

ILLUMENATE Pivotal randomized trial

4-year results

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Presented by: Sean Lyden, MD LINC 2020, Leipzig, Germany, January 28, 2020.

Key outcomes

Independent assessment and adjudication of outcomes

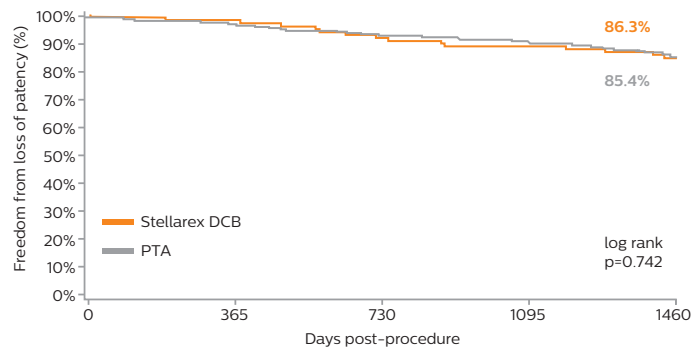
Key 4-year outcomes

Clinically relevant lower CD-TLR and no mortality signal at 4 years

	Stellarex	PTA	p-value
CD-TLR	28.2%	34.1%	0.343
Composite safety endpoint*	71.2%	65.9%	0.399
All-cause death	15.6%	15.2%	0.929
Cardiovascular death	5.6%	8.3%	0.409
Target limb major amputation	0.7%	0.0%	1.000

Survival through 4 years

No difference in mortality through 4 years



ILLUMENATE Pivotal cumulative mortality (exact rates): post-hoc analysis

No mortality signal through 4 years

All cause mortality	DCB	PTA	p-value
12 months	2.5% (5/200)	2.0% (2/100)	1.000
24 months	6.5% (13/200)	8.1% (8/99)	0.615
36 months	9.5% (19/199)	10.4% (10/96)	0.814
48 months	15.6% (30/192)	15.2% (14/92)	0.929

Conclusions

- ILLUMENATE Pivotal 4 year data builds on the robust, consistent long-term data of the Stellarex program
- 4 year data demonstrates clinically relevant lower CD-TLR rates of Stellarex DCB compared with PTA
- Safety analysis shows no mortality signal with Stellarex DCB at 4 years
- Favorable safety and efficacy is applicable within an extensive complex patient cohort, with high proportion of severely calcified lesions
- Stellarex is the only low-dose DCB to demonstrate sustained treatment effect and safety profile through 4 years

Key baseline characteristics

Complex patients with higher rates of comorbidities and severe calcium

Lesion (per core lab†)	Stellarex N = 200	PTA N = 100	p-value
Lesion length (cm)	8.0 ± 4.5	8.9 ± 4.6	0.105
Total occlusions	19.0%	18.0%	0.834
Severe calcification	43.9%	43.0%	0.877
Baseline diameter stenosis (%)	73.9 ± 16.9	74.8 ± 17.0	0.673

Demographics*	Stellarex N = 200	PTA N = 100	p-value
Age (yrs.)	68.3 ± 10.3	69.8 ± 9.8	0.225
Female	44.0%	36.0%	0.185
RCC ≥ 3	68.5%	65.0%	0.542
Diabetes	49.5%	52.0%	0.683
Current or previous smoker	84.0%	75.0%	0.061
ABI	0.75 ± 0.21	0.76 ± 0.2	0.508
Renal Insufficiency	18.0%	16.0%	0.666
BMI ≥ 30	39.5%	30.0%	0.107

Procedural (per core lab†)	Stellarex N = 200	PTA N = 100	p-value
Pre-dilatation*	100%	100%	N/A
Flow-limiting dissection	0.0%	0.0%	N/A
Bail-out stent placement*	6.0%	6.0%	1.0
Post-procedure diameter stenosis (%)	25.2 ± 11.7	27.4 ± 10.1	0.107
Study device inflation time* (min/lesion)	3.9 ± 2.0	3.7 ± 2.3	0.557

† Beth Israel Deaconess Medical Center, Boston, MA

*Site reported data

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