The Demonstr8 study*

Patients with ischemic myocardial symptoms related to de-novo lesions in native coronary arteries evaluated with OCT

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Randomization 1:1

Cre8™ 19 pts	ABBOTT Co-Cr BMS 19 pts

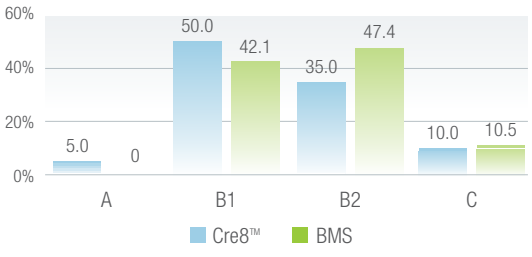
	1M	3M	1Y
Clinical FU	▼	▼	▽
Angiographic/OCT FU	▲ (BMS)	▲ (Cre8)	

Primary endpoint: Cre8™ percentage of sections with RUTTS** score < 30% @ 3-month non inferior to Vision/Multilink percentage of sections with RUTTS score < 30% @ 1-month

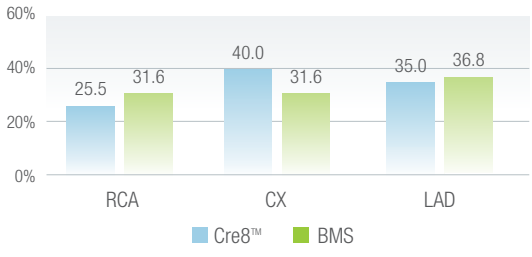
Baseline Clinical Characteristics & Risk Factors

	Cre8™	BMS	p value
Mean Age (yrs)	69.2±8.6	65.0±8.6	ns
Clinical Status			
Silent ischemia	31.6% (6/19)	26.3% (5/19)	ns
Stable angina	57.9% (11/19)	47.4% (9/19)	ns
Unstable angina	5.3% (1/19)	15.8% (3/19)	ns
NSTEMI	5.3% (1/19)	10.5% (2/19)	ns
Patients risk factors			
Diabetes	26.3% (5/19)	15.8% (3/19)	ns
Hypertension	84.2% (16/19)	68.4% (13/19)	ns

Lesion classification ACC/AHA



Vessel Location



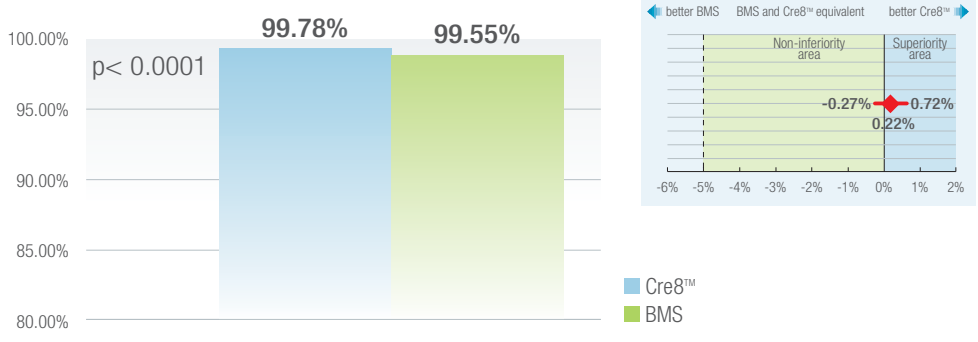
abluminal reservoir technology

The images shown within this document are of a purely illustrative nature and are not intended to depict reality.

*LBT @ EuroPCR 2013 - **RUTTS = Ratio of Uncovered to Total Stent Struts Per Cross Section

Primary Endpoint Results

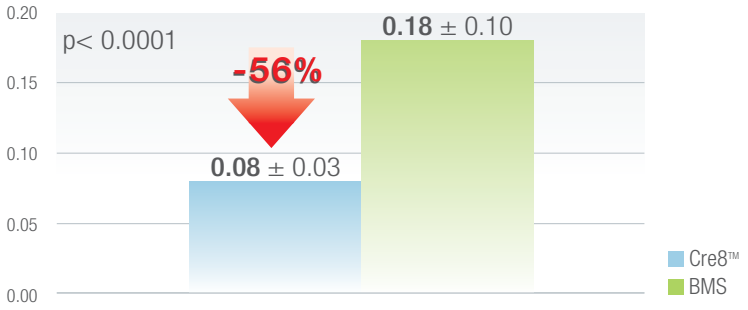
RUTTS score <30%



Cre8™ is statistically non inferior to BMS in terms of struts coverage (RUTTS score<30%; 3-month for Cre8™ vs. 1-month for BMS; p<0.0001).

Secondary Endpoint Results

Mean neointima thickness



Cre8™ at 3-month has a statistically lower and even neointima thickness compared to BMS at 1-month (p<0.0001, standard deviation of 0.03 vs 0.10).

Conclusions

- The Demonstr8 randomised trial has proven that Cre8™ is non-inferior to BMS in terms of strut coverage (RUTTS score < 30%) meeting the study primary endpoint (99,78% at 3-month vs. 99,55% at 1-month; p<0.0001).
- The statistical superiority of Cre8™ vs BMS in reducing neointima thickness (p<0.0001) shows that the high Cre8™ efficacy is achieved without impacting on safety (0,08 ± 0,03 at 3-month vs. 0,18 ± 0,10 at 1-month; p<0.0001).
- Being strut coverage the most powerful predictor of stent thrombosis, the OCT results of the Demonstr8 randomised trial show that it could be safe for Cre8™ to stop DAPT duration at 3-month. Further studies are needed to clinically confirm it.

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