stellarex™
Drug-coated
Angioplasty Balloon

ILLUMENATE European Randomized Trial

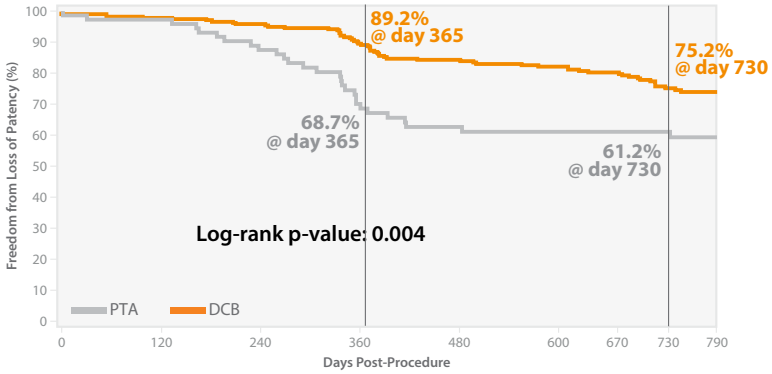
2-Year Results

Presented by: Marianne Brodmann, MD, VIVA; Sep. 13, 2017, Las Vegas, NV

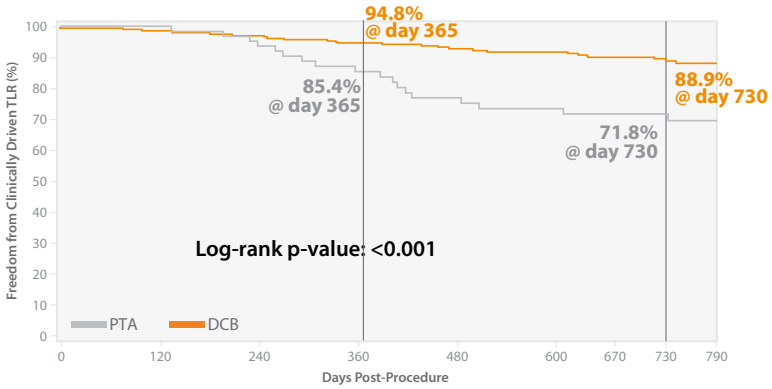
Key Outcomes.

Independent assessment and adjudication of outcomes

Primary Patency Rate: 75.2% at Day 730



Freedom from CD-TLR: 88.9% at Day 730



Key Baseline Characteristics

Demographics	Stellarex N = 222 patients	PTA N = 72 patients	p-value
Age (yrs.)	66.8 ± 9.2 (222)	69.0 ± 8.6 (72)	0.079
Male	72.1% (160/222)	68.1% (49/72)	0.514
RCC ≥ 3*	84.6% (187/221)	78.9% (56/71)	0.260
Diabetes	37.4% (83/222)	36.1% (26/72)	0.846
Previous or current smoker	89.2% (198/222)	83.3% (60/72)	0.188

Lesion (per core lab†)	Stellarex N = 254 lesions	PTA N = 79 lesions	p-value
Lesion length (cm)	7.2 ± 5.2 (250)	7.1 ± 5.3 (79)	0.878
Total occlusions	19.2% (48/250)	19.0% (15/79)	0.967
Severe calcification	12.7% (32/251)	10.1% (8/79)	0.533
Baseline diameter stenosis %	78.7 ± 16.0 (250)	80.8 ± 15.7 (79)	0.297

Procedural (per core lab†)	Stellarex N = 254 lesions	PTA N = 79 lesions	p-value
Pre-dilatation*	100% (254/254)	98.7% (78/79)	0.237
Flow-limiting dissection	0.4% (1/247)	0.0% (0/77)	1.0
Bail-out stent placement*	15.4% (39/254)	11.4% (9/79)	0.381
Post-procedure diameter stenosis (%)	23.6 ± 11.4 (251)	23.1 ± 10.3 (78)	0.724

† SynvaCor, Springfield, IL

* Site reported data

Objective

Demonstrate the safety and efficacy of the Stellarex™ Drug-coated Angioplasty Balloon (DCB) vs. standard PTA for treatment of the superficial femoral and/or popliteal arteries.

Design

- Prospective, randomized (3 DCB:1 PTA), multicenter study
- Follow-up at pre-discharge, 1, 6, 12, 24, 36, 48 and 60 months

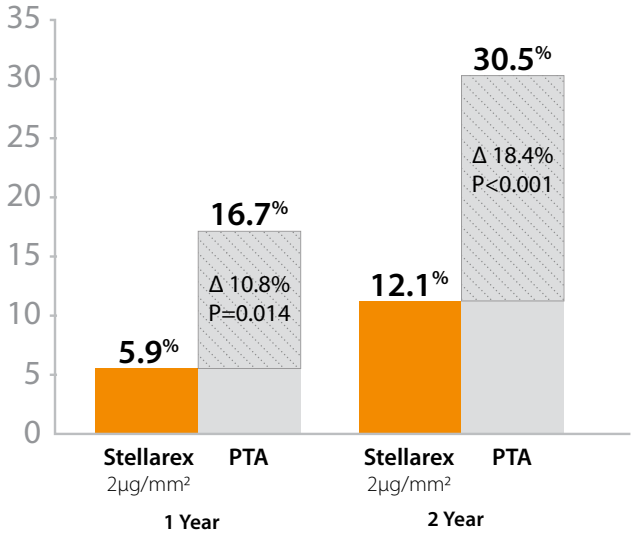
Methods

- Independent assessment and adjudication by Angiographic and Duplex Ultrasound Core Labs, Clinical Events Committee, and Data Safety Monitoring Board
- Data monitoring with 100% source data verification
- 294 randomized patients (222 DCB, 72 PTA) enrolled at 18 sites

Proven Durability.

Clinically-Driven TLR at 1 and 2 Years

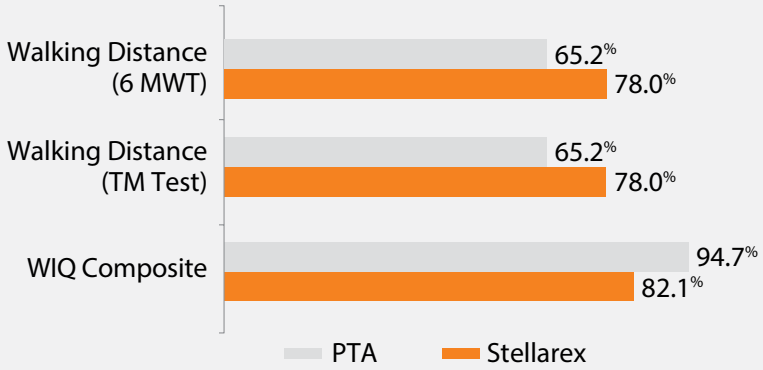
Treatment effect increased from 1 to 2 years



> "Stellarex is the first low-dose DCB to demonstrate a significant treatment effect at 2 years."
>
> — Marianne Brodmann, MD

Percent of Patients with Improvements at 2-Years vs. Baseline

The DCB cohort maintained similar outcomes with 60% fewer reinterventions



Key 2-Year Outcomes

	DCB	PTA	p-value
Primary Patency (Exact Rates)	75.9% (145/191)	61.0% (36/59)	0.025
All-Cause Death	6.5% (13/199)	5.1% (3/59)	1.000
Major Target Limb Amputation	0.0% (0/188)	0.0% (0/58)	1.000
Clinically-Driven TLR	12.1% (23/190)	30.5% (18/59)	<0.001

Numbers are % (n/N). Includes all events reported through 790 days post-procedure.

Conclusions

- Primary safety and efficacy endpoints at 12 months were met and superiority was demonstrated
- Data confirms durable outcomes are achieved with Stellarex DCB
- Stellarex is a low-dose DCB proven safe and effective in common to complex patients
- Durable treatment effect demonstrated with no indication of late catch-up at 2 years

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