Longer Term Safety and Efficacy of Sympathetic Renal Artery Denervation using a Multi-Electrode Renal Artery Denervation Catheter in Patients with Drug-Resistant Hypertension: Eighteen Month Results of a First-in-Human, Multicenter Study

Stephen G Worthley¹,², Vasilios Papademetriou³, Matthew Worthley², Derek Chew⁴, Ajay Sinhal⁴, Ian Meredith⁵, Yuvaraj Malaiapan⁵, Costas Tsioufis⁶,⁷

1. Royal Adelaide Hospital
2. University of Adelaide
3. VA Medical Center, Washington DC
4. Flinders University/Flinders Medical Centre
5. Monash Heart/Monash Cardiovascular Research Center
6. First Cardiology Clinic, University of Athens
7. Hippokration General Hospital of Athens
Exclusion due to renal artery anatomy therefore renal denervation was not attempted.
Study Results: Safety Data

Objective
The primary safety outcome was assessment of all adverse events.

• No Serious Peri-Procedural Events
• Serious device/procedure events through 18 months:
  – Worsening of pre-existing proteinuria (n=1)
  – Symptomatic hypotension (n=1)
  – Worsening of pre-existing renal artery stenosis and new stenotic lesion (n=2 events in 1 patient)

The EnligHTN System delivers renal denervation with no serious peri-procedural events and an acceptable safety profile through 18 months.
Study Results: Renal Function

<table>
<thead>
<tr>
<th></th>
<th>Baseline (n=46)</th>
<th>Month 1 (n=46)</th>
<th>Month 3 (n=46)</th>
<th>Month 6 (n=45)</th>
<th>Month 12 (n=45)</th>
<th>Month 18 (n=44)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>eGFR (mL/min/1.73m²)</strong></td>
<td>87 (±19)</td>
<td>85 (±20)</td>
<td>84 (±22)</td>
<td>82 (±20)</td>
<td>86 (±21)</td>
<td>77 (±16)</td>
</tr>
<tr>
<td><strong>Serum Creatinine (mmol/L)</strong></td>
<td>78 (±17)</td>
<td>79 (±19)</td>
<td>81 (±20)</td>
<td>83 (±20)</td>
<td>80 (±28)</td>
<td>86 (±21)</td>
</tr>
<tr>
<td><strong>Cystatin C (mg/L)</strong></td>
<td>1.14 (±0.29)</td>
<td>1.00 (±0.25)</td>
<td>0.97 (±0.20)</td>
<td>1.00 (±0.23)</td>
<td>0.91 (±0.19)</td>
<td>1.1 (± 0.3)</td>
</tr>
<tr>
<td><strong>Urine Albumin-to-Creatinine Ratio (mg/g)</strong></td>
<td>167.6 ± 493</td>
<td>142.9 (±477)</td>
<td>141.3 (±449)</td>
<td>139.3 (±449)</td>
<td>116.9 (±421)</td>
<td>131.0 (±358)</td>
</tr>
</tbody>
</table>

No clinically significant changes in renal function.
EnligHTN therapy delivers a rapid and significant reduction in Office BP that is sustained through 18 months
EnligHTN therapy delivers a rapid and significant reduction in Office BP that is sustained through 18 months
Responder & Goal Blood Pressure Parameters

- 77% of patients are considered responders at 18 months (>10 mmHg OSBP Reduction from baseline)
- 68% have an OSBP <160 mmHg at 18 months despite a mean baseline of 176 mmHg

~2/3 of patients have a great enough reduction in their BP to move to a lower stage of HTN classification and treatment
### EnligHTN I 18 Month Results

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
</table>
| **Safety**          | • No serious peri-procedural events  
                      • No flow-limiting renal artery vasospasms                                |
| **Short Term Results** | • Office BP was reduced by 28/10 mmHg at one month                          |
| **Long Term Results** | • A significant reduction in office Systolic and Diastolic BP was sustained at 18 months  
                           • 77% of patients are responders at 18 months                           |