Drug-Coated Balloons: A New Therapy for PAD in the Upper Leg

- Drug-coated balloons (DCBs) represent the newest minimally invasive treatment option available to U.S. physicians who treat patients with peripheral artery disease (PAD) in the upper leg.
- DCBs offer a significant benefit compared to previously-available treatments such as percutaneous transluminal angioplasty (PTA) and bare metal stents (BMS), which are associated with the common need for repeat procedures due to recurrent symptoms related to the treated lesion. Additionally, stents leave a permanent foreign implant in the vessel, limiting future treatment options.
- Supported by a robust body of evidence, the IN.PACT Admiral drug-coated balloon from Medtronic has consistently demonstrated the best clinical outcomes of any existing medical technology for the treatment of this common form of PAD, including the lowest reported rate of repeat procedures (clinically-driven target lesion revascularization, or CD-TLR) and the highest reported rate of restored blood flow (primary patency) at 12 months (per Kaplan-Meier Day 360 estimates), while minimizing the need for durable implants (or stents).

**IN.PACT Admiral Clinical Program**
The IN.PACT Admiral drug-coated balloon from Medtronic is the most studied DCB to date. The IN.PACT Admiral clinical program includes ongoing studies involving more than 3,500 patients worldwide that demonstrate positive, consistent results across a broad range of patient populations, both in real-world and randomized controlled settings. Key studies that contributed to the U.S. Food and Drug Administration (FDA) approval of IN.PACT Admiral include 12-month results from IN.PACT SFA Trial, as well as data from the post-market IN.PACT Global Study. The results from the IN.PACT SFA Trial are unprecedented and suggest IN.PACT Admiral as a new primary therapy in the treatment of PAD in the upper leg.

**IN.PACT SFA Trial**
- Randomized controlled trial designed to assess safety and efficacy of IN.PACT Admiral vs. PTA
- **CD-TLR rates** at 12 months were **2.4% for the DCB group** compared to 20.6% for the PTA group (p<0.001)
- **Primary patency** rates were **89.8% for the DCB group** and 66.8% for the PTA group (p<0.001) based on Kaplan-Meier survival estimates at 360 days
- **Exceptional safety profile** with a 95.7% primary safety composite*, combined with a low thrombosis rate (1.4%), proving superior safety to PTA

* Defined as freedom from device-related and procedure-related death at 30 days and freedom from target limb major amputation and CD-TVR at 12 months
**Deeper Look at IN.PACT SFA Trial Patient Population**

A review of select baseline characteristics is indicative of the high prevalence of co-morbidities and complications commonly observed in patients with PAD in the upper leg. These characteristics further increase the risk of heart disease, heart attack, stroke, and health complications related to diabetes that are associated with this challenging-to-treat condition.

**IN.PACT Global Study**

- Largest post-market registry of its kind designed to assess safety and efficacy of the IN.PACT Admiral in real-world clinical practice
- Reproducible, positive outcomes were observed in this study, which included patients with more complex disease and more challenging lesions
- Results from the first 655 patients treated in IN.PACT Global include a 12-month **CD-TLR rate of 8.7%**, which validate the findings from IN.PACT SFA
- The data reinforce strong safety of IN.PACT Admiral, with an 89.6% primary safety composite*, and low thrombosis rate (3.8%)
  * Defined as freedom from device-related and procedure-related death at 30 days and freedom from target limb major amputation and CD-TVR at 12 months

### Select Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>IN.PACT SFA Trial (n=220 IN.PACT Admiral subjects)</th>
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<tbody>
<tr>
<td>Age (years)</td>
<td>67.5 ± 9.5</td>
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<tr>
<td>Male Gender</td>
<td>65.0% (143/220)</td>
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<tr>
<td>Diabetes</td>
<td>40.5% (89/220)</td>
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<tr>
<td>Hypertension</td>
<td>91.4% (201/220)</td>
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<tr>
<td>Coronary Artery Disease</td>
<td>57.0% (122/214)</td>
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<tr>
<td>Carotid Artery Disease</td>
<td>34.9% (73/209)</td>
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<tr>
<td>Current Smoker</td>
<td>38.6% (85/220)</td>
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</tbody>
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### Chart References

7. Tepe, G Charing Cross Symposium. 2014; London, UK
29. Ansel, G Transcatheter Cardiovascular Therapeutics. 2014; Washington, DC