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Disclosure

Speaker name:
Scott O. Trerotola, 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
# Lutonix AV Clinical Trial

## Study Design

<table>
<thead>
<tr>
<th>Study Design</th>
<th>Prospective, Global, Multicenter, Randomized, Core lab Blinded, Safety and Effectiveness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objective</td>
<td>To assess the safety and effectiveness of the LUTONIX® 035 AV Drug Coated Balloon PTA Catheter in the treatment of dysfunctional AV fistulae</td>
</tr>
<tr>
<td>Number of Patients/Sites</td>
<td>285 randomized subjects at 23 clinical sites</td>
</tr>
<tr>
<td>Primary Effectiveness Endpoint</td>
<td>Target Lesion Primary Patency (TLPP) - 6 months</td>
</tr>
<tr>
<td>Primary Safety Endpoint</td>
<td>Freedom from any serious adverse event(s) involving the AV access circuit through 30 days</td>
</tr>
<tr>
<td>Follow Up</td>
<td>1, 3, 6, 9, 12, 18, 24 month visits</td>
</tr>
</tbody>
</table>
| Status                     | First Subject: June 2015  
Enrollment Completion: March 2016 |
Lutonix AV Clinical Trial

Key Inclusion Criteria

**CLINICAL**

Male or non-pregnant female ≥21 years old

Upper extremity AV fistula w/clinical, physiological, or hemodynamic abnormality

Fistula created ≥30 days
- 1+ hemodialysis session
- 2 needles
- catheter removed ≥ 30 days

**ANGIOGRAPHIC**

Length ≤10 cm
≥50% stenosis
Successful pre-dilation

Diameter 4-12 mm
Lutonix AV Clinical Trial

Key Exclusion Criteria

**CLINICAL**
- Lower extremity access
- Central veins
- Thrombosed access

**ANGIOGRAPHIC**
- >2 lesions in circuit
- Secondary non-target lesion that cannot be successfully treated
- Central veins as a secondary lesion, which is clinically significant
- Bare or covered stent in target or secondary non-target lesions
Lutonix AV Clinical Trial

Study Design

Pre-Dilation with PTA

Non-target lesion treated (if needed)
Residual stenosis ≤30%

Pre-dilation lesion(s) treatment area criteria

Residual stenosis >30%
No enrollment in study
Further treatment per standard practice

Residual stenosis ≤30%
Completely efface waist
No clinical significant dissection/ extravasation
Randomization (1:1)
Enrollment in study

Treatment with Lutonix DCB (TEST)
≥ 1:1 Pre-Dil and test balloon sizing

Treatment with Standard PTA (CONTROL)
≥ 1:1 Pre-Dil and control balloon sizing

Follow-up: 1,3,6,9,12,18 and 24 months; unscheduled visits
Lutonix AV Clinical Trial

Fistula Locations

Upper arm
DCB: 61.7% vs. PTA: 73.4%

Antecubital fossa
DCB: 5.0% vs. PTA: 4.9%

Forearm
DCB: 33.3% vs. PTA: 21.7%
## Lutonix AV Clinical Trial

### Target Lesion Locations

<table>
<thead>
<tr>
<th>Location</th>
<th>DCB (n=141)</th>
<th>PTA (n=144)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anastomotic (%)</td>
<td>4.3%</td>
<td>3.5%</td>
</tr>
<tr>
<td>Cephalic arch (%)</td>
<td>18.7%</td>
<td>22.5%</td>
</tr>
<tr>
<td>Cannulation zone (%)</td>
<td>4.3%</td>
<td>9.9%</td>
</tr>
<tr>
<td>Inflow (%)</td>
<td>33.8%</td>
<td>29.6%</td>
</tr>
<tr>
<td>Outflow (%)</td>
<td>24.5%</td>
<td>22.5%</td>
</tr>
<tr>
<td>Swing point (%)</td>
<td>14.4%</td>
<td>12.0%</td>
</tr>
</tbody>
</table>

Image courtesy of Bard: illustration by Paul Schiffmacher
95% CI of the rate and the rate difference at each time point were calculated based on normal approximation and one-sided p-value is from test for non-inferiority, with 10% as non-inferiority margin.
Lutonix AV Clinical Trial
Interim 24 Month TLPP

<table>
<thead>
<tr>
<th></th>
<th>LTX DCB</th>
<th>Standard PTA</th>
<th>Difference % (95% CI)</th>
<th>P-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>730 Day Event Free</td>
<td>32.1% (4.5%)</td>
<td>24.7% (4.4%)</td>
<td>7.4% (6.3%)</td>
<td>0.0513</td>
</tr>
<tr>
<td>Rate (SE)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>95% CI</td>
<td>(23.5%, 41.0%)</td>
<td>(16.5%, 33.7%)</td>
<td>(-5.0%, 19.8%)</td>
<td></td>
</tr>
</tbody>
</table>

Data shown are interim, site reported and subject to change

36.8% Improvement
30% Improvement

*one-sided p-value
<table>
<thead>
<tr>
<th>Title</th>
<th>Type</th>
<th>6 Month</th>
<th>12 Month</th>
<th>24 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lutonix AV IDE Clinical Trial</td>
<td>RCT n=285 AVF</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Percutaneous Angioplasty Using a Paclitaxel-Coated Balloon Improves Target Lesion Restenosis on Inflow Lesions of Autogenous Radiocephalic Fistulas: A Pilot Study Lai et al. JVIR 2014: 25:535-541</td>
<td>RCT n=10 (20 lesions) AVF</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Paclitaxel-Coated vs. Plain Balloon Angioplasty for Dysfunctional Arteriovenous Fistulae: One-Year Results of a Prospective Randomized Controlled Trial Kitrou et al. JVIR 2015;26:348-354</td>
<td>RCT n=40 AVF</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Paclitaxel-Coated Balloon Angioplasty vs. Plain Balloon Dilation for the Treatment of Failing Dialysis Access: 6-Month Interim Results from a Prospective Randomized Controlled Trial Katsanos et al. J Endovasc Ther 2012;19:263-272</td>
<td>RCT n=40 Grafts+AVF</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Lutonix AV Clinical Trial Summary

- First and only DCB with 24 month Level 1 data
- Safety outcomes are non-inferior to PTA
- 24 month results
  - Sustained effectiveness
  - 30% improvement in TLPP over PTA at 24 months
- Next step: Post-approval study
Long Term Effects of LUTONIX® 035 DCB Catheter

Interim 24 Month Results

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