Lutonix AV Global Registry

6 Month Results
Singapore and Taiwan

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Disclosure

Speaker name: 

Chong Tze Tec, MD

I have the following potential conflicts of interest to report:

☐ Consulting
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

☒ I do not have any potential conflict of interest
## Study Design

<table>
<thead>
<tr>
<th>Study Design</th>
<th>A Prospective, Multicenter, Single Arm Real-World Registry Investigating the Clinical Use and Safety of the Lutonix® Drug Coated Balloon PTA Catheter for Treatment of Dysfunctional Native and Synthetic AV Fistulae</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objective</td>
<td>To demonstrate safety and assess the clinical use and outcomes of the Lutonix® DCB for treatment of dysfunctional AV fistulae located in the arm in a heterogeneous patient population in real world clinical practice</td>
</tr>
<tr>
<td>Number of Subjects/Sites</td>
<td>324 subjects enrolled at 25 international sites</td>
</tr>
</tbody>
</table>
| Primary Endpoints | **Efficacy**: Target Lesion Primary Patency (TLPP) through 6 months.  
**Safety**: Freedom from any serious adverse event(s) involving the AV access circuit through 30 days |
| Follow-up      | Clinical assessment at 6 months.  
Clinical or telephone assessment at 3 and 12 months |
| Global PI      | Dimitrios Karnabatidis, MD- Patras, Greece |
Lutonix AV Global Registry

- 324 subjects enrolled in Global Registry
  - 99 subjects enrolled in Singapore and Taiwan
Taiwan has highest prevalence of dialysis
Singapore has 3rd highest prevalence
Diabetes primary cause
Few transplants
- Taiwan 4 per 1000 patients
- Singapore 11 per 1000 patients

1. USRDS Annual Data Report Chapter 11 2018 International Comparisons
### Lutonix AV Global Registry

**Similar Key Patient Demographics**

<table>
<thead>
<tr>
<th></th>
<th>Diabetes</th>
<th>Hypertension</th>
<th>Dyslipidemia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global Registry</td>
<td>41.9%</td>
<td>73.4%</td>
<td>26.9%</td>
</tr>
<tr>
<td>Singapore &amp; Taiwan</td>
<td>42.4%</td>
<td>72.7%</td>
<td>25.3%</td>
</tr>
</tbody>
</table>

Results shown are interim, site reported, and subject to change.
Lutonix AV Global Registry

Similar AVF vs. AVG

**Synthetic Graft/AVG**
- 25% Global Registry
- 25.3% Singapore and Taiwan

**Native Fistula/AVF**
- 75% Global Registry
- 74.7% Singapore and Taiwan

Image courtesy of BD: Illustration by Paul Schiffmacher
Results shown are interim, site reported, and subject to change.
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Access Location

**Upper Arm**
- 47.5% Global Registry
- 38.4% Singapore and Taiwan

**Antecubital Fossa**
- 11.3% Global Registry
- 5.1% Singapore and Taiwan

**Forearm**
- 41.3% Global Registry
- 56.6% Singapore and Taiwan

**Left Arm**
- 73.4% Global Registry
- 74.7% Singapore and Taiwan

Results shown are interim, site reported, and subject to change.

Image courtesy of BD: Illustration by Paul Schiffmacher
# Lutonix AV Global Registry

## Similar Key Lesion Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Mean Target Lesion Length</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Global Registry</strong></td>
<td>32.0 mm ± 20.86mm</td>
</tr>
<tr>
<td><strong>Singapore &amp; Taiwan</strong></td>
<td>35.4mm ± 24.24mm</td>
</tr>
</tbody>
</table>

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### Lutonix AV Global Registry

#### Key Lesion Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Restenotic</th>
<th>ISR</th>
<th>Central Vein</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global Registry</td>
<td>52.9%</td>
<td>11.1%</td>
<td>11.6%</td>
</tr>
<tr>
<td>Singapore &amp; Taiwan</td>
<td>80.5%</td>
<td>10.5%</td>
<td>5.1%</td>
</tr>
</tbody>
</table>

Results shown are interim, site reported, and subject to change.
Lutonix AV Global Registry

97.9% Freedom from Primary Safety Events- Singapore & Taiwan

Results shown are interim, site reported, and subject to change.
Lutonix AV Global Registry

77.6% TLPP at 6 Months Singapore & Taiwan

Results shown are interim, site reported, and subject to change.
## Lutonix AV Global Registry

### 6 Month Similar TLPP

<table>
<thead>
<tr>
<th>Lutonix AV Global Registry</th>
<th>Singapore &amp; Taiwan</th>
<th>Trerotola et. al(^1)</th>
<th>Kitrou et. al(^2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>73.5%</td>
<td>77.6%</td>
<td>71.4%</td>
<td>72.2%</td>
</tr>
</tbody>
</table>


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Lutonix AV Global Registry

63.6% ACPP at 6 Months
Singapore & Taiwan

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Freedom from ACPP Failure with KM Method, ITT Subjects
Singapore & Taiwan Summary

• Despite differences in Asian dialysis population, results were similar
  – Lutonix® DCB safety was similar in Asian patient population to Global Registry
  – 6 month TLPP in Asian patient population was similar to Global Registry
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