SAFETY AND EFICACY REPORT ON THE VENOVALVE®: First in Human

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CVI

- 1.2 million people with C6 in USA (Medicare data base)
- 2.4 million people alone with C4b- C6

Therapies for these patients include:
- Lugli & Maletti procedure
- Tensocompressive
- Wound care
- Surgery
- Stenting

...Disappointing results at best

VENOVALVE

PATIENT CRITERIA

Inclusion Criteria
- Axial Reflux > 1 sec.
- Valvular Insufficiency (primary or secondary)
- CEAP: C5 - C6
- Ability to Walk Unassisted
- ABI > .75
- BMI < 35

Exclusion Criteria
- Hypercoagulable Condition
- DVT or PE
- Lymphedema
- Superficial Reflux
- Iliac/IVC Obstruction
- Uncontrolled Diabetes Mellitus, Thyroidism, Sepsis, Acute Respiratory Disease
VV - FIRST-IN-MAN STUDY: PATIENT ENROLLMENT, N=9

<table>
<thead>
<tr>
<th>AGE</th>
<th>CEAP</th>
<th>AGE</th>
<th>CEAP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient #1</td>
<td>66</td>
<td>C5</td>
<td>Patient #6</td>
</tr>
<tr>
<td>Patient #2</td>
<td>82</td>
<td>C5</td>
<td>Patient #7</td>
</tr>
<tr>
<td>Patient #3</td>
<td>61</td>
<td>C6</td>
<td>Patient #8</td>
</tr>
<tr>
<td>Patient #4</td>
<td>87</td>
<td>C6</td>
<td>Patient #9</td>
</tr>
<tr>
<td>Patient #5</td>
<td>81</td>
<td>C6</td>
<td></td>
</tr>
</tbody>
</table>

Average Age = 70.8 years  N = 9 (7 women; 2 men)

C5 - Healed Venous Leg Ulcer
C6 - Venous Leg Ulcer

VV: FIRST-IN-MAN STUDY END POINTS

‣ Safety: infection; PE; native vein injury; allergic reaction
‣ Reflux: measured by duplex ultrasound
‣ Venous Clinical Severity Score (VCSS) - 10 hallmarks of venous disease rated 0 to 3 in severity and administered by physician to grade disease progression
‣ Visual Analogue Scale (VAS) Score - intensity and frequency of pain
‣ Implantation Technique

VV - OUTPATIENT SURGERY

SAFETY

- 1 Seroma - aspirated
- Over Anticoagulation w/ Coumadin therapy
- 2 Minor wound infections (erythema) treated with antibiotics

6 MONTH RESULTS

<table>
<thead>
<tr>
<th>REFLUX (% Decrease)</th>
<th>VCSS (% Decrease)</th>
<th>VAS (% Decrease)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient #1</td>
<td>80%</td>
<td>63%</td>
</tr>
<tr>
<td>Patient #2</td>
<td>30%</td>
<td>60%</td>
</tr>
<tr>
<td>Patient #3</td>
<td>100%</td>
<td>67%</td>
</tr>
<tr>
<td>Patient #4</td>
<td>65%</td>
<td>38%</td>
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<tr>
<td>Patient #5</td>
<td>30%</td>
<td>69%</td>
</tr>
<tr>
<td>AVERAGE</td>
<td>61%</td>
<td>59%</td>
</tr>
</tbody>
</table>

Percentages based upon Pre-Operative Levels v. 6 months

Average Reduction 59%*

1.8
1.6
1.4
1.2
1.0
0.8
0.6
0.4
0.2
0.0

Average Reduction 59%*
CONCLUSIONS

- No serious safety events at 180 days
- 61% average axial reflux improvement at 180 days
- 59% average improvement in VCSS at 180 days (avg. 7.6 points)
- 54% average improvement VAS at 180 days (reduction in Pain)
- Substantial venous ulcer healing
- Evolved implantation technique
- Feasibility study, needs to evolve to second phase

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Gracias.