Progress In Developing A Site Specific Self-Expanding DES For Use In The Crural Arteries: The SAVAL Trial

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Disclosures
• Education/Training: Abbott, BARD, Boston Scientific, COOK, Phillips
• Advisory Board: Abbott, Medtronic, BARD
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• Ownership: Thermopeutics, Profusa

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Tibial disease (Ca/diffuse)
• Arterial calcification is frequently observed among patients with PAD, especially those with severe claudication or CLI.
• Arterial calcification severity increases in distal arteries.

BTK Interventions (DES & DCB)
Lesion Length

Target lesion length limited by treatment modality in previous studies.
SAVAL Clinical Study - RCT

**Title**: A Randomized Trial comparing the Drug-Eluting Stent (DES) Below the Knee (BTK) Vascular Stent to Pharmacomechanical Angioplasty (PTA) and Intraarterial Balloon Pneumatic Angioplasty (PBMA) in Patients with Lesions Treated with the SAVAL Stent vs PTA

**Investigator**: Jihad Mustapha, MD, FACS, RPVI, Patrick J. Geraghty, MD, PhD, Hans van Overhagen, MD, PhD

**Objective**: To collect additional information on limb salvage and overall quality of life in this patient population.

**Study Design**: Sequential, single-arm study to collect ongoing safety and effectiveness data.

**Endpoints**:
- **Major Adverse Event (MAE)** rate at 6 months defined as:
  - Above ankle amputation of the index limb
  - Major re-intervention
  - 30-day unplanned hospital readmission rate

**Key Additional Endpoints**
- **Primary patency** measured via DUS at 1, 6, 12, 24, and 36 months post-procedure
- **Clinically-driven target lesion revascularization** at each time point
- **Drug-elution rate**
- **Change in Rutherford classification** at 3, 6, 12, 24, and 36 months post-procedure
- **Quality of Life** changes at 1, 3, 6 and 12 months post-procedure

**Patients**
- Chronic, symptomatic lower limb ischemia (Rutherford categories 4 or 5)
- Segmental, restenotic or occluded target lesion(s) located in the iliofemoral, superficial femoral, popliteal, posterior tibial and/or anterior tibial arteries associated with or not associated with an ulcer
- Reference vessel diameter 2.5 - 3.75 mm
- Lesions in the iliofemoral, superficial femoral, popliteal, posterior tibial and/or anterior tibial arteries associated with or not associated with an ulcer
- Lesions <140 mm in length
- **Follow-up**: Office visits at 1, 6, 12, 24, and 36 months post procedure; Telephone follow-up at 36 and 52 months post procedure.
Conclusions

- Chronic Limb Threatening Ischemia (CLTI) is associated with high amputation rates and poor clinical outcomes
- CLTI is commonly associated with below-the-knee lesions and challenging anatomy
- Endovascular treatment has potential to increase wound healing and reduce amputation rates
- The SAVAL clinical study will investigate safety and efficacy of a drug-eluting stent designed for use below-the-knee