### Study objective

First Head-to-Head RCT to compare two different Paclitaxel coated balloons (with different coatings and different paclitaxel dose density) in the treatment of patients with symptomatic femoropopliteal peripheral arterial disease

**Investigational device:**
Ranger™ Paclitaxel Coated PTA Balloon Catheter (Paclitaxel dose 2µg/mm²)

**Control device:**
IN.PACT™ Admiral or IN.PACT™ Pacific Drug Eluting Balloon (Paclitaxel dose 3.5µg/mm²)

### Study Set-up

- **Investigator Initiated Trial (IIT)**
- **Principal Investigator:** Prof. Dierk Scheinert
- **Study sponsor:** University of Leipzig
- **Funded through a research grant of Boston Scientific**
- **Independent monitoring with 100% source data verification**
- **Independent corelab for angio and duplex**
- **Clinical events committee**

### Study Sites COMPARE Pilot (n=15)

- University Hospital Leipzig, Germany
- Prof. Schenner
- Diakoniewerk Hall – Dr. Hüffner
- KKH Hamburg – Dr. Maier
- KKH Eilenburg – Dr. Ali
- Romedio Klinik Rothenburg – Prof. Tepe
- Franziskus KH Berlin – Dr. Brecht
- Jüdisches KH Berlin – Dr. Schröder
- St. Gertrauden KH – Dr. Langhoff
- Universitätsklinikum Dresden – Prof. Weis
- Klinik für Herz- und Gefäßzentrum Bad Bevensen – Dr. Euringer
- Angiologikum Hamburg – Dr. Sixt
- Medizinische Klinik Sohnberg – Dr. Thiem
- Klinikum Karlshorst – Prof. Blessing
- Herzzentrum Barmbek – Prof. Zell

### Study Design

- Prospective, multicenter, randomized trial
- Randomization 1:1
- Phase 1: Pilot Study (150 patients)
- Phase 2: Extension (up to 414 patients) for testing of a formal non-inferiority hypothesis
- Stratification according to lesion length
- Follow-up clinical visits at 6, 12, 24 months
- Protocol pre-specified interim analysis of the first 150 patients (COMPARE Pilot) after 12 months of follow-up
  -> Presented today
Key In- and Exclusion criteria

- Symptomatic PAD Rutherford 2-4
- Stenosis (>70%) or occlusion of the SFA or proximal popliteal artery
- De-novo or restenotic lesions (no ISR)
- No severe calcification
- Lesion length up to 30 cm

- Stratification in 3 groups
  - <=10 cm
  - >10cm and <=20cm
  - >20cm and <=30cm
- At least one patent BTK outflow vessel to the foot

Study Endpoints

Selected Secondary endpoints (assessed at 6,12, 24 mo):

- TLR rate
- Duplex-defined restenosis
- Sustained clinical improvement: improvement in the Rutherford classification of one class in amputation and TVR free surviving patients
- Walking capacity assessment by Walking Impairment Questionnaire (WIQ)

Baseline Demographics of first 150pts

<table>
<thead>
<tr>
<th></th>
<th>RANGER DCB (n=74)</th>
<th>IN.PACT DCB (n=76)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>68.6±9.2</td>
<td>68.9±9.5</td>
<td>0.5</td>
</tr>
<tr>
<td>Male gender</td>
<td>44 (60%)</td>
<td>53 (70%)</td>
<td>0.2</td>
</tr>
<tr>
<td>Weight, kg</td>
<td>77.9±15.8</td>
<td>79.1±14.7</td>
<td>0.6</td>
</tr>
<tr>
<td>Prior myocardial infarction</td>
<td>11 (15%)</td>
<td>5 (7%)</td>
<td>0.2</td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>21 (29%)</td>
<td>21 (28%)</td>
<td>0.9</td>
</tr>
<tr>
<td>Cerebrovascular disease</td>
<td>12 (16%)</td>
<td>8 (11%)</td>
<td>0.3</td>
</tr>
<tr>
<td>Hypertension</td>
<td>65 (88%)</td>
<td>68 (90%)</td>
<td>0.8</td>
</tr>
<tr>
<td>Renal Insufficiency</td>
<td>12 (16%)</td>
<td>14 (18%)</td>
<td>0.6</td>
</tr>
<tr>
<td>Smoking</td>
<td>32 (43%)</td>
<td>38 (50%)</td>
<td>0.4</td>
</tr>
<tr>
<td>Current</td>
<td>27 (37%)</td>
<td>20 (26%)</td>
<td>0.2</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>25 (34%)</td>
<td>28 (37%)</td>
<td>0.7</td>
</tr>
<tr>
<td>Claudication (RC 2-3)</td>
<td>69 (93%)</td>
<td>71 (94%)</td>
<td>0.6</td>
</tr>
<tr>
<td>Critical limb ischemia (RC 4)</td>
<td>5 (7%)</td>
<td>5 (6%)</td>
<td></td>
</tr>
</tbody>
</table>

Data are given as means±SD or number (%).

Lesion Characteristics* of first 150pts

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Target lesion length, mm</td>
<td>117.4±100.4</td>
<td>122.3±91.2</td>
<td>0.8</td>
</tr>
<tr>
<td>Diameter stenosis, %</td>
<td>82.7±17.5</td>
<td>84.2±18.2</td>
<td>0.6</td>
</tr>
<tr>
<td>Reference vessel diameter, mm</td>
<td>4.3±0.6</td>
<td>5.0±0.8</td>
<td>0.3</td>
</tr>
<tr>
<td>Minimal vessel diameter, mm</td>
<td>0.8±0.9</td>
<td>0.8±1.0</td>
<td>0.9</td>
</tr>
<tr>
<td>Total occlusion</td>
<td>29 (39.2%)</td>
<td>34 (44.7%)</td>
<td>0.5</td>
</tr>
<tr>
<td>Total occlusion length, mm</td>
<td>110.9±65.1</td>
<td>64.8±67.9</td>
<td>0.5</td>
</tr>
<tr>
<td>P tex, popliteal involvement</td>
<td>14 (18.9%)</td>
<td>11 (14.9%)</td>
<td>0.2</td>
</tr>
<tr>
<td>Lesion calcification</td>
<td>0.7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>8 (11.1%)</td>
<td>8 (10.7%)</td>
<td>0.7</td>
</tr>
<tr>
<td>Mild</td>
<td>21 (28.9%)</td>
<td>18 (24%)</td>
<td>0.4</td>
</tr>
<tr>
<td>Moderate</td>
<td>1.14%</td>
<td>0.0%</td>
<td>0.05</td>
</tr>
<tr>
<td>Moderately severe</td>
<td>25 (34.7%)</td>
<td>33 (44%)</td>
<td></td>
</tr>
<tr>
<td>Severe</td>
<td>17 (23.6%)</td>
<td>16 (21.3%)</td>
<td></td>
</tr>
<tr>
<td>0-1 patent run off vessels</td>
<td>20 (26.9%)</td>
<td>25 (32.9%)</td>
<td>0.6</td>
</tr>
</tbody>
</table>

* Per angiographic core lab assessment.

Data are given as means±SD or number (%).
Procedural Outcomes* of first 150 pts

<table>
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<th>IN.PACT DCB (n=76)</th>
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<tbody>
<tr>
<td>Bailout stent placement</td>
<td>19 (25.7%)</td>
<td>17 (22.4%)</td>
<td>0.6</td>
</tr>
<tr>
<td>MVD postprocedure, mm</td>
<td>3.6±0.8</td>
<td>3.7±0.9</td>
<td>0.8</td>
</tr>
<tr>
<td>Diameter stenosis postprocedure, %</td>
<td>25.8±11.6</td>
<td>26.0±14.6</td>
<td>0.9</td>
</tr>
<tr>
<td>Residual stenosis &gt; 30%</td>
<td>26 (35.1)</td>
<td>29 (38.2)</td>
<td>0.7</td>
</tr>
<tr>
<td>Dissection</td>
<td>70 (92.1%)</td>
<td>70 (94.6%)</td>
<td>0.7</td>
</tr>
<tr>
<td>Type A/B, n (%)</td>
<td>54 (77.1%)</td>
<td>44 (62.8%)</td>
<td>0.1</td>
</tr>
<tr>
<td>Type C-F, n (%)</td>
<td>16 (22.9%)</td>
<td>26 (37.2%)</td>
<td></td>
</tr>
<tr>
<td>Complications</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Embolic event</td>
<td>2 (2.7%)</td>
<td>1 (1.3%)</td>
<td></td>
</tr>
<tr>
<td>AV-Fistel (local)</td>
<td>5 (6.8%)</td>
<td>5 (6.6%)</td>
<td></td>
</tr>
<tr>
<td>Target Vessel Perforation</td>
<td>1 (1.4%)</td>
<td>1 (1.3%)</td>
<td></td>
</tr>
</tbody>
</table>

* Per angiographic core lab assessment. Data are given as mean±SD or number (%).

Primary efficacy endpoint: Patency rate*

- Patency defined as absence of clinically driven TLR or restenosis with PVR>2.4 evaluated by duplex ultrasound scan, both per core lab assessment.

Summary

- Head-to-head comparison of Ranger™ DCB vs. IN.PACT™ DCB in femoropopliteal interventions
- Complex real world lesion subset with lesion length ~12cm and proportion of CTO’s ~40%
- Excellent efficacy at 1 year of both tested DCB in the interim analysis of first 150 randomized patients
- Similar primary patency of the low-dose Ranger™ DCB (2µg/mm²) compared to the Inpact™ DCB (3.5µg/mm²) during the 1 year surveillance period
- Recruitment of full study cohort (414 patients) has been finished in November 2018