Lutonix
SFA Long Lesion Study
Two Year Results

A Prospective, Multicenter, Single-Arm Trial with the Lutonix® Drug Coated Balloon for Treatment of Long Lesions in Femoropopliteal Arteries

M. Banyai ,MD

Disclosure

M. Banyai, M.D.

I have the following potential conflicts of interest to report:

X Consulting

Employment in industry

Stockholder of a healthcare company

Owner of a healthcare company

Other(s)

I do not have any potential conflict of interest

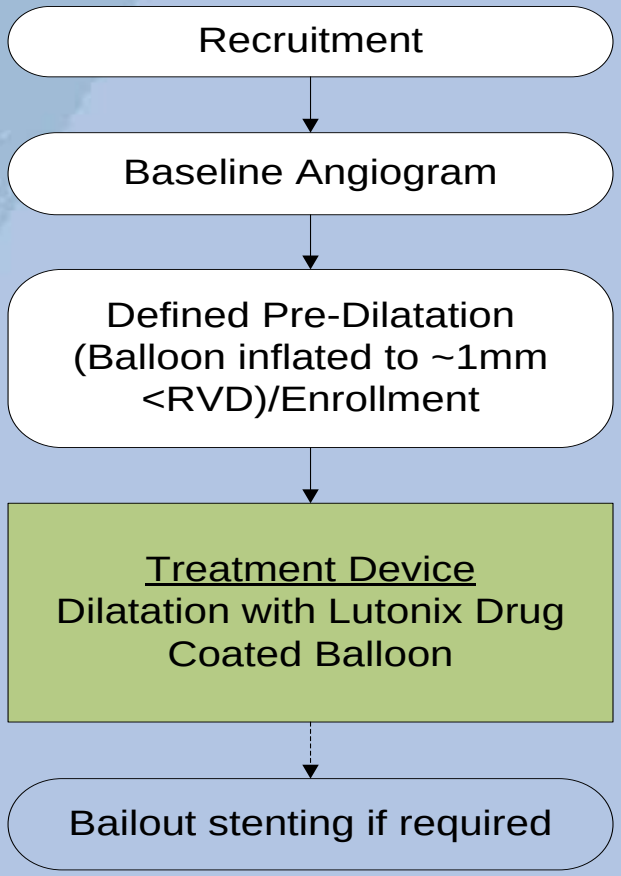
Conflicts of Interest

Consultant to Bard

Study Design

Study Design	Single Arm, Prospective, EU, Multicenter, Safety and Effectiveness Study
Objective	To investigate the safety, clinical use, and outcomes of the Lutonix Drug Coated Balloon for treatment of Long Lesions (≥ 14 cm) in the femoropopliteal artery
Number of patients/sites	118 DCB patients – 14 sites
Inclusion Criteria	Rutherford Class: 2-4, ≥ 70% stenosis lesion, Lesion Length ≥ 14 cm, Vessel diameter of 4-7 mm
Exclusion Criteria	Life expectancy < 1 yr

Single-Arm Study - Levant 2 Design



Patient Follow-Up

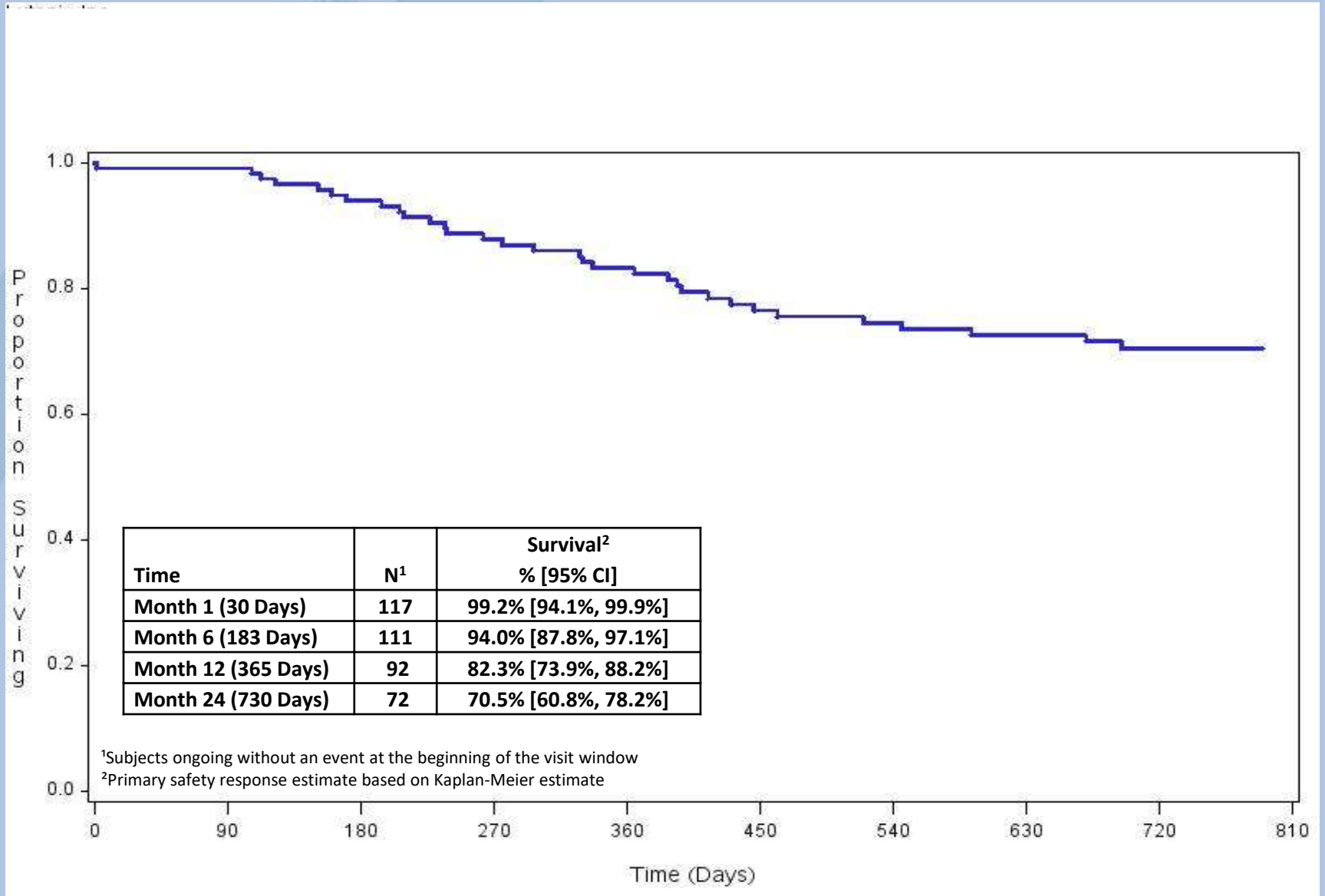
EVENT	Pre-Procedure (Baseline)	Procedure	Post-Procedure	1 Month	6 Month	12 Month	24 Month	36 Month	Repeat Angio/Revasc
Inclusion/Exclusion Criteria	√	√							
Informed Consent	√								
Medical History	√								
Physical Exam	√		√	√	√	√	√		√
Medication Compliance	√			√	√	√	√	√	√
Resting ABI	√		√	√	√	√	√		√
Rutherford Classification	√				√	√	√		√
WIQ & EQ5D Questionnaires	√				√	√	√		
Angiogram		√							√
Adverse Event Monitoring		√	√	√	√	√	√	√	√
Duplex Ultrasound			√		√	√	√		

AEs CEC Adjudicated

Demographics / Procedural Information

Description	Lutonix Long Lesion Study DCB Subjects
Age (Years), Mean ± SD (n)	67.6 ± 9.23 (118)
BMI ≥30 kg/m^2 (n/N)	26.3 % (30/114)
Diabetes	36.4% (43/118)
Baseline Target Limb Rutherford Grade, % (n/N)	
2	24.1% (28/116)
3	69.0% (80/116)
4	5.2% (6/116)
Baseline ABI of Target Limb, Mean ± SD (n)	0.69 ± 0.26 (111)
Highest TASC Classification, % (n/N)	
B	0.8% (1/118)
C	**77.1% (91/118)**
D	**22.0% (26/118)**
Total Target Lesion Length (mm), Mean ± SD (n)	212.5 ± 68.32 (117)
Maximum Lesion Length (mm)	**450mm**
Balloons per Subject, Mean ± SD (n) / Range	2.2 ± 0.62 (118) / (1.0, 4.0)
CTO, % (n/N)	**52.1% (61/117)**
RVD (mm), Mean ± SD (n)	4.7 ± 0.76 (117)
Calcification, % (n/N)	**88.1% (104/118)**
Severe Calcification	21.2% (22/104)

Freedom from Primary Safety Events*



Time	N[1]	Survival[2] % [95% CI]
Month 1 (30 Days)	117	99.2% [94.1%, 99.9%]
Month 6 (183 Days)	111	94.0% [87.8%, 97.1%]
Month 12 (365 Days)	92	82.3% [73.9%, 88.2%]
Month 24 (730 Days)	72	70.5% [60.8%, 78.2%]

[1]Subjects ongoing without an event at the beginning of the visit window
[2]Primary safety response estimate based on Kaplan-Meier estimate

*Composite of freedom from all-cause peri-procedural (≤30 day) death and freedom at 1 year from the following: index limb amputation (above or below the ankle) and index limb re-intervention.

Safety Profile Comparison to Levant 2

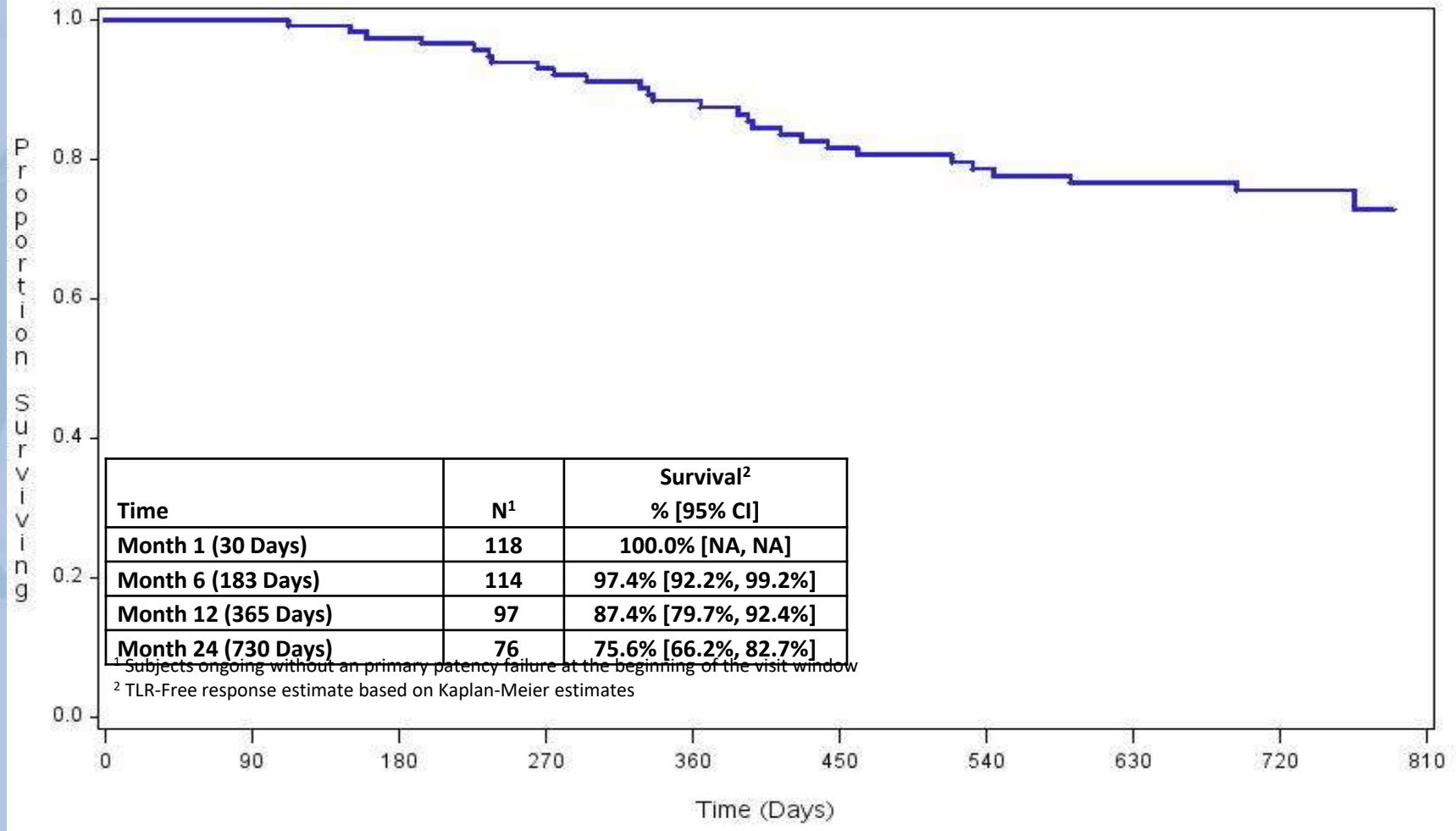
Freedom From	Long Lesion Study % (n/N)	LEVANT 2 Study DCB % (n/N)
All Cause Death	94.5% (103/	% (257/278)
Major Amputation	98.1%	99.6% (260/261)
Minor Amputation	9	99.6% (259/260)
TVR	% (78/	78.5% (208/265)

Freedom	sion Study % (n/N)	LEVANT 2 Study DCB Subjects % (n/N)
Vas mplicati 30 day	97.4% (112/115)	95.34.7% (295/308)

3.5x Longer Lesions with Similar Safety Profile

Low 2.6% Vascular Complications Rate

Freedom from TLR – 2 Year



Time	N[1]	Survival[2] % [95% CI]
Month 1 (30 Days)	118	100.0% [NA, NA]
Month 6 (183 Days)	114	97.4% [92.2%, 99.2%]
Month 12 (365 Days)	97	87.4% [79.7%, 92.4%]
Month 24 (730 Days)	76	75.6% [66.2%, 82.7%]

[1] Subjects ongoing without an primary patency failure at the beginning of the visit window

[2] TLR-Free response estimate based on Kaplan-Meier estimates

Clinical Benefit Improvement

Assessment	From Baseline Improvement at 24m
Rutherford	~80% of Subjects Improved by at Least One Category >60% of Subjects Improved by at Least Two Categories
ABI	35% Improvement

Lutonix Long Lesion vs. Zilver PTX

	Long Lesion Study	Zilver PTX
Age (Years), Mean ± SD (n)	67.6 ± 9.23 (118)	66.9 ± 9.5 (110)
Male, % (n/N)	73.7% (87/118)	74.5% (82/110)
Hypertension% (n/N)	86.4% (102/118)	82.7% (91/110)
Hypercholestermia% (n/N)	38.1% (45/118)	62.7% (69/110)
Any Diabetes % (n/N)	36.4% (43/118)	39.1% (43/110)
Type 1	0.8% (1/118)	9.3% (4/43)
Type 2	35.6% (42/118)	90.7% (39/43)
Smoking % (n/N)	70.3% (83/118)	79.1% (87/110)
Current Smoker	41.5% (49/118)	39.1% (43/110)
Past Smoker	28.8% (34/118)	40.0% (44/110)
Renal Disease % (n/N)	27.1% (32/118)	13.6% (15/110)
Any Calcification% (n/N)	88.1% (104/118)	86.2% (100/116)
Severe Calcification	21.2% (22/104)	17.2% (20/116)

Lutonix Long Lesion vs. Zilver PTX

Kaplan- Meier Freedom From	Long Lesion Study (Mean length 212.5±68.3mm / Range 100.0, 450.0)	Zilve (Lesion 240mm)
TLR (12 months)	87.4%	75.6%
TLR (24 months)		71.3%

DES LIKE OUTCOMES!

Conclusions

- Complex Long Lesions:
  - Lesion Lengths Up to **450mm**
  - **88% Calcification**
    - **21% Severely Calcified**
  - **99.1% TASC C and D Lesions**
- Similar Safety Profile to Levant 2
  - **Low (2.6%) Vascular Complications Rate**
- Rutherford Category Improvement
  - ~80% of Subjects Improved by at Least One Category
  - >60% of Subjects Improved by at Least Two Categories
- Higher Freedom From TLR at 12 and 24 Months than Zilver PTX

DES LIKE OUTCOMES!

Safety Profile

Freedom From	Long Lesion Study % (n/N)
All Cause Death	94.5% (103/109)
Major Amputation	98.1% (104/106)
Minor Amputation	98.1% (103/105)
TVR	73.6% (78/106)

Freedom From	Long Lesion Study % (n/N)
Vascular Complications 30 days	97.4% (112/115)

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