Interim Results from the Prospective Study of the Zilver® Vena™ Venous Stent in the Treatment of Symptomatic Iliofemoral Venous Outflow Obstruction in Europe (VIVO-EU)

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Zilver® Vena™ Venous Stent

- CE Marked in 2010
- Intended for the treatment of symptomatic iliofemoral outflow obstruction
- Design characteristics:
  - Self-expanding nitinol stent
  - 7 Fr delivery system
  - 14 and 16 mm diameters
  - 60, 100, and 140 mm lengths

VIVO-EU Study Design

- Prospective, nonrandomized study in the EU
- Objective: to evaluate the Zilver Vena Venous Stent in the treatment of symptomatic iliofemoral outflow obstruction
- Enrollment: 35 patients with symptomatic iliofemoral outflow obstruction demonstrated by:
  - CEAP “C” ≥ 3, or
  - VCSS pain score ≥ 2
- Patients treated as per usual medical practice

Key Exclusion Criteria

- Planned surgical/interventional procedures of the target limb within 30 days prior to or any time after the study procedure
- Except: thrombolysis, thrombectomy, or IVC filter placement prior to stent implantation
- Lesions with intended treatment lengths extending into the IVC or below the lesser trochanter
- Previous stent placement within the target vessel

Follow-up Schedule

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<th>Follow-up (months)</th>
<th>Pre-Procedure</th>
<th>Post-Procedure</th>
<th>Follow-up</th>
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<td>Clinical assessment and adverse events</td>
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<td>Venography</td>
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Baseline Lesion Data (Site Reported)

- Lesion length (mm; mean ± SD) 106 ± 69 (range: 20-256)
- Total occlusion 12.9% (4/31)
- Left side 94.3% (33)
- Common iliac vein 54.3% (19)
- Common femoral, external iliac, common iliac veins 20.0% (7)

Procedural Venography Results

>100% Diameter Improvement in Both Projections

- Distribution of Patients by VDS
  - Pre-procedure: 30%
  - 1 Month: 25%
  - 6 Months: 20%
  - 12 Months: 15%
- Mean VCSS
  - Pre-procedure: 10
  - 1 Month: 9
  - 6 Months: 7
  - 12 Months: 5

Conclusions

- VIVO-EU included patients and lesions representative of the “real world” population with iliofemoral venous outflow obstruction
- Zilver Vena Venous Stent placement resulted in a greater than 100% luminal diameter improvement immediately post-procedure
- Based on interim analysis, venous clinical symptoms improved following treatment, suggesting that the stent is beneficial to patients