LUTONIX® DCB Interim 24 Month Outcomes from Global BTK Registry

A Prospective, Multicenter, Single-Arm Real-World Registry Investigating the Clinical Use and Safety of the Lutonix Drug Coated Balloon PTA Catheter for Treatment of Below-the-Knee (BTK) Arteries

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Study Design

Study Design	Prospective, Multicenter, Single Arm Registry
Objective	To demonstrate safety and assess the clinical use and outcomes of the Lutonix DCB for treatment of stenosis or occlusion of native below-the-knee arteries in a heterogeneous patient population in real world clinical practice
Number of patients/sites	371 subjects enrolled from 26 international sites
Inclusion Criteria	Rutherford Class: 3-5, ≥ 70% stenosis lesion, target vessel(s) reconstitute(s) at or above the ankle
Exclusion Criteria	Neurotrophic ulcer or heel pressure ulcer or ulcer potentially involving calcaneus (index limb)
Primary Endpoints	Safety: Freedom from BTK MALE+POD at 30-days Efficacy: Freedom from TLR at 6 months
Follow-up	1, 6, 12 and 24 Months

Interim data, subject to change.

Study Centers

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Prof. Brountzos
Dr. Rossato
Dr. Cioppa
Dr. Tolva
Dr. Butterfield
Dr. Rana

Patient Follow-Up

EVENT	Pre-Procedure	Procedure	Post-Procedure	30 Day	6 Month	12 Month	24 Month
Visit Window				±2 Weeks	±1 Month	±1 Month	±2 Months
Inclusion/Exclusion Criteria	√	√					
Informed Consent	√						
Medical History	√						
Routine Physical Exam	√		√	√[1]	√	√	√[1]
Current Medication	√			√	√	√	√
Rutherford Classification	√			√[1]	√	√	√[1]
Adverse Event Monitoring		√	√	√	√	√	√
Wound Healing Assessment	√			√[1]	√	√	√[1]

Interim data, subject to change.
[1]Required only if clinical visit occurs

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Demographics / Baseline Characteristics

Description	BTK Registry (N=371)
Age (Years), Mean ± SD (n)	73.5 ± 9.59 (371)
Gender, % (n/N)	
Female	27.8% (103/371)
Male	72.2% (268/371)
BMI ≥30 kg/m², % (n/N)	23.5% (86/366)
Hypertension, % (n/N)	87.1% (323/371)
Dyslipidemia, % (n/N)	62.8% (233/371)
Current/Previous Smoker, % (n/N)	51.7% (192/371)
Diabetes	63.9% (237/371)
Rutherford Category	
3	24.1% (89/370)
4	10.5% (39/370)
5	65.4% (242/370)

RCC 5
65.4%
(242/370)

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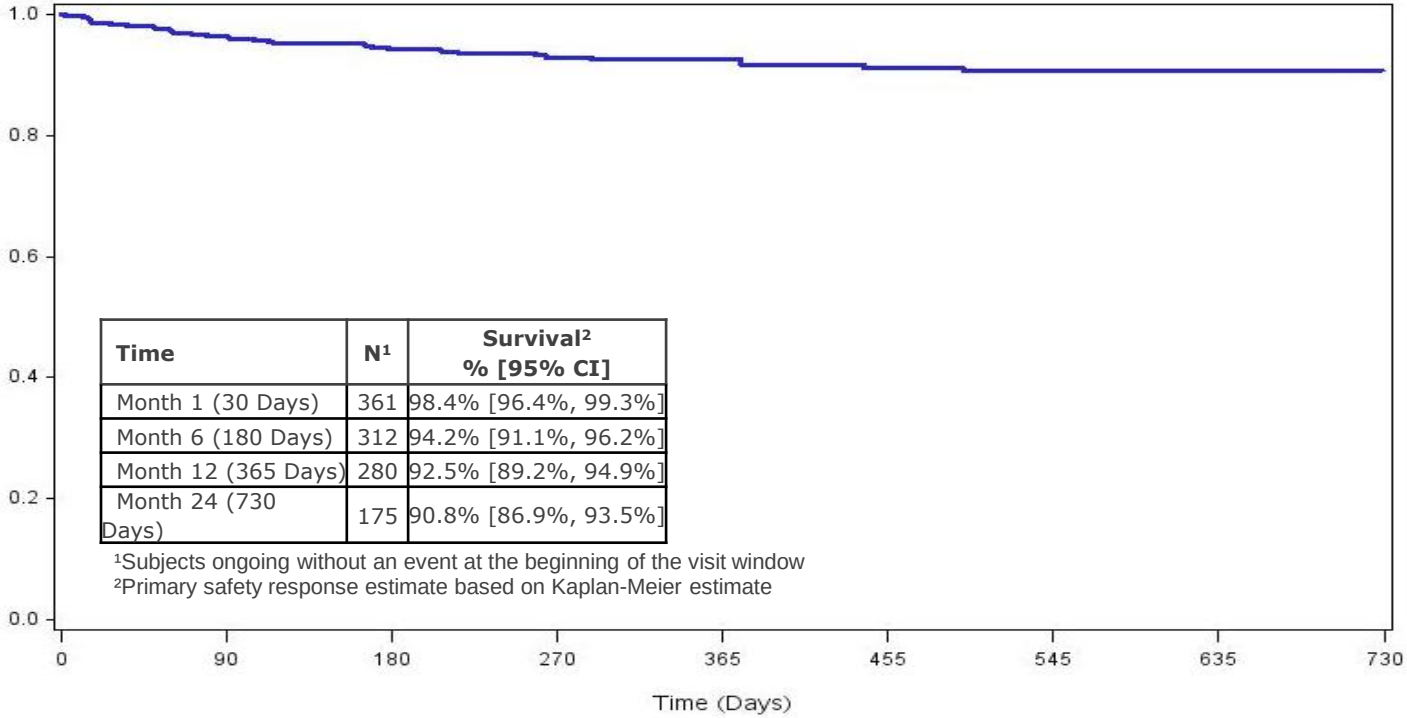
Lesion Characteristics

Description	BTK Registry (N=371)
Lesion Location[1]	
Popliteal	6.8% (25/370)
Tibioperoneal Trunk	20.3% (75/370)
Anterior Tibial	51.1% (189/370)
Posterior Tibial	22.4% (83/370)
Peroneal	22.4% (83/370)
Total Target Length (mm), Mean ± SD (n)	121 ± 98.7 (370)
Average RVD (mm), Mean ± SD (n)	2.7 ± 0.52 (367)
(min, max)	(1.7, 4.5)
Calcification, % (n/N)	68.4% (242/354)
Severe Calcification, % (n/N)	20.5% (73/356)
TASC	
A	25.1% (93/370)
B	25.7% (95/370)
C	17.3% (64/370)
D	14.1% (52/370)
Unknown	17.8% (66/370)

Freedom from Primary Safety Events



Time	N[1]	Survival[2] % [95% CI]
Month 1 (30 Days)	361	98.4% [96.4%, 99.3%]
Month 6 (180 Days)	312	94.2% [91.1%, 96.2%]
Month 12 (365 Days)	280	92.5% [89.2%, 94.9%]
Month 24 (730 Days)	175	90.8% [86.9%, 93.5%]

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

- Freedom at 790-Days from the composite of all-cause death, above-ankle amputation or major re-intervention, i.e., new bypass graft,
- jump/interposition graft revision, or thrombectomy/thrombolysis of the index limb involving a below-the-knee artery.

Interim data, subject to change.

Additional Safety Profile – 24 Months

Freedom From	N[1]	Survival[2] % [95% CI]
All Cause Death Survival	187	80.3% [75.2%, 84.5%]
Major Amputation	179	93.7% [90.3%, 95.9%]
Re-intervention for Thrombosis/Thrombolysis	168	88.9% [84.5%, 92.1%]
Re-intervention For Distal Embolization	187	100.0% [NA, NA]
Unexpected Device or Drug Related Event	187	100.0% [NA, NA]

Major Amputation free rate: 93.7%

Interim data, subject to change.

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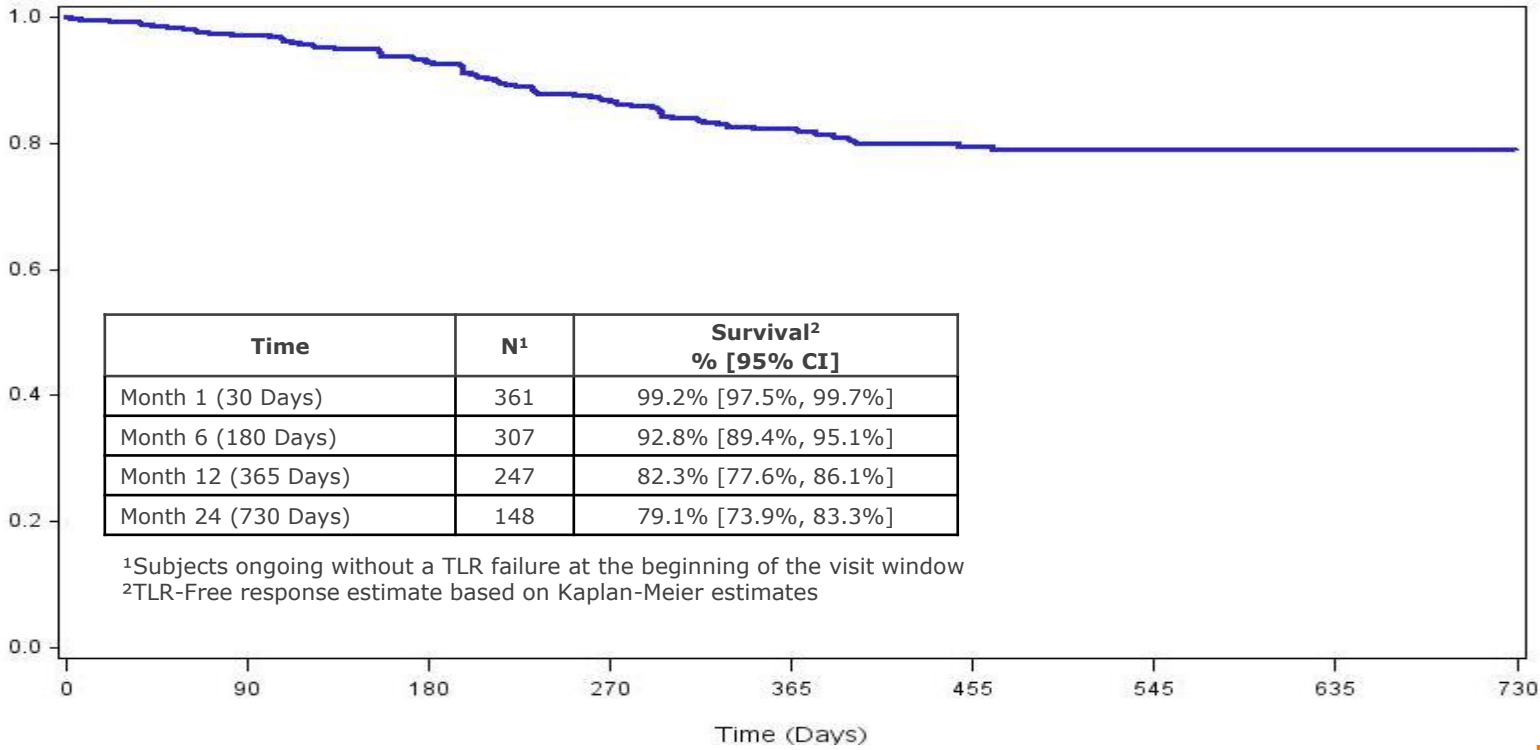
Freedom from TLR



Time	N[1]	Survival[2] % [95% CI]
Month 1 (30 Days)	361	99.2% [97.5%, 99.7%]
Month 6 (180 Days)	307	92.8% [89.4%, 95.1%]
Month 12 (365 Days)	247	82.3% [77.6%, 86.1%]
Month 24 (730 Days)	148	79.1% [73.9%, 83.3%]

[1]Subjects ongoing without a TLR failure at the beginning of the visit window
[2]TLR-Free response estimate based on Kaplan-Meier estimates

Interim data, subject to change.

Rutherford Category Shift – 24 Months

Description	BTK Registry (N=371)
Improved by 5 Levels	32.1% (36/112)
Improved by 4 Levels	9.8% (11/112)
Improved by 3 Levels	16.1% (18/112)
Improved by 2 Levels	17.9% (20/112)
Improved by 1 Levels	6.3% (7/112)
No Change	16.1% (18/112)
Worsened by 1 Levels	1.8% (2/112)

82.2% Improved by ≥1 RCC
58.0% Improved by ≥3 RCC

Interim data, subject to change.

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Conclusion

- Only BTK Registry Multi Center On-going Study
- Freedom from Re-intervention For Distal Embolization: 100%
- Freedom from TLR: 79.1%
- Freedom from Major Amputation Rate: 7.1%
- 58.0% Improvement by ≥3 Rutherford Classifications
- Freedom from all cause death: 80.3%
- BDPI is continuing to work with FDA on the PMA submission

Interim data, subject to change.