ACURATE TA™ CE Mark Trial Results – TA 90

TA CE Mark (n=90)

- Symetis conducted a CE Mark trial at 5 sites in Germany between November 2009 and August 2011 enrolling 90 patients with severe aortic stenosis
- The primary endpoint is 30-day mortality
- Secondary performance endpoints include procedure success and device success at 30 days, 6 months and 1 year
- Secondary safety endpoints are incidence of MACCE out to 5 years
- Survival at 2 years is 73.0%
- Patients are currently returning for 3Y follow-up

Baseline patient characteristics

	TA 90
n=	90
Age [years]	83.4 ± 4.1
Logistic EuroSCORE [%]	20.2 ± 8.7
STS Score [%]	7.9 ± 4.6
NYHA Class III/IV [%]	100
Female [%]	69.0
Mean aortic gradient [mmHg]	50.7 ± 14.6
Mean effective orifice area (cm2)	0.6 ± 0.2

Procedure success

Implant procedures [n]	90
Procedural success [n/%]	
■ 2 VnV*	85 / 94.4
■ 3 conversions to SAVR**	
New pacemaker required by DC [n/%]	10 / 11.1
Average implant time: DS in, DS out [min]	4

*VnV with SAPIEN TA after inadequate BAV leading to incomplete expansion of ACURATE TA
*VnV with SAPIEN TA for too high placement due to premature deployment of ACURATE TA
**Conversion for significant leak resistant to treatment by VnV bailout with 2 SAPIEN TA
**Conversion after annular dissection
**Conversion after coronary occlusion

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Efficacy

	Baseline	30D	12M
n=	90	*80	**68
NYHA Class I/II [%]	0.0	81.0	92.0
Mean gradient [mmHg]	50.7 ± 14.6	11.6 ± 4.6	10.4 ± 4.9
Mean AVA/EOA [cm2]	0.6 ± 0.2	1.4 ± 0.3	1.5 ± 0.6
PVL +2 (moderate) [n/%]		2 / 2.9	2 / 3.3
PVL >+2 [n/%]		0 / 0.0	0 / 0.0

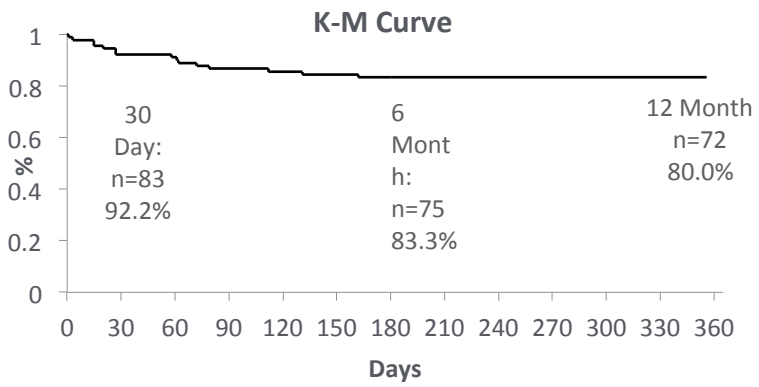
*7 deaths, 2 VnV, 1 conversion
** 18 deaths, 1 VnV, 3 consent withdrawals

Safety

	30D	12M
All-cause mortality [n/%]	7 / 7.8	18 / 20.0
Stroke [n/%]	3 / 3.3	5 / 5.5
MI [n/%]	*2 / 2.2	*2 / 2.2
**Re-intervention post-DC [n/%]	0 / 0.0	0 / 0.0
30D VARC Device Success [n/%]	84 / 93.3	
30D VARC Combined Safety [n/%]	16 / 17.8	

*2 MI in one patient due to pre-treatment PCI and stent thrombosis 5 days post-TAVI
**No further re-intervention performed post-procedure

TA90 Survival



Freedom

Freedom from Death (n=90)			
Visit	30D	6M	12M
Yes (n)	83	75	72
No Death (%)	92.2	83.3	80.0

Freedom from MACCE (n=90)			
Visit	30D	6M	12M
Yes (n)	76	71	68
No MACCE (%)	84.4	78.0	75.6

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