2 year results from the COMPARE trial
- Low-dose vs. high-dose DCB in femoropopliteal arteries

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Disclosure

Speaker name: 
.................................................................................

I have the following potential conflicts of interest to report:

☐ Consulting
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☑ Others: Bayer, C.R. Bard

☐ I do not have any potential conflict of interest
COMPARE RCT: Study objectives

**Study aim**
To compare high dose vs. low dose paclitaxel coated balloons for the treatment of high grade stenotic or occluded femoropopliteal lesions

**Patient population**
Patients with Rutherford class 2-4

**Principal investigator**
Dierk Scheinert, MD; University of Leipzig

**Study sites**
15 sites in Germany

**Investigational Device**
- Low dose DCB: Ranger™
- Paclitaxel Dose: 2.0μg/mm²
- TransPax coating; Excipient: Citrate ester

**Control Device**
- High dose DCB: IN.PACT Admiral™/IN.PACT Pacific™
- Paclitaxel Dose: 3.5μg/mm²
- FreePac™ hydrophilic coating; Excipient: Urea
## COMPARE RCT: Study Design and Methods

| Study Design | ➢ Investigator-initiated, prospective, multicenter, non-inferiority trial  
|             | ➢ 414 patients undergoing 1:1 randomization  
|             | ➢ Stratification according to lesion length  
|             | ➢ Independent monitoring with 100% source data verification  
|             | ➢ Independent corelab for angio and duplex  
|             | ➢ Clinical events committee  

| Funding      | ➢ Study sponsor: University of Leipzig  
|             | ➢ Funding through a research grant from Boston Scientific  
|             | ➢ Funding source not involved in collecting, monitoring and analyzing study data  

| Follow-up    | ➢ In-house visits: 6, 12, **24 months (efficacy and safety)**  
|             | ➢ Telephone calls: 1 month, 36, 48, 60 months (safety)  

## Key baseline characteristics

<table>
<thead>
<tr>
<th></th>
<th>Low dose DCB (n=207)</th>
<th>High dose DCB (n=207)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Demographics</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td>68.2 ± 10.0</td>
<td>68.4 ± 9.3</td>
<td>0.79</td>
</tr>
<tr>
<td>Female gender</td>
<td>79 (38.2)</td>
<td>75 (36.2)</td>
<td>0.68</td>
</tr>
<tr>
<td>Rutherford class (RC) ≥ 3</td>
<td>184 (88.9)</td>
<td>176 (85)</td>
<td>0.56</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>63 (30.6)</td>
<td>76 (36.9)</td>
<td>0.18</td>
</tr>
<tr>
<td>Previous/current smoking</td>
<td>160 (77.3)</td>
<td>155 (74.9)</td>
<td>0.63</td>
</tr>
<tr>
<td><strong>Lesion</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lesion length (mm)</td>
<td>123.9±97.8</td>
<td>128.3±97.3</td>
<td>0.65</td>
</tr>
<tr>
<td>Total occlusions</td>
<td>84 (40.6)</td>
<td>89 (43)</td>
<td>0.62</td>
</tr>
<tr>
<td>Calcification PACSS 3-4</td>
<td>105 (50.5)</td>
<td>117 (57.1)</td>
<td>0.80</td>
</tr>
<tr>
<td>0-1 run off vessels</td>
<td>75 (38.5)</td>
<td>71 (36.6)</td>
<td>0.89</td>
</tr>
<tr>
<td><strong>Total paclitaxel dose (µg)</strong></td>
<td>6971±4026</td>
<td>13035±7483</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td><strong>Bail-out stenting</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>-Type E-F Dissection</td>
<td>4 (2.0)</td>
<td>2 (1)</td>
<td>0.61</td>
</tr>
<tr>
<td><strong>Procedural</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diameter stenosis pp (%)</td>
<td>26.4±12.5</td>
<td>26.1±12.5</td>
<td>0.8</td>
</tr>
<tr>
<td>Residual stenosis ≥ 30%</td>
<td>74 (35.8)</td>
<td>81 (39.1)</td>
<td>0.48</td>
</tr>
</tbody>
</table>

Data are given as mean±std or number (%).
Primary endpoint analysis at 12 months

### Efficacy: Primary patency

<table>
<thead>
<tr>
<th></th>
<th>DCB Low dose</th>
<th>DCB High dose</th>
<th>Δ (two-sided 90% lower bound)</th>
<th>$P_{\text{non-inferiority}}$</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Efficacy</strong></td>
<td><strong>Primary patency</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low dose</td>
<td>83% (156/188)</td>
<td>81.5% (141/173)</td>
<td>1.5% (-5.2%)</td>
<td>$&lt;0.01$</td>
</tr>
</tbody>
</table>

### Safety: Freedom from MAE

<table>
<thead>
<tr>
<th></th>
<th>DCB Low dose</th>
<th>DCB High dose</th>
<th>Δ (two-sided 90% lower bound)</th>
<th>$P_{\text{non-inferiority}}$</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Safety</strong></td>
<td><strong>Freedom from MAE</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low dose</td>
<td>91% (182/200)</td>
<td>92.6% (175/189)</td>
<td>-1.6% (-6.5%)</td>
<td>$&lt;0.01$</td>
</tr>
</tbody>
</table>

Patient flow diagram through 2 years

414 patients enrolled
- 47 screen failures
- 17 general criteria
- 30 angiographic criteria

Ranger™ DCB
- 207 patients
- Strata:
  - ≤ 10 cm: 69 patients
  - >10 and ≤ 20 cm: 70 patients
  - >20 and ≤ 30 cm: 68 patients
- 5 deaths
- 2 withdrawals

12-Month Visit
- 200 patients
- 8 withdrawals
- 2 deaths
- 1 lost to FU

24-Month Visit
- 189 patients

In.PACT™ DCB
- 207 patients
- Strata:
  - ≤ 10 cm: 69 patients
  - >10 and ≤ 20 cm: 68 patients
  - >20 and ≤ 30 cm: 70 patients
- 3 deaths
- 5 withdrawals
- 5 lost to FU
- 1 withdrawal by investigator

12-Month Visit
- 193 patients
- 12 withdrawals
- 1 death
- 3 lost to FU

24-Month Visit
- 177 patients
Primary patency through 790 days

Patients without an event at 790 days of follow-up or later were censored at 790 days.

<table>
<thead>
<tr>
<th>KM-estimate (95%CI)</th>
<th>@ 365days</th>
<th>730 days</th>
<th>790 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low dose DCB</td>
<td>87.6% (±2.5)</td>
<td>70.6% (±3.4)</td>
<td>64.4% (±3.6)</td>
</tr>
<tr>
<td>High dose DCB</td>
<td>88.7% (±2.4%)</td>
<td>71.4% (±3.5)</td>
<td>63.7% (±3.7)</td>
</tr>
</tbody>
</table>
## Key outcomes through 790 days

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Low dose DCB (n=207)</th>
<th>High dose DCB (n=207)</th>
<th>P value§</th>
</tr>
</thead>
<tbody>
<tr>
<td>All-cause mortality</td>
<td>3.6% (7/196)</td>
<td>2.2% (4/181)</td>
<td>0.6</td>
</tr>
<tr>
<td>Device or procedure-related death</td>
<td>0</td>
<td>0</td>
<td>1.0</td>
</tr>
<tr>
<td>Major amputation</td>
<td>0% (0/189)</td>
<td>0.6% (1/177)</td>
<td>1.0</td>
</tr>
<tr>
<td>Clinically driven TLR</td>
<td>17.3% (33/191)</td>
<td>13.0 % (23/177)</td>
<td>0.3</td>
</tr>
<tr>
<td>All TLR*</td>
<td>17.8% (34/191)</td>
<td>13.0 % (23/177)</td>
<td>0.3</td>
</tr>
<tr>
<td>Primary sustained clinical improvement†</td>
<td>69.5% (121/174)</td>
<td>74.3% (124/167)</td>
<td>0.4</td>
</tr>
<tr>
<td>Haemodynamic improvement‡</td>
<td>69.2% (117/169)</td>
<td>67.3% (107/169)</td>
<td>0.5</td>
</tr>
</tbody>
</table>

Values are percentage (n/N). The numerator is the number of subjects with events prior to the close of the visit window. The denominator includes subjects with events or those without events having follow-up on or past the opening of the visit window.

*Includes clinically-driven TLR and duplex-driven/incidental TLR.

† Defined as improvement in Rutherford classification by one or more categories compared with baseline, without TLR.

‡ Defined as an increase in the ankle-brachial index by ≥0·10 compared with baseline or to an ankle-brachial index ≥0·90, without TLR.

§ P-values based on Fisher’s-exact test.
Distribution of Rutherford categories

≈70% of patients with no or minimal symptoms @ 2y
Walking impairment questionnaire

Walking impairment
Baseline
24 MFU
Distance scores
Baseline
24 MFU
Speed scores
Baseline
24 MFU
Stair climbing scores
Baseline
24 MFU
Summary

- First head-to-head comparison of two DCBs with different paclitaxel dosages and coating technologies for femoropopliteal interventions
- Complex real world lesion subset with high proportion of CTO`s >40%
- Low dose DCB (Ranger 2.0μg/mm²) and high dose DCB (IN.PACT 3.5μg/mm²) showing both excellent primary patency and low TLR rates through 2 years
- Low mortality after 2 years; Follow-up ongoing up to 5 years