# Latest 24-month BTK global real-world registry Lutonix DCB outcomes

Prof. Dierk Scheinert,

for the Lutonix BTK Registry Investigators

University of Leipzig Medical Center

Head of Medical Department V - Angiology

# Disclosure

Advisory Board /Consultant:

Abbott, Alvimedica, Bayer, Boston Scientific, Cook Medical, Cardionovum, CR Bard, Gardia Medical/Allium, Medtronic, Philips, Upstream Peripheral Technologies

# 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 (11 countries) |
| 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[1]: Freedom from BTK MALE+POD at 30-days<br>Efficacy: Freedom from TLR at 6 months |
| Follow-up | 1, 6, 12 and 24 Months |

*[1]MALE+POD = Major Adverse Limb Event + Peri-operative Death*

# Study Centers

| PI Name |
|---|
| Prof. Willfort-Ehringer |
| Prof. Loewe |
| Prof. Brodmann |
| Prof. Hausegger |
| Dr. Lerut |
| Dr. Lansink |
| Dr. Clemens |
| Prof. Zech |
| Dr. Giménez-Gaibar |
| Dr. Alves |
| Prof. Sapoval |
| Dr. Lichtenberg – Study Co-PI |
| Dr. Thieme |

| PI Name |
|---|
| Prof. Scheinert – Study Co-PI |
| Prof. Eckstein |
| Dr. Sunderdiek |
| Prof. Tepe |
| Dr. Oplustil |
| Prof. Zeller |
| Prof. Karnabatidis |
| Prof. Brountzos |
| Dr. Rossato |
| Dr. Cioppa |
| Dr. Tolva |
| Dr. Butterfield |
| Dr. Rana |

# 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, % (n/N) | 63.9% (237/371) |
| Rutherford Category*, % (n/N) | |
| 3 | 24.1% (89/370) |
| 4 | 10.5% (39/370) |
| 5 | 65.4% (242/370) |

# Lesion Characteristics

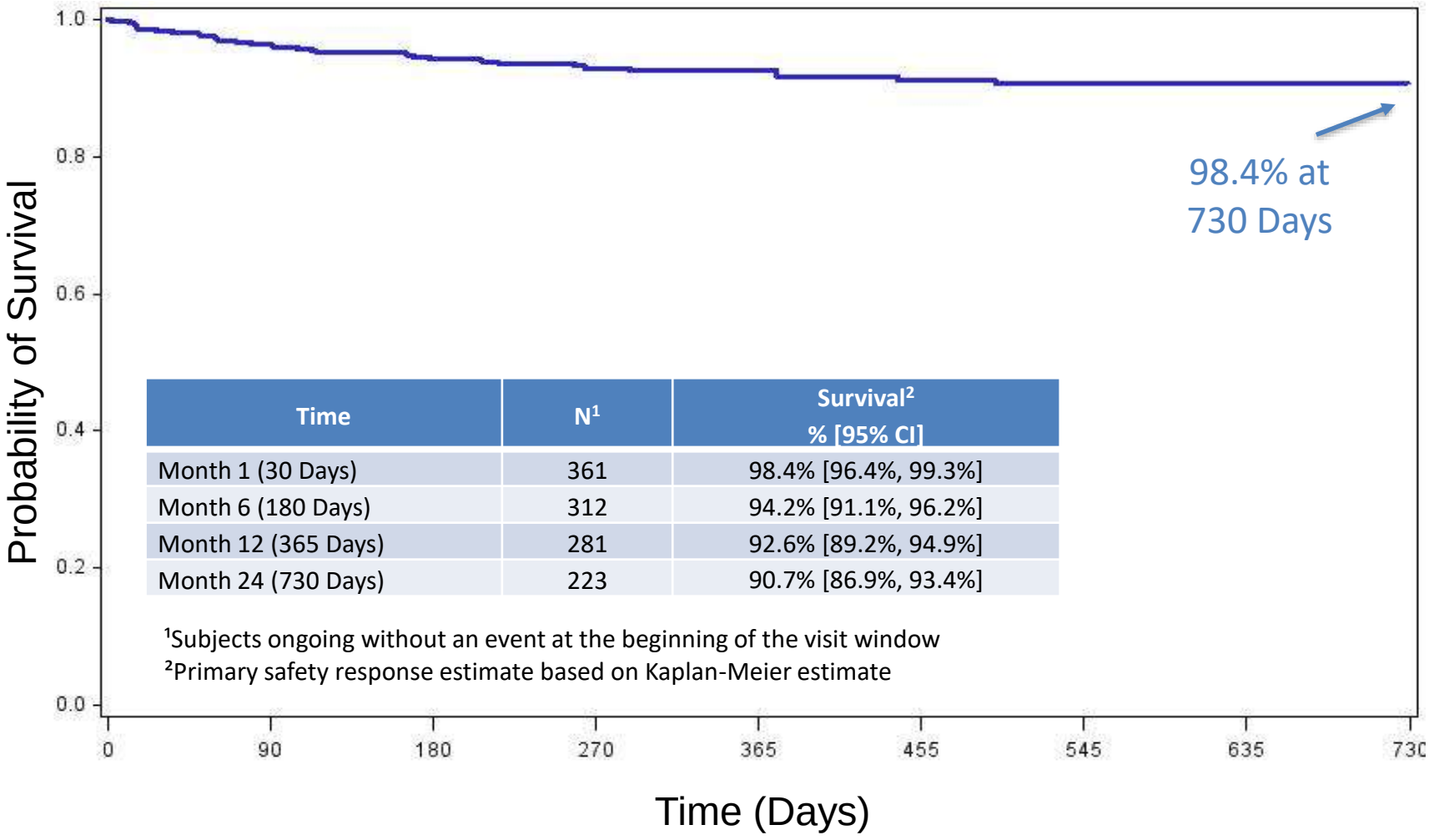
| Description | BTK Registry (N=371) |
|---|---|
| Lesion Location[1], % (n/N) | |
| Popliteal | 6.2% (23/370) |
| Tibioperoneal Trunk | 20.3% (75/370) |
| Anterior Tibial | 50.8% (188/370) |
| Posterior Tibial | 22.2% (82/370) |
| Peroneal | 22.4% (83/370) |
| Total Target Length (mm), Mean ± SD (n) | 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, % (n/N) | |
| A | 25.1% (93/370) |
| B | 25.7% (95/370) |
| C | 17.3% (64/370) |
| D | 14.1% (52/370) |
| Not classified | 17.8% (66/370) |

*[1]Subjects may be in more than one category.*

# Primary & Secondary Endpoints

- **Primary Safety:** Freedom from a primary safety event (BTK MALE+POD) at 30 days
  - Freedom at 30 days from the composite of all-cause death, above-ankle amputation or major reintervention (i.e. new bypass graft, jump/interposition graft revision, or thrombectomy/ thrombolysis, of the index limb involving a below-the-knee artery)
- **Primary Efficacy:** Freedom from clinically-driven target lesion reintervention (TLR) at 6 months
- **Secondary:**
  - Reintervention for treatment of thrombosis of the target vessel(s)
  - Reintervention for embolization to its distal vasculature
  - Unexpected device or drug-related adverse events
  - Change/Improvement in Rutherford Class (target limb)
  - Freedom from All-Cause Death

# Freedom from Primary Safety Events

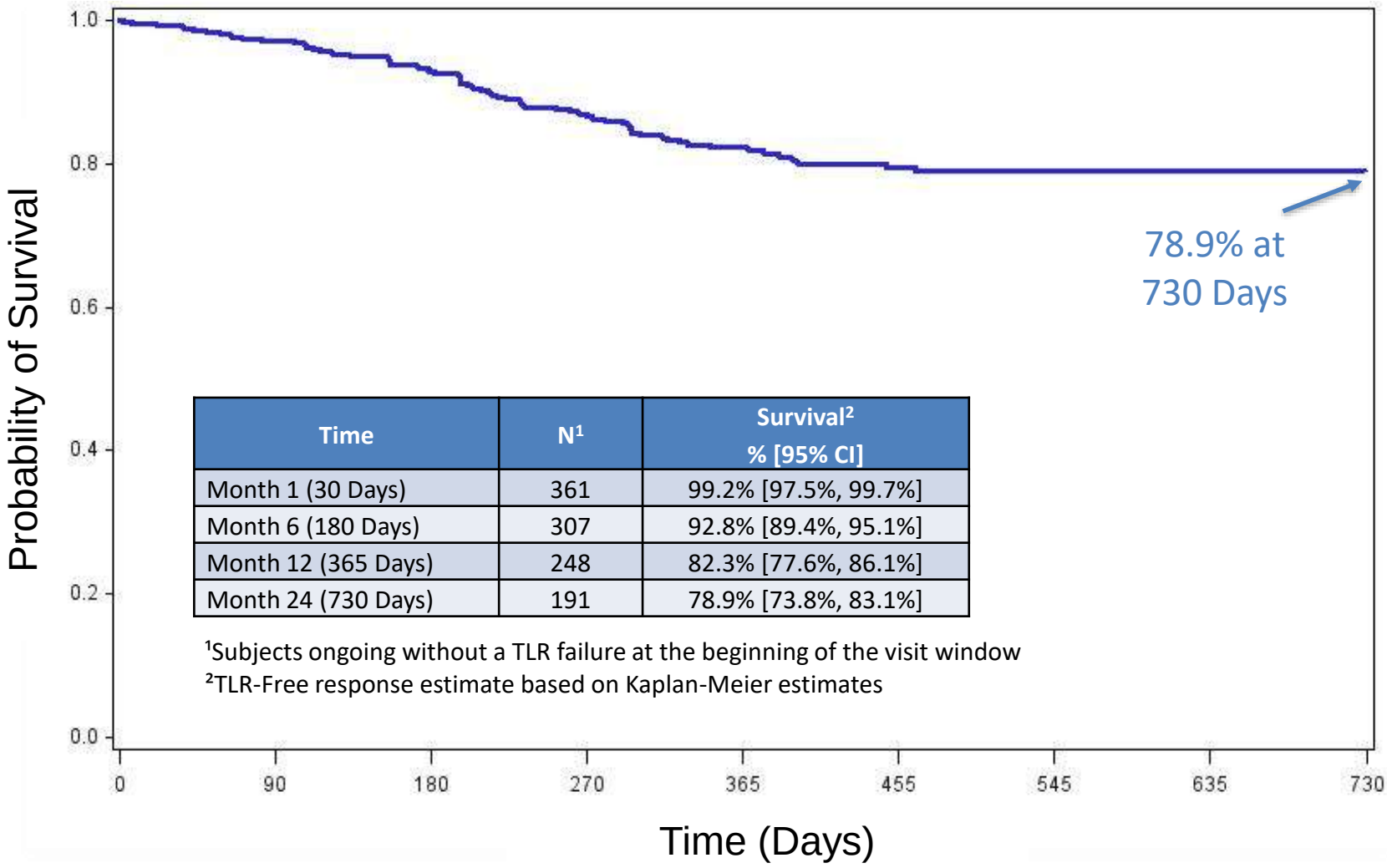



| Time | N[1] | Survival[2] % [95% CI] |
|---|---|---|
| Month 1 (30 Days) | 361 | 98.4% [96.4%, 99.3%] |
| Month 6 (180 Days) | 312 | 94.2% [91.1%, 96.2%] |
| Month 12 (365 Days) | 281 | 92.6% [89.2%, 94.9%] |
| Month 24 (730 Days) | 223 | 90.7% [86.9%, 93.4%] |

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

Freedom from the composite of all-cause death, above-ankle amputation, or major re-intervention

# 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) | 248 | 82.3% [77.6%, 86.1%] |
| Month 24 (730 Days) | 191 | 78.9% [73.8%, 83.1%] |

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

# Secondary Endpoints: 24-Month

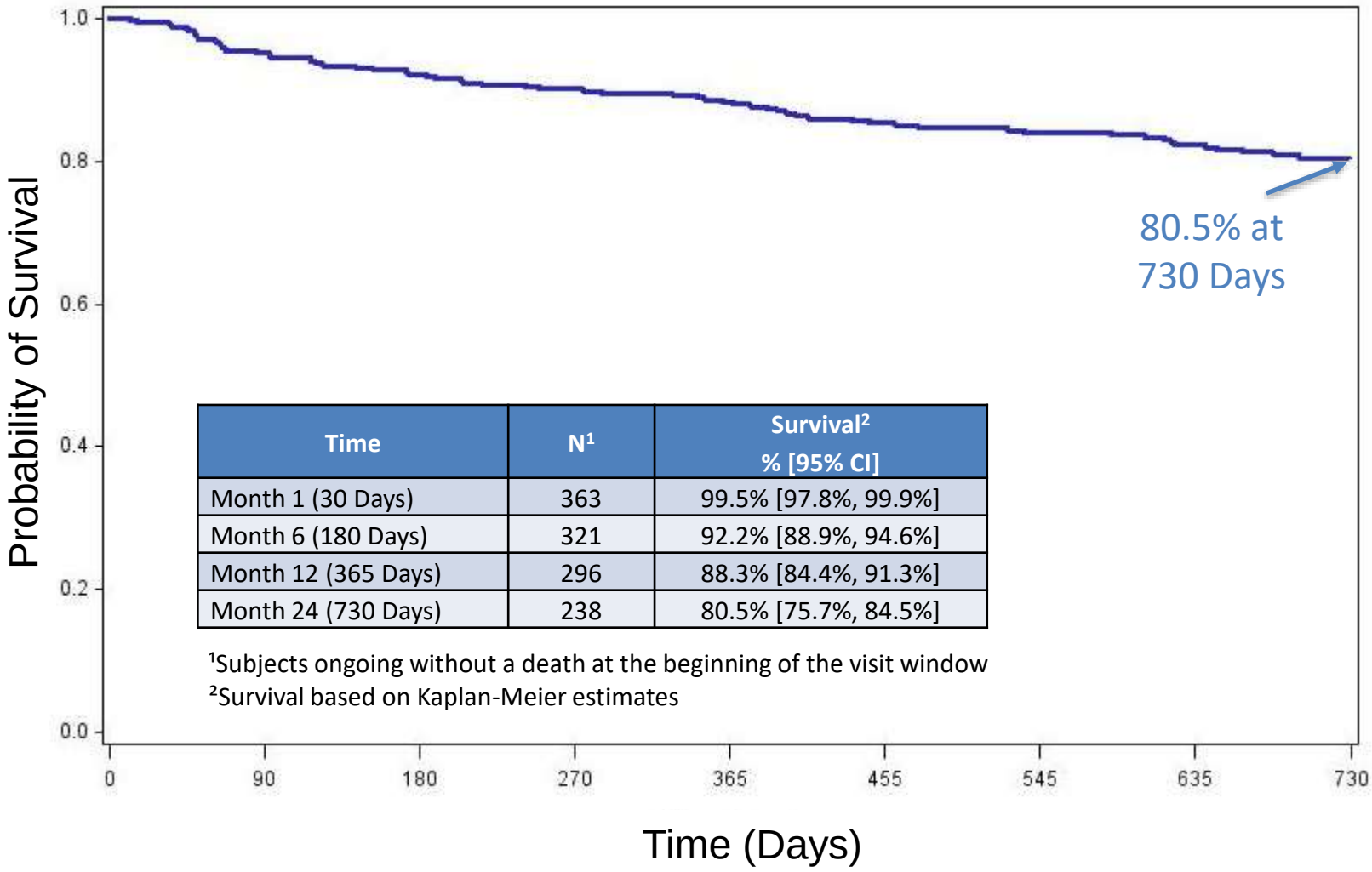
| Freedom From | N[1] | Survival[2] % [95% CI] |
|---|---|---|
| Major Amputation | 227 | 93.4% [90.0%, 95.6%] |
| Re-intervention for Thrombosis/Thrombolysis | 214 | 89.1% [84.9%, 92.1%] |
| Re-intervention For Distal Embolization | 238 | 100.0% [NA, NA] |
| Unexpected Device or Drug Related Event | 238 | 100.0% [NA, NA] |

Freedom from Major Amputation: 93.4%

*[1]Subjects ongoing without a failure at the beginning of the visit window*

*[2]Survivor rate based on Kaplan-Meier Estimate*

# Freedom from All-Cause Death




| Time | N[1] | Survival[2] % [95% CI] |
|---|---|---|
| Month 1 (30 Days) | 363 | 99.5% [97.8%, 99.9%] |
| Month 6 (180 Days) | 321 | 92.2% [88.9%, 94.6%] |
| Month 12 (365 Days) | 296 | 88.3% [84.4%, 91.3%] |
| Month 24 (730 Days) | 238 | 80.5% [75.7%, 84.5%] |

[1]Subjects ongoing without a death at the beginning of the visit window
[2]Survival based on Kaplan-Meier estimates

# Rutherford Category Shift – 24 Months

| Rutherford Category Improvement, % (n/N) | BTK Registry (N=371) |
|---|---|
| Improved by 5 Levels | 33.6% (48/143) |
| Improved by 4 Levels | 8.4% (12/143) |
| Improved by 3 Levels | 17.5% (25/143) |
| Improved by 2 Levels | 16.8% (24/143) |
| Improved by 1 Levels | 5.6% (8/143) |
| No Change | 16.8% (24/143) |
| Worsened by 1 Levels | 1.4% (2/143) |

81.9% Improved by $\geq$ 1 Rutherford Category
59.5% Improved by $\geq$ 3 Rutherford Categories

# Summary of Current 24-Month Data

- Freedom from Re-intervention For Distal Embolization: 100%
- Freedom from TLR: 78.9%
- Freedom from Major Amputation Rate: 93.4%
- 59.5% Improvement by ≥3 Rutherford Categories
- Freedom from all-cause death: 80.5%

# Latest 24-month BTK global real-world registry Lutonix DCB outcomes

Prof. Dierk Scheinert,

for the Lutonix BTK Registry Investigators

University of Leipzig Medical Center

Head of Medical Department V - Angiology