Global Study Comparing a rivArxaban-based Antithrombotic Strategy to an antiPlatelet-based Strategy After TAVR: Main Results of The GALILEO Trial

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RATIONALE for STUDY and UNMET NEED

Optimal antithrombotic strategy post-TAVR is unknown.

Risk of stroke remains high early and late post TAVR despite antiplatelet Rx.

Tissue factor and thrombin triggered by native valve leaflets, turbulent flow around leaflets and frame, and aortic wall injury.

Observation of reduced subclinical valve thrombosis and resolution with oral anticoagulation.
GALILEO First randomized assessment of OAC+ASA versus DAPT post-TAVR

Primary hypothesis: rivaroxaban-based strategy would be superior to the antiplatelet-based strategy with respect to incidence of death or thromboembolic events

Trial was stopped early due to increase in all-cause mortality, thromboembolic and bleeding events in rivaroxaban-treated patients
Result interpretation/clarification

- Patient population
- Dosing Strategy
- Timing of intervention: risk-laden periods
- ? Association of TE events and death with treatment interruption/discontinuation/physician response to bleeding
- ? Association of AF incidence, dose escalation, and bleeding
- Unknown incidence of subclinical paroxysmal AF
1. AGE AND COMPLEXITY OF PATIENT POPULATION

- High prevalence of vascular disease, cerebral angiopathy, abnormal renal function - Rivaroxaban arm treatment naive

2. DOSING STRATEGY STUDIED

<table>
<thead>
<tr>
<th>Indication</th>
<th>Ortho ppx</th>
<th>Acute VTE Rx</th>
<th>Stable CVD</th>
<th>AF</th>
<th>Post TAVR</th>
</tr>
</thead>
<tbody>
<tr>
<td>AGE</td>
<td>63</td>
<td>56</td>
<td>68</td>
<td>73</td>
<td>80</td>
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<tbody>
<tr>
<td>Dose</td>
<td>10 mg QD</td>
<td>15 BID; 20 mg QD</td>
<td>2.5 BID</td>
<td>20 mg or 15 mg QD</td>
<td>10 mg QD</td>
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</tbody>
</table>
3. Period-specific treatment effects
? Association of TE events and death with treatment interruption/discontinuation/reversal with major bleeds/physician response to any bleed

AF incidence-reported to be as high as 30% post TAVR.
Did patients with dose escalation affect bleeding rates/Rx discontinuation?
Subclinical AF may have contributed to mortality and stroke
Implications of Galileo

• Await results of other trials in the TAVR population

• Rivaroxaban 2.5 mg BID may be a reasonable next study

• Potential population for Factor Xla inhibition-contact pathway

• Medically complicated high risk population with mean age 80 years, combination therapy may not be feasible
Thank you!