Safety and Efficacy Report on the BlueLeaf Endovenous Valve Formation System: Update on Intl and US Clinical Research

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Disclosures

• InterVene, Inc.
• Boston Scientific Corporation

InterVene’s Technology: Endovenous Valve Formation (EVF)

BlueLeaf® System:
• Non-implantable, non-surgical Tx for DVR
• 16Fr Retrograde Common Femoral Access
• IVUS and Fluoro Guided
• Multiple Valves Per Procedure
• Primary & Secondary disease capable

Surgical Analog: The Maleti Neovalve

<table>
<thead>
<tr>
<th>Surgeon</th>
<th>Maleti</th>
<th>Hoshino</th>
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<tbody>
<tr>
<td>Procedures (patients)</td>
<td>40 (36)</td>
<td>10 (10)</td>
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<tr>
<td>Median follow-up (months)</td>
<td>36.5 (28-78)</td>
<td>16.5 (6-26)</td>
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<tr>
<td>Ulcer healing</td>
<td>96% (1-10) weeks</td>
<td>100% (12 weeks)*</td>
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</tbody>
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2: Hoshino et al. EVF 2016 abstract
3: Maleti et al. Eur J Vasc Endovasc Surg (011) 41, 837-848
Example of BlueLeaf Valves - Cadaveric Tissue

Monocuspid

Bicuspid

Feasibility Study: INFINITE-OUS

Investigation of Femoropopliteal In Situ Valve Formation with the InterVene System

- Study Device: BlueLeaf EVF System
- Sponsor: InterVene, Inc
- Key Inclusion / Exclusion
  - C3-C6 (Only C4-C6 treated to date)
  - No active superficial reflux or outflow obstruction
  - Failed Conservative Therapy
  - Significant DVR (>1.0 s RT in 2 contiguous segments - Prox Fem, Dist Fem, Pop)
  - Adequate inflow, no acute DVT, suitable target site
- Anticoagulation: LMWH (min 7 days), bridge to Warfarin or DOAC for 6mo
- Follow-Up: Duplex @ 7d, 30d, 90d, 7mo, 1yr
- Core Lab adjudicated

Consistent Procedural Success

- n=14 subjects treated, fu 30 days to 1 year
  - 13/14 (92%) procedural success (completing all valve formation steps within a vein wall)
  - Valves formed per procedure:
    - Mean: 1.4 valves/subject
    - Range: 0–3
    - All monocuspid valves to date

Safety Results

- No Occlusive DVT to Date

Notable Device/Procedure related AE’s:

- n=4 subjects w/ thrombus behind leaflet, all resolved by 90d fu
- n=1 subject w/ symptomatic AVF bruising, resolved w/ compression
- n=6 subjects w/ access site AE’s, 1 requiring surgical intervention (evac of hematoma)

Clinical Improvement @ 7 Months

- Venous Clinical Severity Score (rVCSS):
  - n=10 subjects w/ procedural success & 7 mo fu
  - 4.9 Point Mean rVCSS Improvement
  - 8/10 subjects w/ 2-point improvement

Trial Status Update & Next Steps

- INFINITE-OUS will continue enrollment in Australia, New Zealand & Canada → will report on 1yr fu in Q3 when data are available
- US Early Feasibility Study (EFS) approved by FDA, starting early 2020. Limited number of sites to start, then expanding.
- Company focused on procedure and device optimization, clin trials, and plan for optimal Pivotal study design as informed by Feasibility results
Gen 3 Cadaveric Tissue Testing

Endovenous Valve Formation

Conclusion

- INFINITE-QUS experience demonstrates viability, repeatability, ease of use of BlueLeaf EVF in primary & secondary CVI patients
- Initial results yield favorable safety with an absence of occlusive DVT, and AEs limited to access site issues and av fistula treated with compression
- Data suggest improving rVCSS trends out to 7-months and ulcer healing
- Early feasibility study planned in US for Q1 2020 (Gen 3)

Thank You