ADVANCING 1-MONTH DAPT EVIDENCE

Onyx ONE Clear Study\(^1\)
Evaluating Resolute Onyx™ DES in \(\sim 1,500\)
highly complex high bleeding risk (HBR)
patients with 1-month DAPT,\(^*\) including
\(\sim 600\) patients in the U.S. and Japan.

RESOLUTE ONYX DES BEAT PERFORMANCE GOAL FOR CARDIAC DEATH AND MI

\[^p < 0.001\]
\[^n = 1,491/1,506\]

<table>
<thead>
<tr>
<th>Event Rates (%)</th>
<th>1–12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Endpoint</td>
<td>Cardiac Death/Mi</td>
</tr>
<tr>
<td>7.0</td>
<td>2.6</td>
</tr>
<tr>
<td>4.8</td>
<td>3.4</td>
</tr>
<tr>
<td>0.7</td>
<td></td>
</tr>
</tbody>
</table>

†Performance goal derived from contemporary 1-month DAPT trials.**

<table>
<thead>
<tr>
<th>NO VESSEL OR LESION LIMITATIONS</th>
<th>REAL-WORLD PATIENT POPULATION</th>
<th>BROADEST HBR INCLUSION CRITERIA(^††)</th>
</tr>
</thead>
<tbody>
<tr>
<td>79% B2/C LESIONS</td>
<td>37 mm AVERAGE STENTED LENGTH</td>
<td>39% MODERATE TO SEVERE CALCIFIED LESIONS</td>
</tr>
<tr>
<td>50% AVERAGE AGE</td>
<td>74 AVERAGE AGE</td>
<td>36% PRIOR REVASC</td>
</tr>
<tr>
<td>1.6 HBR CRITERIA PER PATIENT</td>
<td>44% PATIENTS HAVING TWO OR MORE HBR CRITERIA</td>
<td></td>
</tr>
</tbody>
</table>

**First prospective, randomized, 1-month DAPT trial comparing a DES to a DES in HBR patients.

††First study in the U.S. and Japan evaluating 1-month DAPT duration in HBR patients with a current DES.

\[^\text{medronic}\]
which include subacute and late vessel thrombosis, vascular breached.

**Warnings**

- Patients with a known hypersensitivity to the drug components, including sirolimus, everolimus, or similar drugs or any other analogue or derivatives.

- Patients with a known hypersensitivity to the Biolyon® polymer or its individual components.

- Coronary artery stenting is contraindicated for use in patients in whom antithrombotic and/or anticoagulation therapy is contraindicated.

- Patients who are judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the stent or stent delivery system.

**Precautions**

- Only physicians who have received adequate training should perform implantation of the stent.

- The use of this product carries the same risks associated with percutaneous coronary artery stent implantation procedures, which include subacute and late vessel thrombosis, vascular complications, and/or bleeding events.

- This product should not be used in patients who are not likely to comply with the recommended antiplatelet therapy.

**Indications**

The Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System is indicated for improving coronary luminal diameters in patients, including those with diabetes mellitus, with symptomatic ischemic heart disease due to de novo lesions of length ≤ 35 mm in native coronary arteries with reference vessel diameters of 2.0 mm to 9.0 mm. In addition, the Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System is indicated for treating de novo chronic total occlusions.

**Contraindications**

The Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System is contraindicated for use in patients with evidence of an acute ST-elevation MI and patients with prior exposure to a drug-eluting stent.

**Warnings**

- Please ensure that the inner package has not been opened or damaged as this would indicate the sterile barrier has been breached.

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