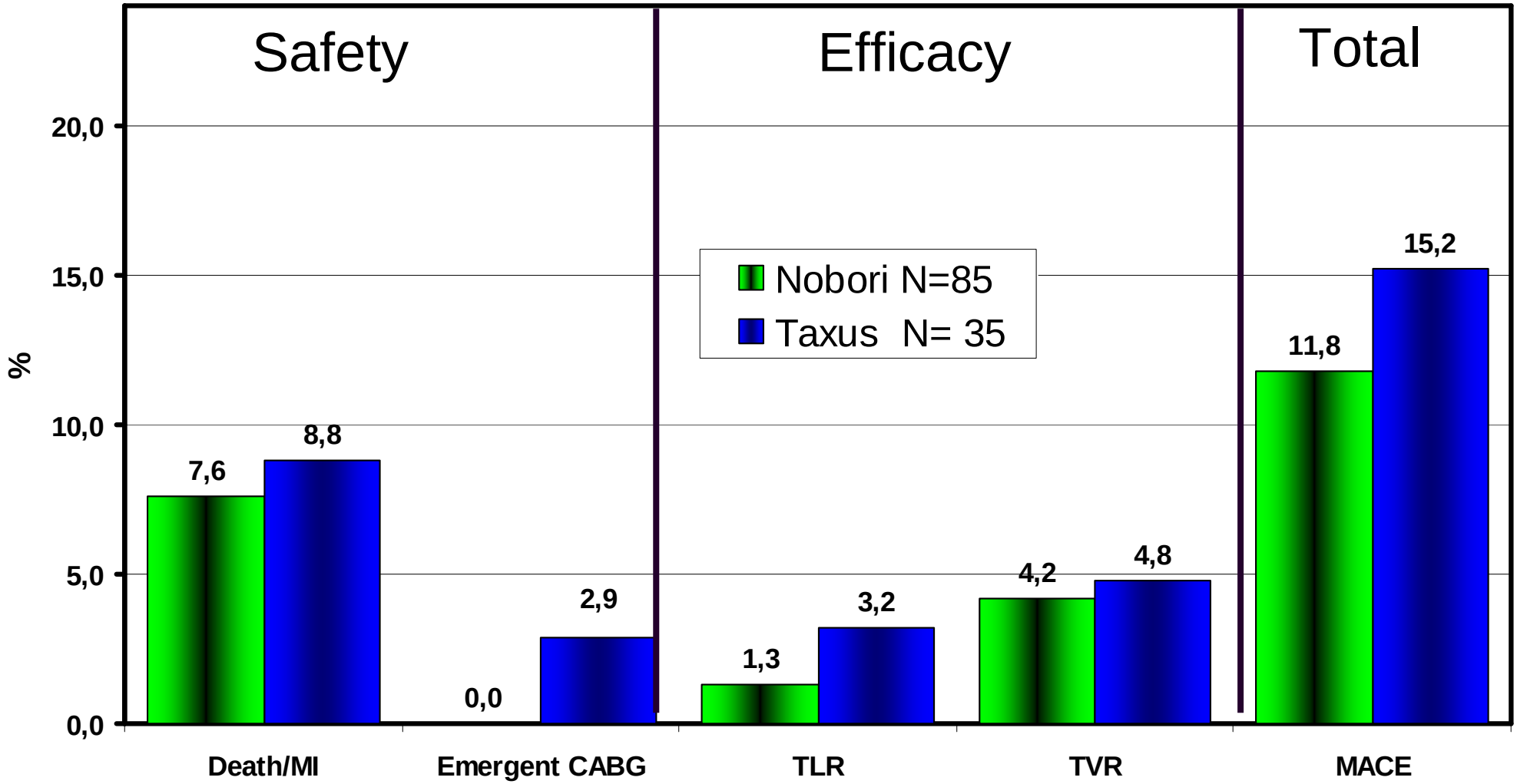
Binary Restenosis



NOBORI 1
Main IVUS Findings at 9 months

IVUS	N =101 Nobori	N =53 Taxus	P value
Volume obstruction (%)	1.93±5.54	6.76±8.04	<0.001
Neointimal hyperplasia (mm3)	3.11±8.84	13.50±20.4	0.003
Mean plaque area (mm2)	0.15±0.48	0.52±0.64	<0.001

Adverse Events at 3 Years
Pooled data both phases



MACE = Death, MI, TVR

Clinical Outcomes at 5 Years

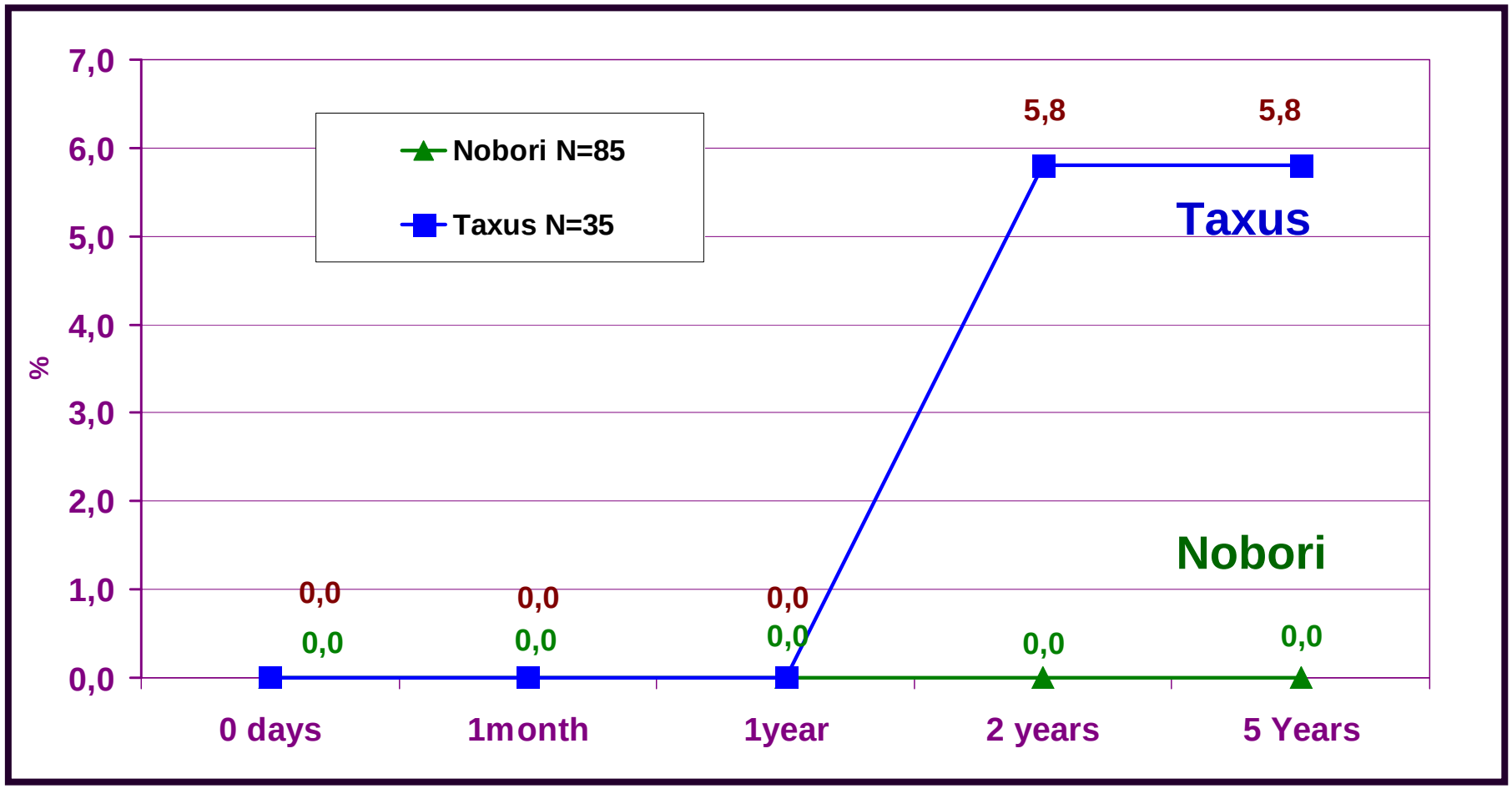
	Nobori N=76	Taxus N=30
Angina Status		
No Angina, %	90.7	86.7
Stable Angina, %	9.3	10.0
Unstable Angina, %	0.0	3.3
Dual Antiplatelet Therapy, %	18.0	7.0

Adverse Events
Up to 5 Years Follow-up

All Events (%)	Nobori Arm N=85	Taxus Arm N=35
Cardiac Death	5.9	5.7
MI - Total	5.9	14.3
MI Q Wave	1.2	5.7
MI Non-Q Wave	5.9	8.6
CABG – TV related	1.2	2.9
TL Re-PCI-Clinically driven	0.0	8.6
TV-non-TL Re-PCI-Clinically driven	3.5	5.7
Non-Target Vessel Revascularization	14.1	11.4
MACE - hierarchical	14.1	22.9
Target Vessel Failure	12.9	20.0

MACE = Cardiac Death, MI, TVR
TVF=Cardiac deat, MI-TV related, TVR

Stent Thrombosis at 5 years



Stent thrombosis = Definite and Probable according to ARC definition

Conclusions

- Final 5 years results of NOBORI 1 study showed preserved efficacy of Nobori DES and give indication about good safety
- Five years after stent implantation
  - 86% of the patients treated with Nobori stent were free of major adverse cardiac events
  - No stent thrombosis in Nobori arm
  - No TLR in Nobori arm
- Biodegradable polymer, abluminal coating, good healing process observed in animal studies, and reported better preservation of endothelial function with Nobori stent, could contribute to this excellent findings
- Ongoing large studies with more complex patients population continue to show similar trend observed in this first clinical trials