ELUVIA™ Drug-Eluting Vascular Stent System

87.9% Primary Patency in the IMPERIAL Long Lesion Sub-Study (162.8 mm lesion length)

OBJECTIVE: To evaluate the safety and effectiveness of the Eluvia Drug-Eluting Vascular Stent System for treating Superficial Femoral Artery (SFA) and/or Proximal Popliteal Artery (PPA) lesions >140 mm and ≤ 190 mm in length.

TRIAL DESIGN: A 50 subject concurrent, non-blinded, non-randomized, single arm (Eluvia) long lesion sub-study.

Primary Safety Endpoints
The primary safety endpoint assesses the 12-month MAE-free rate.

Primary Effectiveness Endpoint
The primary effectiveness endpoint assesses the 12-month primary patency.

BASELINE CHARACTERISTICS:

<table>
<thead>
<tr>
<th>Patient Demographics</th>
<th>Eluvia (n=50)</th>
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</thead>
<tbody>
<tr>
<td>Age (Years)</td>
<td>68.2±8.9</td>
</tr>
<tr>
<td>Male Gender</td>
<td>64.0%</td>
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<tr>
<td>Diabetes Mellitus</td>
<td>40.0%</td>
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<tr>
<td>History of Smoking</td>
<td>84.0%</td>
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<tr>
<td>Hypertension</td>
<td>92.0%</td>
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<tr>
<td>Hyperlipidemia</td>
<td>82.0%</td>
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<tr>
<td>Coronary Artery Disease</td>
<td>56.0%</td>
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<table>
<thead>
<tr>
<th>Lesion Characteristics</th>
<th>Eluvia (n=50)</th>
</tr>
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<tbody>
<tr>
<td>Target Lesion Length (mm)</td>
<td>162.8±34.7</td>
</tr>
<tr>
<td>Reference Vessel Diameter (mm)</td>
<td>4.7±0.7</td>
</tr>
<tr>
<td>Moderate Calcification</td>
<td>42.0%</td>
</tr>
<tr>
<td>Severely Calcified</td>
<td>28.0%</td>
</tr>
<tr>
<td>Percent Diameter Stenosis</td>
<td>81.9±15.0</td>
</tr>
<tr>
<td>Total Occlusions</td>
<td>32.0%</td>
</tr>
<tr>
<td>Extending into Distal SFA (including proximal popliteal)</td>
<td>76.0%</td>
</tr>
<tr>
<td>Stented Segment Length (mm)</td>
<td>193.3±28.9</td>
</tr>
</tbody>
</table>

12-MONTH PRIMARY PATENCY RESULTS: Eluvia demonstrated **87.9% primary patency** in the IMPERIAL Long Lesion Sub-Study.

KAPLAN-MEIER PRIMARY PATENCY RATE

1. Primary Patency: percentage (%) of lesions (target stented segments) that reach endpoint without a hemodynamically significant stenosis on DUS and without clinically-driven TLR or, bypass of the target lesion before or on the DUS FU visit.
There may be other potential adverse events that are unforeseen at this time. Eluvia is a registered or unregistered trademark of Boston Scientific Corporation or its affiliates. All other trademarks are property of their respective owners.

Hematologic dyscrasia (including leukopenia, neutropenia, thrombocytopenia) • Hepatic enzyme changes • Histologic changes in vessel wall, including inflammation, cellular damage or necrosis • Myalgia/Arthralgia • Peripheral neuropathy

that may be unique to the paclitaxel drug coating: • Allergic/immunologic reaction to drug (paclitaxel or structurally-related compounds) or the polymer stent coating (or its individual components) • Alopecia • Anemia • Gastrointestinal symptoms •

• Thrombosis/thrombus • Transient hemodynamic instability (hypotensive/hypertensive episodes) • Vasospasm • Vessel injury, including perforation, trauma, rupture and dissection • Vessel occlusion

Probable adverse events not captured above

• 100%
• 80%
• 60%
• 40%
• 20%
• 0%

RUTHERFORD CATEGORY

Baseline Eluvia pre-procedure Eluvia 1 month post-procedure Eluvia 6 month post-procedure Eluvia 12 months post-procedure

Eluvia
(n=50)

12-month MAE 6.5%
All Causes of Deaths at 1 Month 0.0%
Target Limb Major Amputation 0.0%
Target Lesion Revascularization 6.5%
Stent Thrombosis 0.0%

6.5% TLR in 162.8 mm Lesions

PATIENT OUTCOMES:

• 87.2% of Eluvia patients presented with no or minimal claudication (Rutherford 0-1) at 12 months
• 91.5% of Eluvia patients had improvement by at least 1 Rutherford category compared with baseline without the need for TLR

12-MONTH SAFETY RESULTS:

• 93.5% of patients were free of Major Adverse Events at 12 months

Eluvia
(n=162.8 mm Lesions)

1.85 mm TLR
12-month results

PERIPHERAL INTERVENTIONS

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