# New DCB era for BTK:

## 6-months results from the China **AcoArt II Study**

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on behalf of the AcoArt II Investigators

# Disclosure

Speaker name: Wei Guo

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I have the following potential conflicts of interest to report:

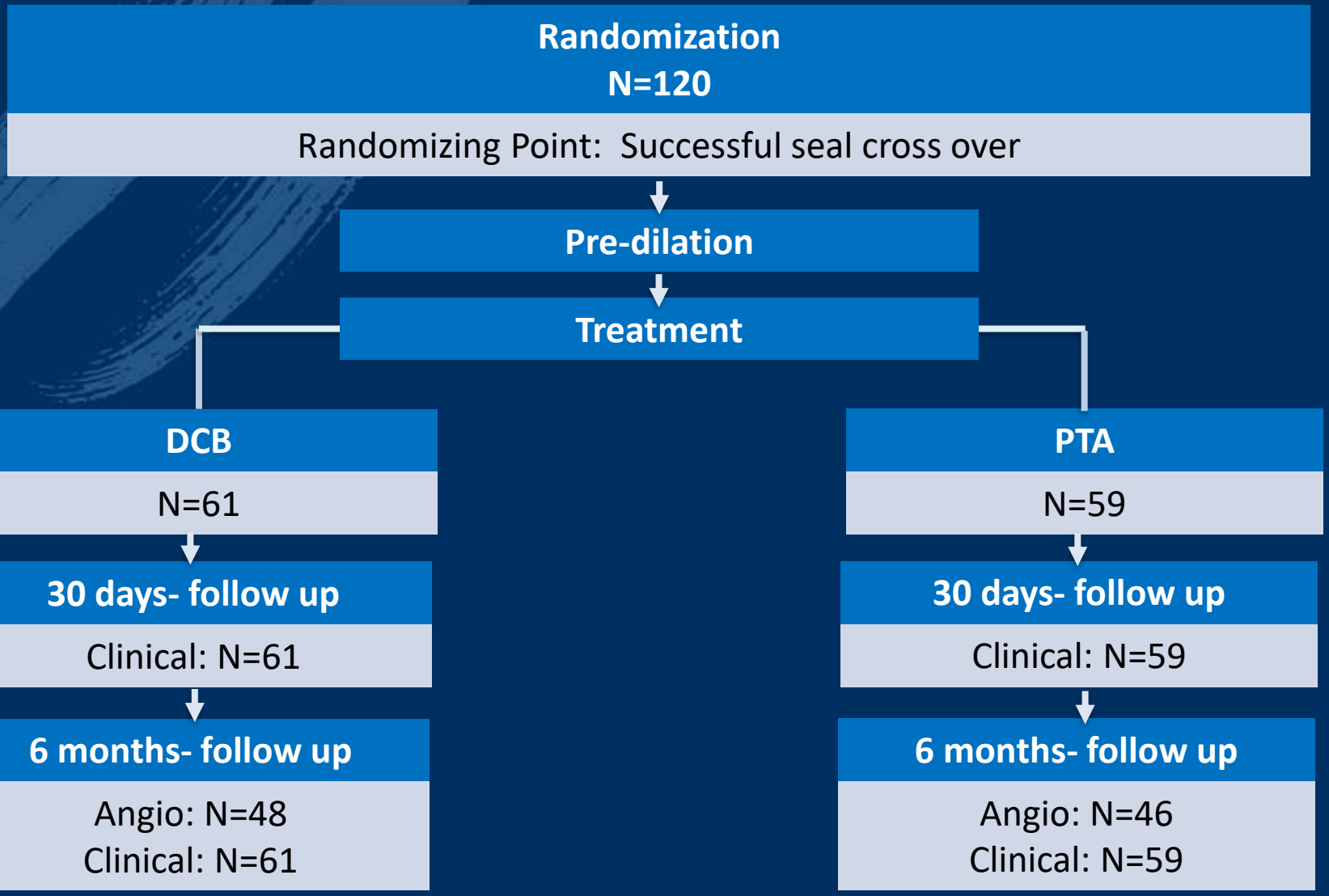
- ☐ Consulting
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

- ☑ I do not have any potential conflict of interest

# AcoArt II Study Overview

| | |
|---|---|
| Objective | To evaluate the safety and efficacy of the Litos & Tulip ® drug-coated balloon (DCB) for treatment below the knee(BTK) arterial disease |
| Primary Endpoint | 6-mon Angiographic:<br>• Primary patency (PP) – freedom from target lesion occlusion，clinically-driven target revascularization (CD-TLR) and major amputation above ankle. |
| Key Secondary Endpoint | Angiographic:<br>• Late lumen loss (LLL) at 6 months<br>Clinical:<br>• CD-TLR at 6 months<br>• ABI at 6 months |
| Complications | MAE (death, major amputation, CD-TLR)-6mon |
| Subjects | 11 sites, 120 pts , randomized 1:1 DCB vs. PTA |

# Study Design



# Eligibility

**Inclusion criteria:**

- Age 18-85
- Rutherford 4-6
- BTK target
  - ✓ stenosis (≥70％)
  - ✓ total occlusion
- Life expectancy ≥ 1 year
- At least 1 run-off vessel
- Signed ICF

**Exclusion criteria:**

- GRF<30ml/min
- Acute thrombus in target vessel
- Prior lower limb vascular surgery or thrombolysis within 6 weeks
- ISR
- Unsuccessful lesion crossing
- Planned major amputation
- Lesion length ≥150mm in inflow arteries
- Hemorrhagic tendency, etc.

# AcoArt II Baseline

| | DCB (N=61) | PTA (N=59) | P Value |
|---|---|---|---|
| Age, yrs | 70.7±7.4 | 70.8±9.0 | 0.95 |
| Male (%) | 59%(36) | 61%(36) | 0.82 |
| History of Risk Factors | | | |
| CHD | 36%(22) | 34%(20) | 0.81 |
| Hypertension | 82%(50) | 75%(44) | 0.33 |
| Hyperlipidemia | 41%(25) | 27%(16) | 0.11 |
| Diabetes | 74%(45) | 71%(42) | 0.75 |
| Current smoker | 26%(16) | 27%(16) | 0.60 |
| Current alcoholic | 16%(10) | 10%(6) | 0.32 |
| Rutherford | | | |
| 3 | 2%(1) | 0 | |
| 4 | 44%(27) | 41%(24) | 0.76 |
| 5 | 39%(24) | 47%(28) | |
| 6 | 15%(9) | 12%(7) | |
| ABI* | 0.56±0.27 | 0.51±0.31 | 0.41 |

Values are % (n/N), or mean ±SD. *Calculated by excluding ABI≥1.3.

# Target Lesion Characteristics

| | DCB | PTA | P |
|---|---|---|---|
| Patients（No） | 61 | 59 | |
| Lesions （No） | 65 | 66 | |
| Target vessels | | | |
| TA | 1.5%(1) | 1.5%(1) | |
| TA+PTA | 9.2%(6) | 6.1%(4) | |
| TA+PA | 4.6%(3) | 7.6%(5) | 0.59 |
| ATA | 49%(32) | 50%(33) | |
| PTA | 26%(17) | 18%(12) | |
| PA | 9.2%(6) | 17%(11) | |
| Target lesion length (mm) | 177±86 | 186±82 | 0.56 |
| Minimal lumen diameter (mm) | 0.20±0.41 | 0.15±0.33 | 0.43 |
| Reference vessel diameter (mm) | 2.55±0.34 | 2.53±0.35 | 0.71 |
| Diameter stenosis(%) | 92% | 94% | 0.43 |
| CTO (%) | 75.4%（49/65） | 78.8%（52/66） | 0.54 |

Values are % (n/N), or mean ±SD.

TA= tibiofibular artery; ATA= anterior tibial artery; PTA= posterior tibial artery; PA= peroneal artery

# Procedural Data

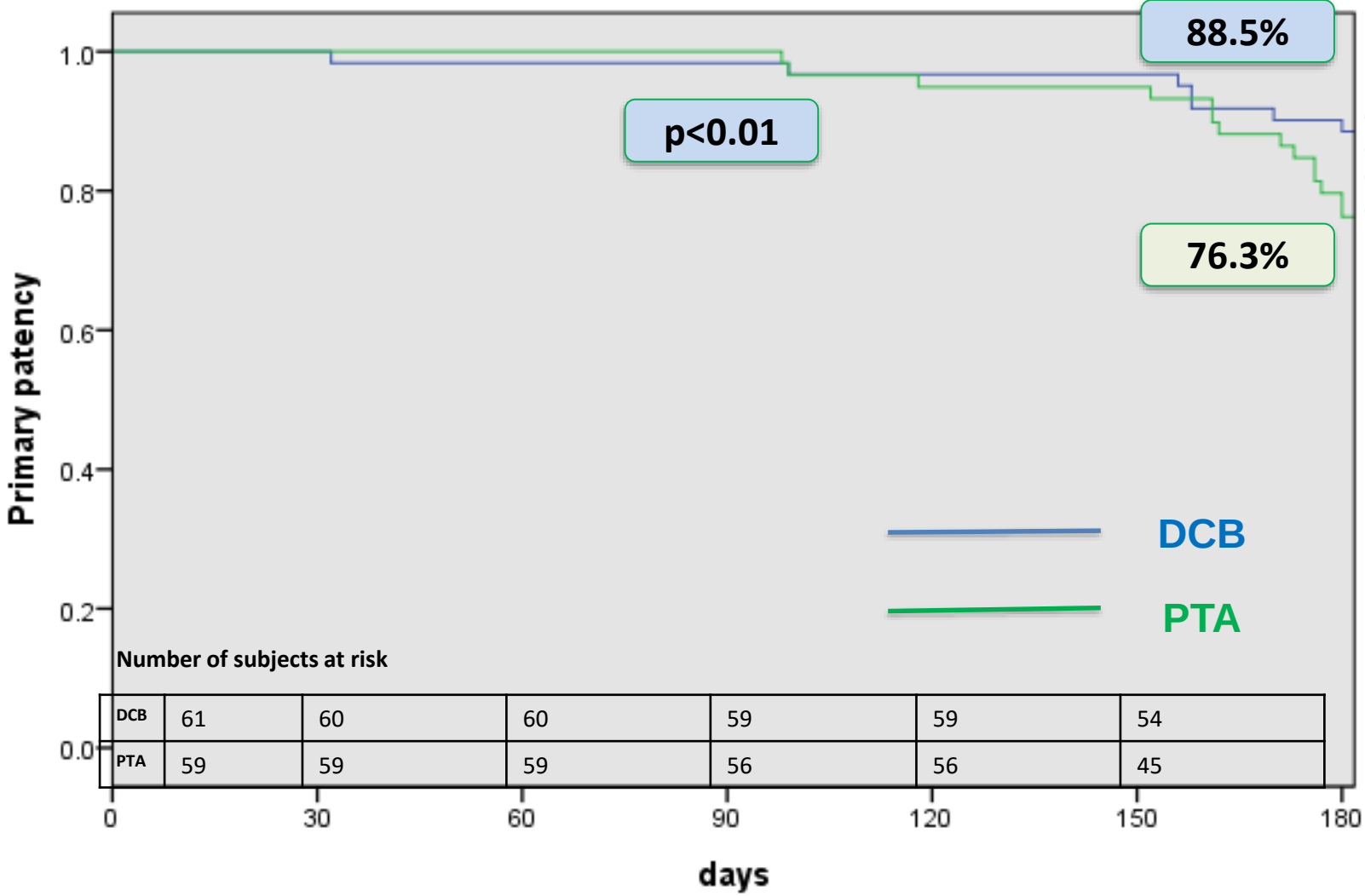
| | DCB | PTA | P |
|---|---|---|---|
| Treatment balloon diameter (mm) | 2.72±0.25 | 2.64±0.25 | 0.07 |
| Provisional stenting % | 0 | 1.5% (1/66) | 0.32 |
| Device success | 100% | 100% | / |

# Primary Endpoint
## (180 days postoperative)

| | DCB N=48 | PTA N=46 | P |
|---|---|---|---|
| Primary Patency | 78.7% (37/48) | 28.3% (13/46) | <0.001 |
| Occlusion | 8 | 27 | |
| TLR | 3 | 12 | |
| Amputation | 1 | 1 | |

- Primary patency was defined as *Freedom from occlusion and CD-TLR and major amputation above ankle .*

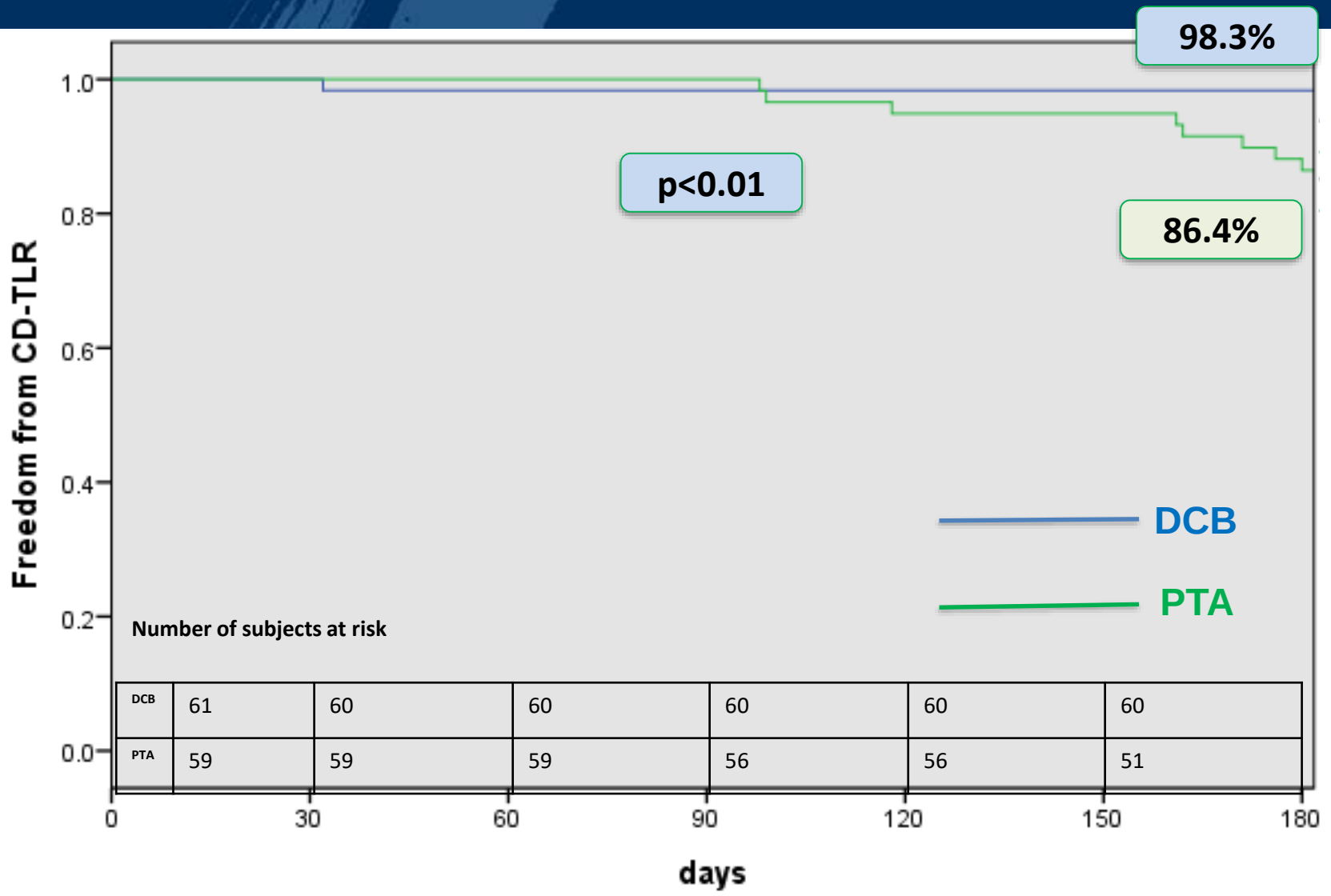
# Primary Endpoint (KM 6 month)



# Secondary Endpoint

| | DCB | PTA | P-value |
|---|---|---|---|
| Angiographic: | | | |
| MLD | | | |
| post procedure | 1.66±0.41 | 1.56±0.35 | 0.13 |
| 6-mon | 1.33±0.78 | 0.49±0.59 | <0.001 |
| LLL | 0.35±0.74 | 1.08±0.62 | <0.001 |
| Clinical: | | | |
| CD-TLR | 4.9% (3/61) | 20.3% (12/59) | 0.006 |
| 6-mon ABI | 0.86±0.17 | 0.77±0.20 | 0.04 |

# KM 6mon CD-TLR



# 30-Day Safety

| | DCB N=61 | PTA N=59 | P value |
|---|---|---|---|
| Death | 0 | 0 | / |
| Major amputation | 0 | 0 | / |
| CD-TLR | 1.6% (1) | 0% (0) | 0.33 |

# Major adverse event (MAE)-6mon

| | DCB | PTA | P value |
|---|---|---|---|
| Death | 1(1/61) | 0 | 0.33 |
| Major amputation | 1.6% (1/61) | 1.7% (1/59) | 0.98 |
| CD-TLR | 4.9% (3/61) | 20.3% (12/59) | 0.01 |

# Mortality during follow up time

| AcoArt II-BTK (N=120) | | | |
|---|---|---|---|
| Accumulative Death | DCB | PTA | P-value |
| 6 month | 1 (N=61) | 0(N=59) | 0.33 |
| 12 mon going on | 1(N=48) | 2(N=50) | 0.59 |
| 24 mon going on | 4(N=38) | 6(N=42) | 0.62 |

| AcoArt I-SFA(N=200) | | | |
|---|---|---|---|
| Accumulative Death | DCB | PTA | P-value |
| 1 year | 2(N=97) | 3(N=96) | 0.64 |
| 2 years | 8(N=96) | 6(N=95) | 0.60 |
| 5 years going on | 13(N=60) | 15(N=62) | 0.74 |

# Conclusion

- AcoArt II is the first randomized BTK clinical trial in China. The trial demonstrated the safety and efficacy of coating technology (Mg-stearate) of AcoTec™ DCB in treating BTK lesions.
- The positive results further improved the evidence of DCB for BTK, which inspired utilization of DCB for BTK definitely in the further clinical practice.
- But,the long term outcome still keep in follow up.

# Thank you for your attention

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