

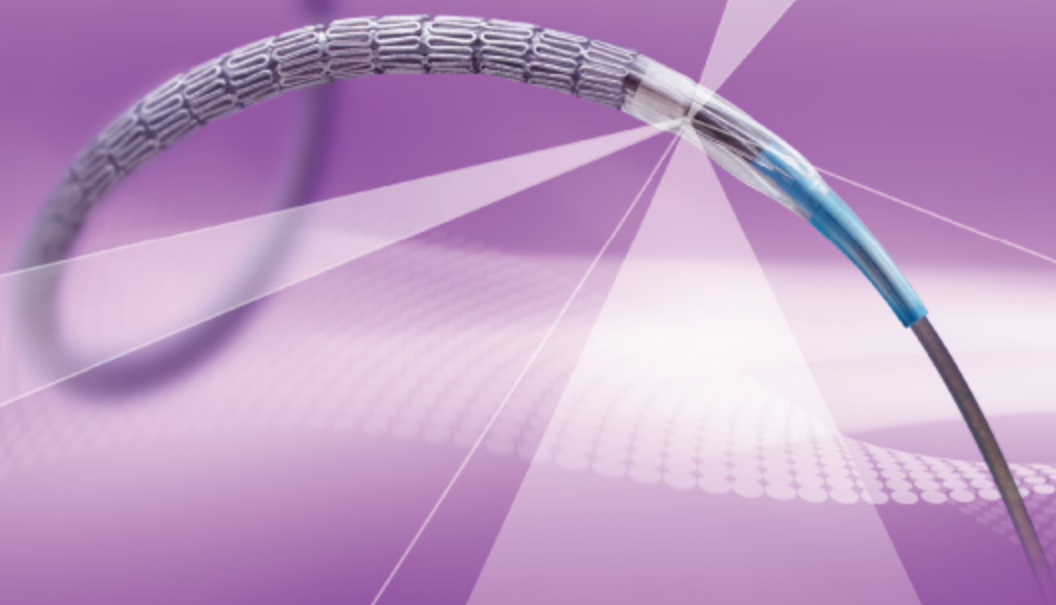


The Only DES
Indicated
for ACS

Endeavor Sprint

ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM

PCR09: Late-Breaking Clinical Trial Data



Late-Breaking Data Summary

- **ENDEAVOR II 5-year follow-up**
 - Endeavor demonstrates excellent long-term efficacy with low 7.5% TLR at 5 years
 - This represents an increase of only 0.3% from year 3 to 5
- **ENDEAVOR Pooled Analysis 5-year data¹**
 - Endeavor maintains a unique safety profile with very low 0.8% ARC Def/Prob ST (BMS = 1.7%, $p = 0.069$) despite only 39% of patients on DAPT at 1 year
 - Significant reduction in CD/MI versus BMS (Endeavor 5.6% vs 8.4%, $p = 0.012$)
- **ENDEAVOR program²**
 - In 2009, over 1,000 patients followed to 5 years and over 20,000 included in the ENDEAVOR clinical program.
- **The only DES indicated for ACS**
 - Endeavor provides long-term reassurance for ACS patients

¹ ENDEAVOR Pooled Analysis: EI, EII, EII CA, EIII, EIV, EpK

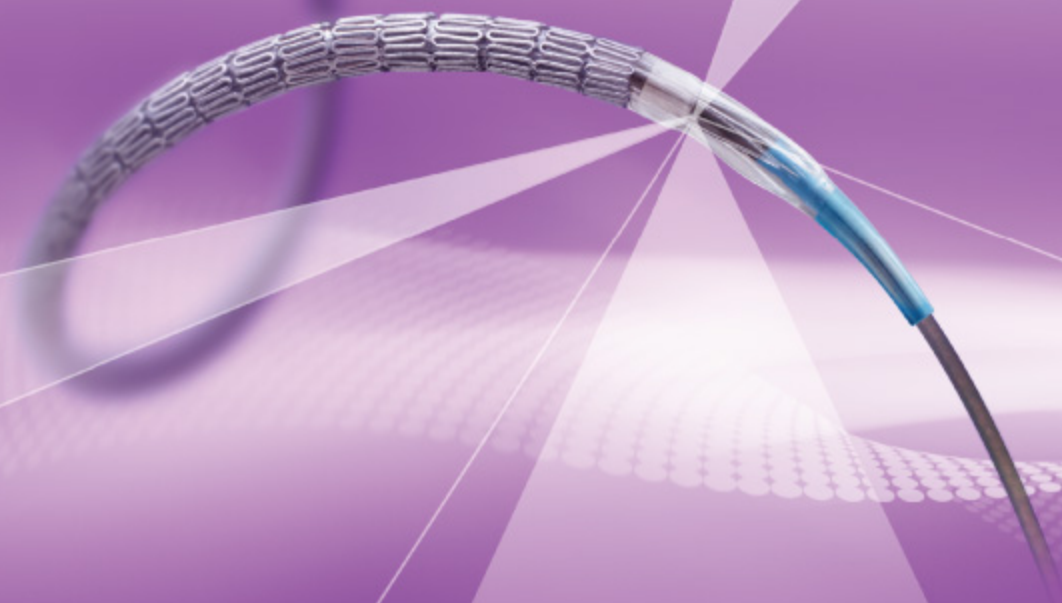
² ENDEAVOR Program: EI, EII, EII CA, EIII, EIV, EpK, E-Japan, E-Five, PROTECT



Endeavor Sprint

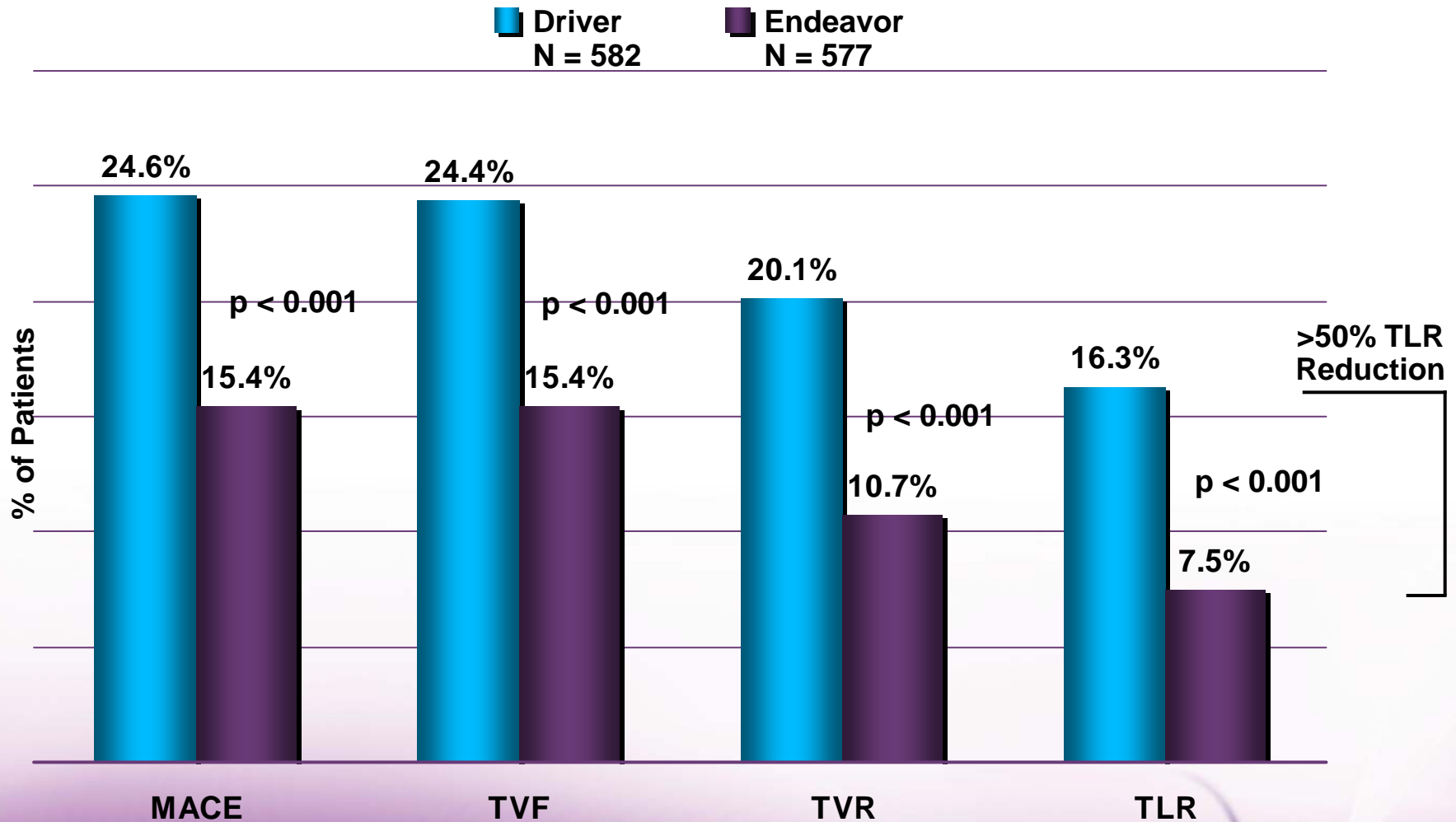
ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM

ENDEAVOR II 5 year Follow-Up



ENDEAVOR II: Durable Efficacy

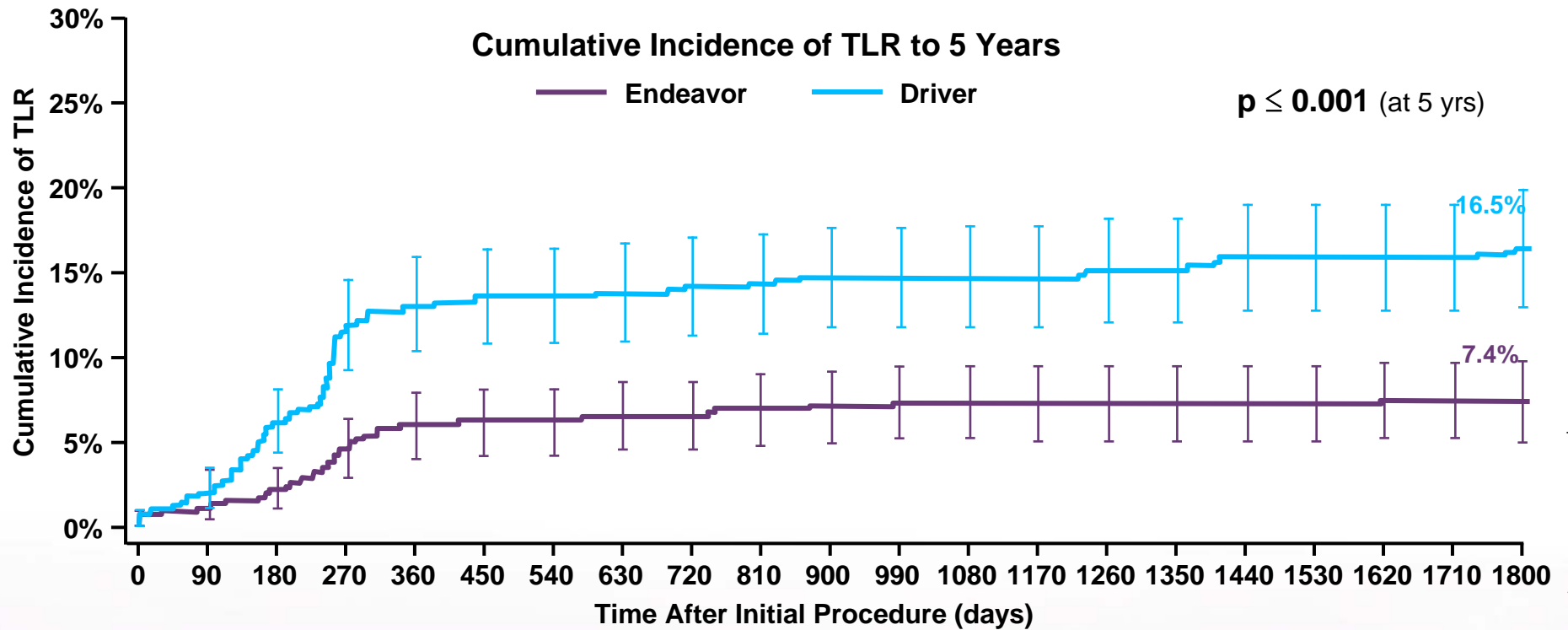
Sustained Clinical Performance Out to 5 Years



p values are unadjusted for multiple comparisons

Endeavor Sprint ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM

ENDEAVOR II: Low and Sustained TLR Rates to 5 Years



TLR	0	90	180	270	360	450	540	630	720	810	900	990	1080	1170	1260	1350	1440	1530	1620	1710	1800
Endeavor	597	595	584	575	552	538	536	534	529	529	522	519	516	515	513	509	508	505	499	494	491
# of Events	2	5	6	14	18	1	0	2	0	2	1	1	0	0	0	0	0	0	1	0	0
% CI	0.3	1.2	2.2	4.6	6.0	6.1	6.1	6.5	6.5	6.9	7.0	7.2	7.2	7.2	7.2	7.2	7.2	7.2	7.4	7.4	7.4
Driver	596	595	579	552	504	489	483	480	479	474	469	465	462	456	454	452	450	445	444	440	437
# of Events	1	12	24	33	7	3	0	1	2	1	2	0	0	0	2	0	4	0	0	0	3
% CI	0.2	2.2	6.3	11.9	13.2	13.7	13.7	13.9	14.2	14.4	14.8	14.8	14.8	14.8	15.2	15.2	15.9	15.9	15.9	15.9	16.5

p values are unadjusted for multiple comparisons.

Endeavor Sprint ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM

Pivotal Trials: DES Arms

Baseline Characteristics and Demographics

	ENDEAVOR II N = 598	TAXUS IV N = 662	SIRIUS N = 533
RVD (mm)	2.73	2.75	2.78
Lesion Length (mm)	14.0	13.4	14.4
Stent-to-lesion length ration	1.84	1.58	1.40
B2/C Lesions (%)	78.5	50.8	58.6
Diabetes Mellitus (%)	18.2	24.4	25.0
LAD (%)	43	40	44
Recommended Plavix/Ticlid LOT (month)	3	6	3
Inclusion 2.25 vessels	Yes	No	No

SIRIUS, Holmes et al., *Circulation*, 2004.

TAXUS IV, Stone et al., *Circulation*, 2004.

ENDEAVOR II trial: international enrollment; TAXUS IV and SIRIUS: US enrollment.

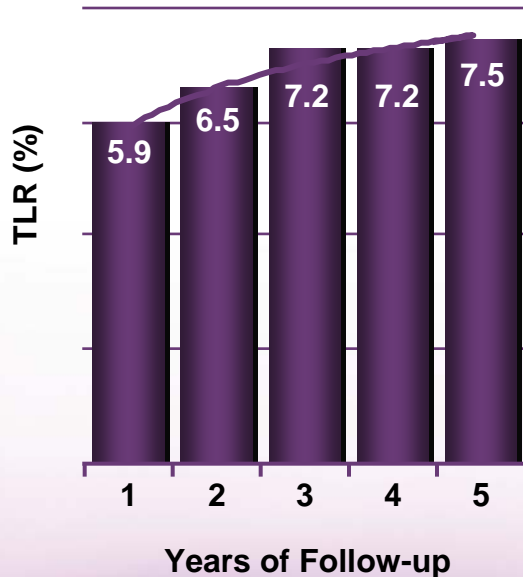
Endeavor Sprint ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM

Pivotal Trials TLR: DES Arms

*Endeavor's Durable Efficacy:
Trend to Plateau after 3 years*

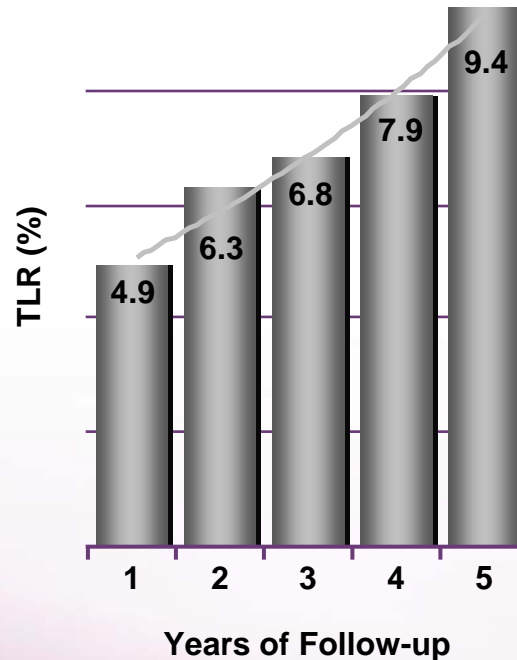
ENDEAVOR II
(n=577/598)

$R^2 = 0.9665$



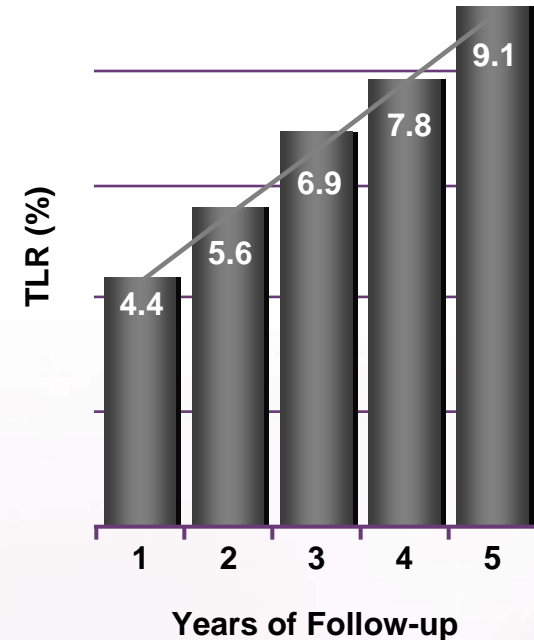
SIRIUS
(n=501/533)

$R^2 = 0.9762$



TAXUS IV
(n=618/662)

$R^2 = 0.9973$



SIRIUS, Holmes et al., *Circulation*. 2004.
TAXUS IV, Stone et al., *Circulation*. 2004.
ENDEAVOR II: International enrollment;
TAXUS IV & SIRIUS: US enrollment.

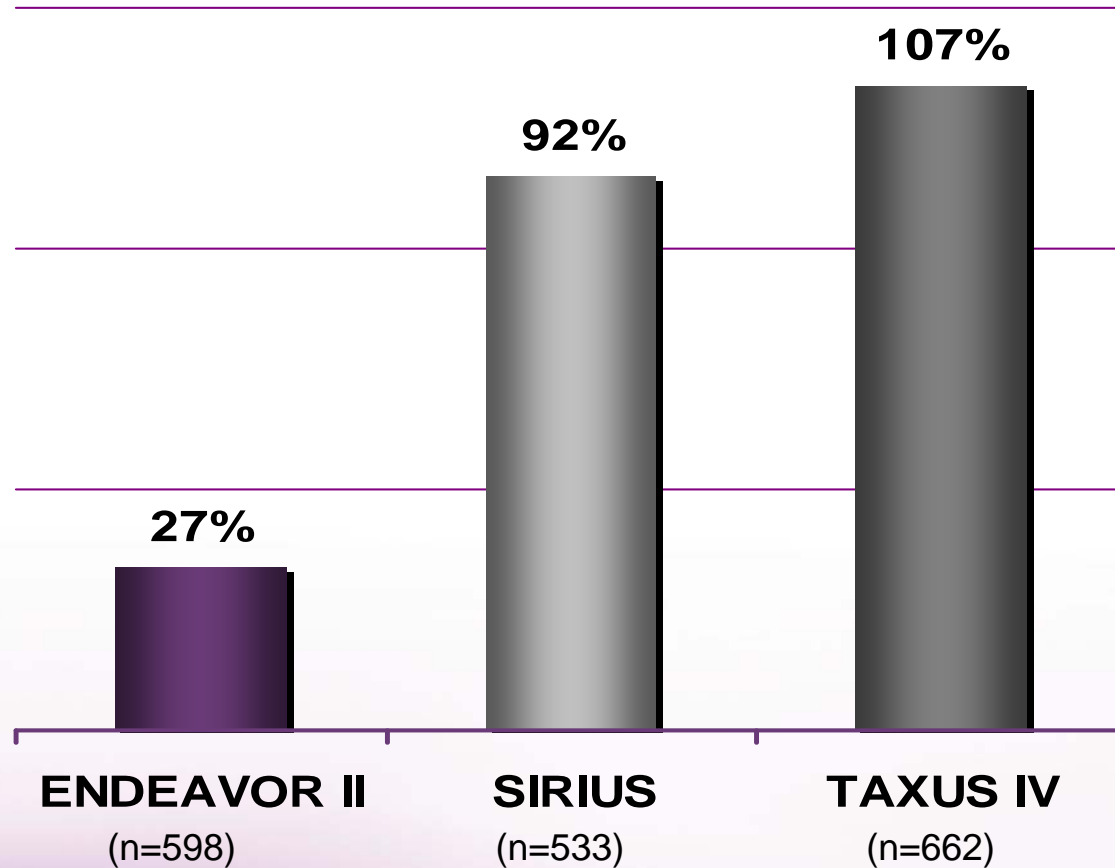
Data come from different trials and could differ in a head-to-head comparison.
 R^2 values calculated by Medtronic.
SIRIUS 6yr TLR = 11.9% (Presented at CRT, March 2009)

Endeavor Sprint ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM

Pivotal Trials TLR: DES Arms

Endeavor's Durable Efficacy:

Low TLR Rate Relative Increase from Year 1 to Year 5



SIRIUS Trial, Holmes et al, *Circulation* 2004

TAXUS IV, Stone et al, *Circulation* 2004

Data comes from different trials and could differ in a head-to-head comparison.

ENDEAVOR II: International enrollment; TAXUS IV & SIRIUS: US enrollment.

E II year 1 and year 5 TLR rates are 5.9% and 7.5% .

SIRIUS year 1 and year 5 TLR rates are 4.9% and 9.4%.

SIRIUS 6yr TLR = 11.9% (Presented at CRT, March 2009)

TAXUS IV year 1 and year 5 TLR rates are 4.4% and 9.1%.

Endeavor Sprint ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM

ENDEAVOR II: Safety

Sustained Clinical Performance at 5 Years

	Endeavor N = 577	Driver N = 582	p value
Death (all) – % (#)	6.2 (36)	7.6 (44)	0.418
Cardiac	3.1 (18)	3.6 (21)	0.745
MI (all) – % (#)	3.8 (22)	4.8 (28)	0.470
Q-wave	0.3 (2)	1.2 (7)	0.178
Non-Q-wave	3.5 (20)	3.6 (21)	1.000
Cardiac Death + MI (all) – % (#)	6.6 (38)	8.4 (49)	0.265

p values are unadjusted for multiple comparisons

Endeavor Sprint ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM

ENDEAVOR II: Safety

Low Rates of Stent Thrombosis at 5 Years

	Endeavor N = 577	Driver N = 582	p value
Stent Thrombosis (protocol)			
Stent Thrombosis (all) – % (#)	0.5 (3)	1.2 (7)	0.342
0-30 days	0.5 (3)	1.2 (7)	0.342
31-360 days	0.0 (0)	0.0 (0)	NA
361-1800 days	0.0 (0)	0.0 (0)	NA
Stent Thrombosis (ARC def/prob)			
Stent Thrombosis (all) – % (#)	0.9 (5)	1.5 (9)	0.421
0-30 days	0.5 (3)	1.2 (7)	0.342
31-360 days	0.2 (1)	0.2 (1)	1.000
361-1800 days	0.2 (1)	0.2 (1)	1.000

p values are unadjusted for multiple comparisons

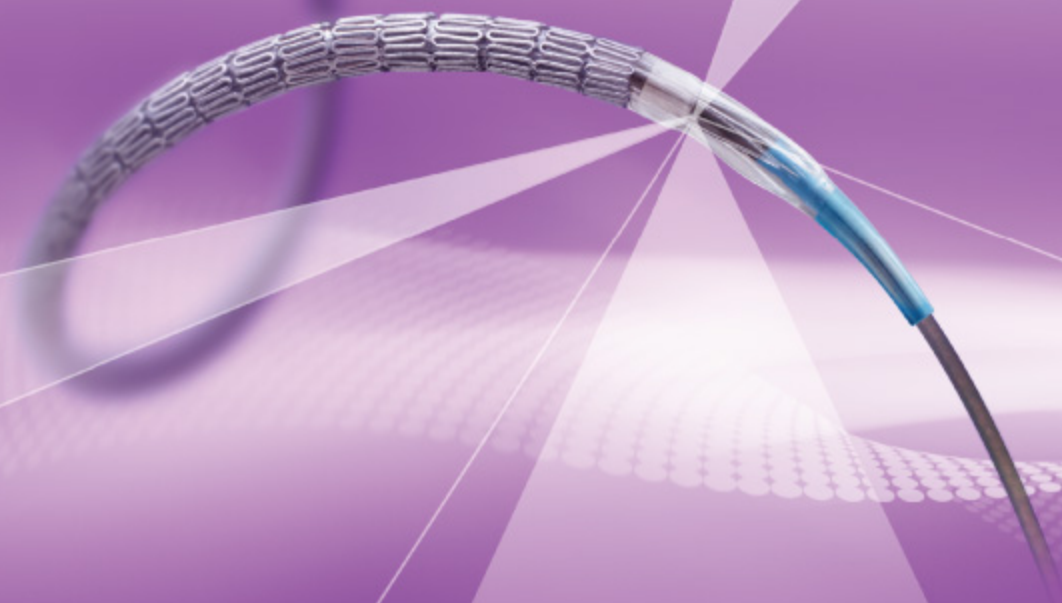
Endeavor Sprint ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM



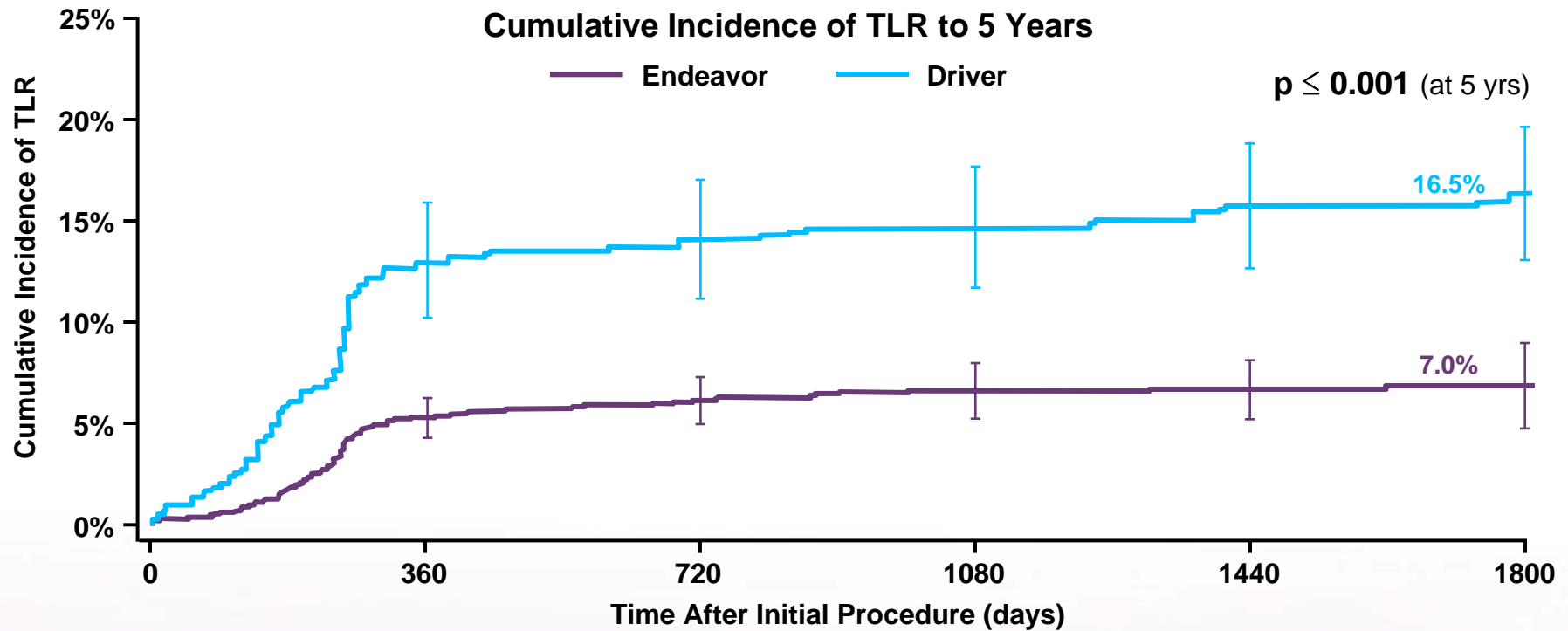
Endeavor Sprint

ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM

ENDEAVOR Pooled Efficacy & Safety to 5 years



ENDEAVOR Pooled: Significant TLR Reduction at 5yrs

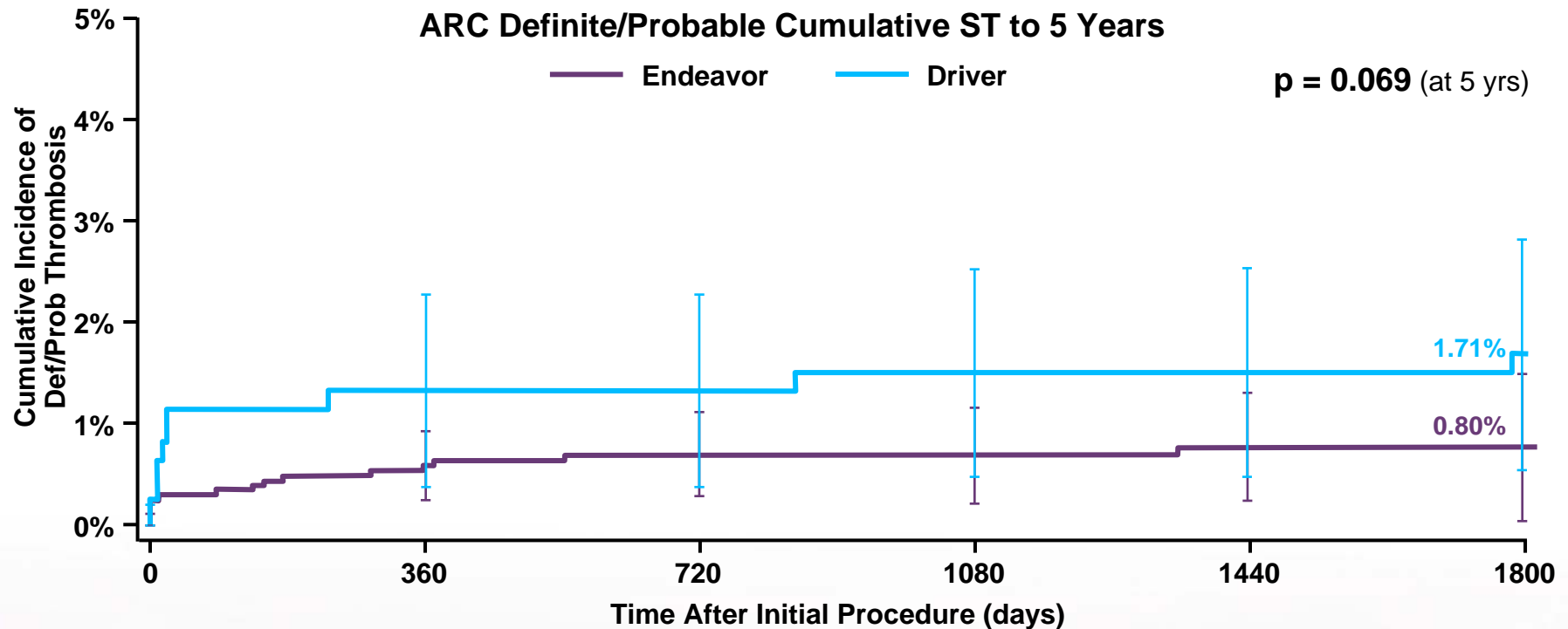


Days	0	360	720	1080	1440	1800
Endeavor	2132	2130	1901	1530	1120	1005
# of Events	2	111	16	6	1	1
% CI	0.09	5.43	6.24	6.74	6.82	6.98
Driver	596	595	489	474	456	445
# of Events	1	76	6	3	6	3
% CI	0.17	13.16	14.23	14.78	15.91	16.49

Pooled data used for analysis: EI 5 year, EII 5 year, EII CA 4 year, EIII 4 year, EIV 2 year, EpK 2 year.
p values are unadjusted for multiple comparisons. Pooled Kaplan-Meier analysis.

Endeavor Sprint ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM

ENDEAVOR Pooled: Very Low ST Rates to 5 Years

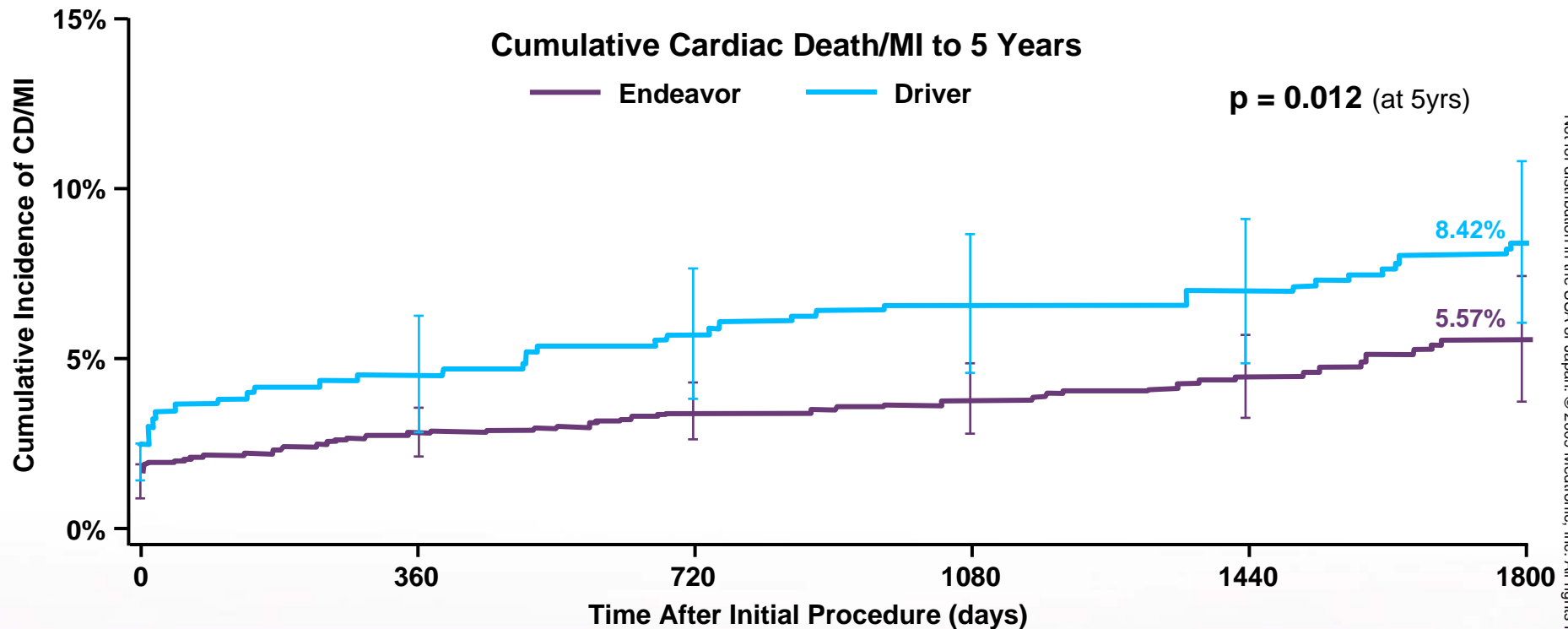


Days	0	360	720	1080	1440	1800
Endeavor	2132	2131	2037	1656	1222	1089
# of Events	1	12	2	0	1	0
% CI	0.05	0.62	0.71	0.71	0.80	0.80
Driver	596	595	570	559	543	538
# of Events	1	7	0	1	0	1
% CI	0.17	1.35	1.35	1.52	1.52	1.71

Pooled data used for analysis: EI 5 year, EII 5 year, EII CA 4 year, EII 4 year, EIV2 year, EpK 2 year.
p values are unadjusted for multiple comparisons. Pooled Kaplan-Meier analysis.

By Intention To Treat (ITT), an Endeavor patient in EIII had a ST at 1349 days. Per ARC definition, this uncensored event is included in the primary ITT analysis although the event may not have been related to the Endeavor stent

ENDEAVOR Pooled: Significant Reduction in CD/MI vs BMS at 5 yrs



Days	0	360	720	1080	1440	1800
Endeavor	2132	2102	2002	1622	1190	1059
# of Events	30	30	12	5	8	7
% CI	1.41	2.83	3.42	3.82	4.48	5.57
Driver	596	581	555	544	529	523
# of Events	15	12	7	5	2	8
% CI	2.52	4.54	5.75	6.62	6.98	8.42

Pooled data used for analysis: EI 5 year, EII 5 year, EII CA 4 year, EIII 4 year, EIV 2 year, EpK 2 year.
p values are unadjusted for multiple comparisons. Pooled Kaplan-Meier analysis.

Endeavor Sprint ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM

DES Pooled Programs

Baseline Characteristics and Demographics

	Endeavor DES ¹ E I, E II, E II CA, E III, E IV (n = 2132)	Cypher DES ² RAVEL, SIRIUS, E-SIRIUS, C-SIRIUS (n = 878)	Taxus DES ² TAXUS I, II, IV, V (n = 1400)	Xience V/Promus ³ SPIRIT II, SPIRIT III (n = 892)
Age (year)	62	62	62	63
Male sex (%)	74	72	72	70
Diabetes (%)	23	22	25	27
Hypertension (%)	69	64	72	73
Hyperlipidemia (%)	81	71	70	71
LAD (%)	44	47	40	41
RVD (mm)	2.73	2.72	2.70	2.75
Lesion length (mm)	14.6	13.8	14.6	14.3
DAPT (months)	≥3 ¹	≥3	≥6	≥6

¹Meredith *et al.*, EuroPCR 2008. Note: DAPT≥6 mo in E IV.

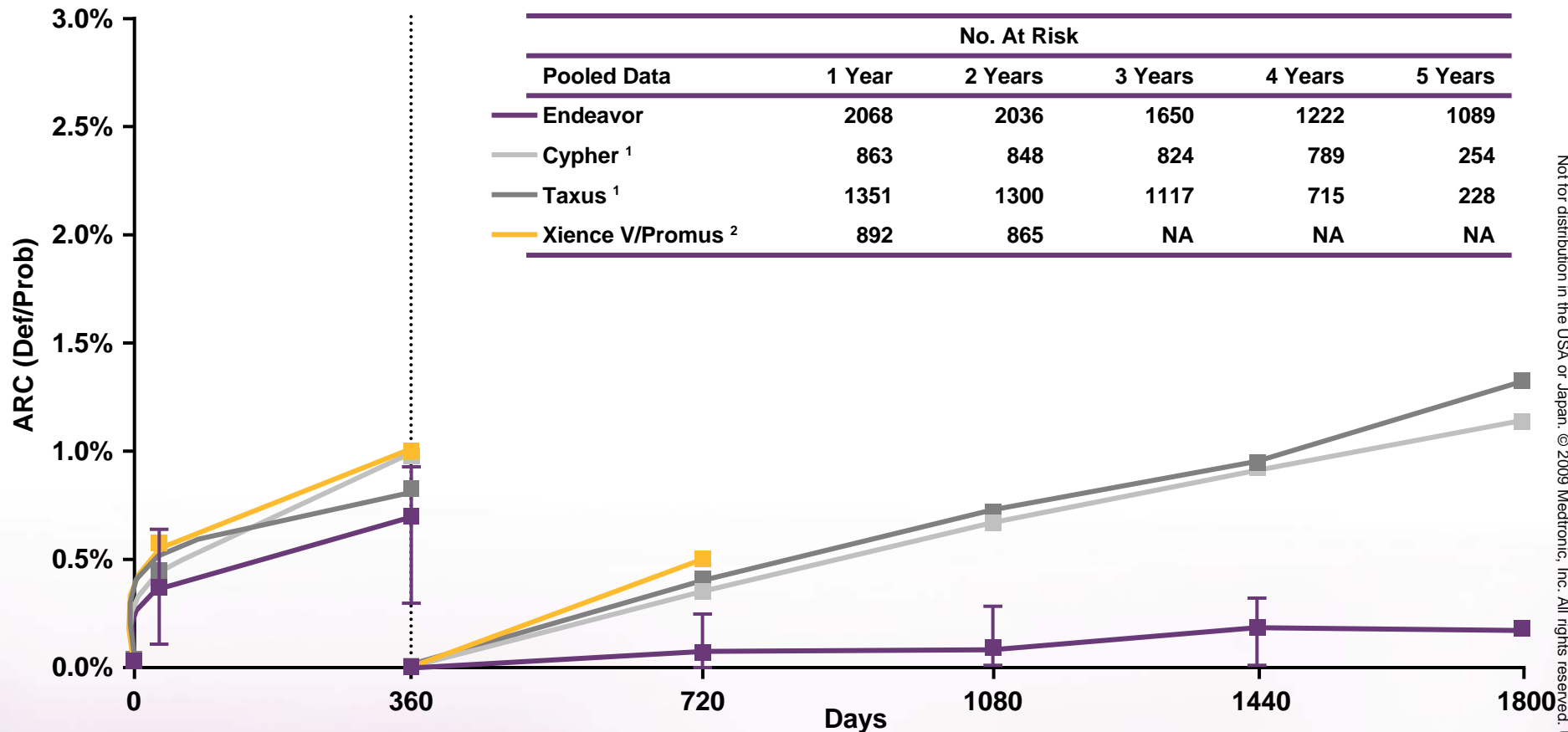
²Mauri L *et al.*, *N Engl J Med*, 356:1020–1029, 2007. Note: TAXUS V was a post-market trial.

³Serruys PW *et al.*, ACC.08. Stone GW *et al.*, EuroPCR 2008. Note: SPIRIT II and SPIRIT III included single/dual *de novo* lesions. Xience V/Promus data is a weighted average from SPIRIT II and SPIRIT III.

Data come from different trials and may differ in a head-to-head comparison.

Pooled DES Data

ARC Definite/Probable ST to 5 Years



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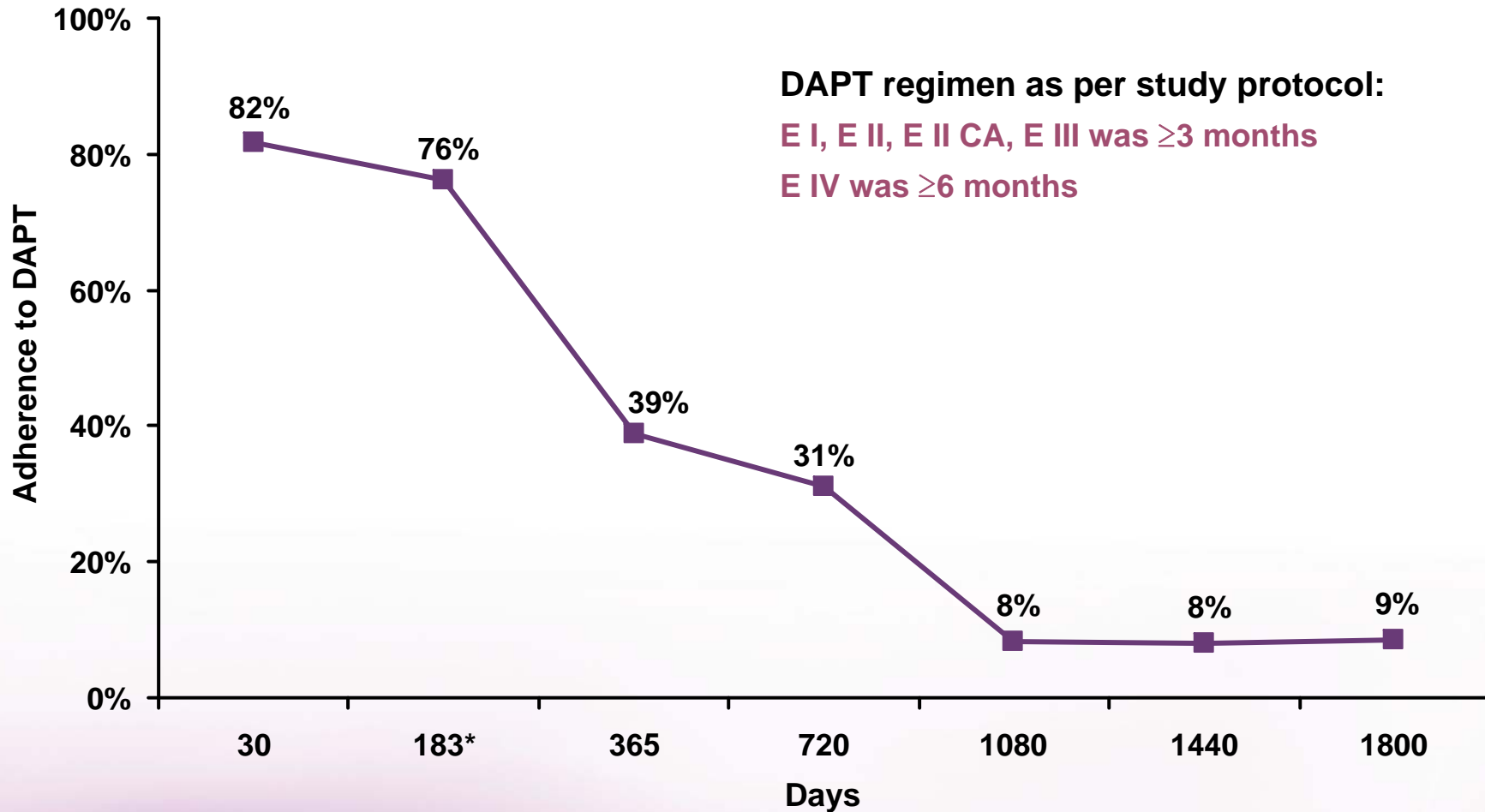
- Stent thrombosis is a low-frequency event that current DES clinical trials are not adequately powered to fully characterise.
- The true rate of VLST is unknown; however, pooled data exists from the various DES programs that are shown here.

¹Mauri L et al., *N Engl J Med.* 2007;356:1020-1029.

²Serruys PW et al., ACC 08. Stone GW et al., EuroPCR 2008.

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Excellent Safety Despite Only 39% of Endeavor Patients on DAPT by 1 Year



*6 month data not available for EI.

Pooled data used for analysis: EI 5 year, EII 5 year, EII CA 4 year, EII 4 year, EIV 2 year, EpK 2 year.

DAPT usage based on case report forms.

The optimal duration of dual antiplatelet therapy, specifically clopidogrel, is unknown and DES thrombosis may still occur despite continued therapy.

Endeavor Sprint ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM

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 - Significant reduction in CD/MI versus BMS (Endeavor 5.6% vs 8.4%, $p = 0.012$)
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 - Endeavor provides long-term reassurance for ACS patients

¹ ENDEAVOR Pooled Analysis: EI, EII, EII CA, EIII, EIV, EpK

² ENDEAVOR Program: EI, EII, EII CA, EIII, EIV, EpK, E-Japan, E-Five, PROTECT

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