The XIENCE Short DAPT Program:

XIENCE 90/28

Evaluating the Safety of 3-month and 1-month DAPT in HBR Patients

Roxana Mehran, MD and Marco Valgimigli, MD, PhD

on Behalf of the XIENCE 90/28 Investigators
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@vlgmrc
### Disclosure Statement of Financial Interest

Within the past 12 months, I, **Roxana Mehran**, or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

<table>
<thead>
<tr>
<th>Affiliation/Financial Relationship</th>
<th>Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consultant / Advisory / Speaking Engagements</td>
<td>Abbott Laboratories (to institution), Abiomed (spouse), Boston Scientific, Idorsia Pharmaceuticals Ltd. (no fee), Janssen, Medscape/WebMD, Medtelligence (Janssen Scientific Affairs), Roivant Sciences Inc, Sanofi, Siemens Medical Solutions, Regeneron Pharmaceuticals (no fee), Spectranetics/Philips/Volcano Corp (to institution), The Medicines Company (spouse)</td>
</tr>
<tr>
<td>Research Funding to Institution</td>
<td>Abbott Laboratories, Abiomed, AstraZeneca, Bayer, Beth Israel Deaconess, BMS, CERC, Chiesi, Concept Medical, CSL Behring, DSI, Medtronic, Novartis, OrbusNeich</td>
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<tr>
<td>Scientific Advisory Board</td>
<td>Bristol-Myers Squibb (to institute), Medtelligence (Janssen Scientific Affairs), Merck (spouse)</td>
</tr>
<tr>
<td>Equity, &lt;1%</td>
<td>Claret Medical, Elixir Medical</td>
</tr>
<tr>
<td>DSMB Membership Paid to Institution</td>
<td>Watermark, Research Partners</td>
</tr>
<tr>
<td>Associate Editor</td>
<td>ACC, AMA</td>
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</tbody>
</table>
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<tr>
<td>Grant/Research Support</td>
<td>Daiichi Sankyo, Medicure, Terumo, CoreFLOW</td>
</tr>
<tr>
<td>Consulting Fees/Honoraria</td>
<td>Abbott, Alvimedica/CID, Astra Zeneca, Bayer, CoreFLOW, Chiesi, IDORSIA,</td>
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<td></td>
<td>Bristol Myers Squib SA, Medscape, Vesalio, Universität Basel Dept. Klinische Forschung</td>
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<tr>
<td>Major Stock Shareholder/Equity</td>
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<td>Royalty Income</td>
<td>None</td>
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<tr>
<td>Ownership/Founder</td>
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<td>Intellectual Property Rights</td>
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<tr>
<td>Other Financial Benefit</td>
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</tr>
</tbody>
</table>
Background

- DAPT is essential for the prevention of ischemic events after PCI but inevitably increases the risk of bleeding.
- Patients at high bleeding risk (HBR) constitute up to 40% of subjects undergoing PCI\(^1\).
- As hemorrhagic events following PCI have substantial prognostic implications\(^2,3\), bleeding-avoidance strategies are vital to improve patient outcomes\(^4\).
- Recent trials on next-generation DES have shown an acceptable safety profile with a short course of DAPT\(^5-8\); however, the optimal DAPT duration in HBR patients remains unknown.

**Stent Platform**

Multilink Stent Design  
CoCr L-605 Alloy  
Strut thickness: 81 μm

**Polymer Coating**

Durable Fluoropolymer Coating  
Fluoropassivation properties selectively retain albumin and minimize platelet adhesion

**Drug**

Everolimus  
Average drug concentration: 100 µg/cm²
In HBR patients who have undergone successful PCI with the XIENCE stent and completed a short DAPT regimen of 1 month (XIENCE 28) or 3 months (XIENCE 90) without experiencing adverse ischemic events, continued treatment with aspirin monotherapy would be non-inferior to DAPT for up to 12 months with respect to ischemic events and superior with respect to bleeding.
Trial Objectives

Among HBR patients who have undergone successful PCI with the XIENCE stent:

**Primary Objective:**
- To evaluate the safety (all death or MI) of a short DAPT regimen (1 or 3 months) versus DAPT for up to 12 months

**Secondary Objectives:**
- To determine the impact of short DAPT (1 or 3 months) versus DAPT for up to 12 months on clinically relevant bleeding (BARC 2-5)
- To evaluate stent thrombosis (definite/probable) against a performance goal*

* Only for XIENCE 90
XIENCE Short DAPT Program

XIENCE Short DAPT Program

3-month DAPT
101 sites in USA
2,047 patients

1-month DAPT
Global
52 sites
963 patients

USA
58 sites
642 patients

TOTAL OF ~3,600 PATIENTS WITH 1-MONTH OR 3-MONTH DAPT
# Short DAPT Program Organization

<table>
<thead>
<tr>
<th>Role</th>
<th>Members</th>
</tr>
</thead>
</table>
| PIs                         | Dr. Roxana Mehran  
|                             | Dr. Marco Valgimigli                                                   |
| Executive Committee         | Drs. Dominick J. Angiolillo, Sripal Bangalore, Deepak L. Bhatt, Junbo Ge,  
|                             | James Hermiller, Rajendra R. Makkar, Franz-Josef Neumann, Shigeru Saito,  
|                             | Marco Valgimigli, Roxana Mehran                                         |
| Steering Committee          | Drs. Jose M De La Torre Hernandez, Vijay Kunadian, Gennaro Sardella,  
|                             | Holger Thiele, Olivier Varenne, Pascal Vranckx, Stephan Windecker,  
|                             | Yujie Zhou                                                              |
| Independent Biostatistician | Dr. Joseph Massaro (Boston University)                                  |
| DSMB                        | Axio Research                                                           |
| CEC                         | Cardiovascular Research Foundation                                      |
| Sponsor                     | Abbott                                                                  |
Participating Sites

**XIENCE 28 USA**
58 Sites U.S. & Canada

**XIENCE 28 Global**
52 Sites Europe & Asia

**XIENCE 90**
101 Sites U.S.
### Key Inclusion Criteria

#### HBR Criteria

- Age ≥75 years
- Chronic OAC therapy
- CKD (creatine ≥ 2.0 mg/dl or dialysis)
- Anemia (hemoglobin <11 g/dl)
- Hematological disorders (platelet count <100,000/mm³ or any coagulation disorder)
- Major bleeding in the last 12 months
- History of stroke

#### Angiographic Criteria

- Successful PCI
- Exclusive use of XIENCE stents
- Target vessel diameter of 2.25 - 4.25 mm
- Target lesion ≤32 mm in length*
- ≤3 target lesions with ≤2 target lesions per vessel

* Only for XIENCE 90
Key Exclusion Criteria

**Clinical Criteria**
- STEMI presentation
- LVEF <30%
- Planned surgery within 1 or 3 months* of PCI

**Angiographic Criteria**
- Target lesion containing thrombus †
- PCI with overlapping stents
- Target lesion in one of the following:
  - left main coronary artery
  - arterial or saphenous vein graft
  - in-stent restenosis
  - chronic total occlusion

* 1 month in XIENCE 28; 3 months in XIENCE 90
† Only for XIENCE 90
A prospective, single-arm, multicenter, open-label, non-randomized trial

**Trial Design**

**Index PCI**
- **P2Y\textsubscript{12} inhibitor + ASA***
- **Stop P2Y\textsubscript{12} inh. if event-free** †
- **Primary analysis period:** from 3 to 12 months

**Follow-up**
- 3 M
- 6 M

**End of study**
- 12 M

---

**Index PCI**
- **P2Y\textsubscript{12} inhibitor + ASA***
- **Stop P2Y\textsubscript{12} inh. if event-free** †
- **Primary analysis period:** from 1 to 6 months

**Follow-up**
- 3 M
- 6 M

**End of study**
- 12 M

---

* For patients on chronic OAC, dual therapy (OAC plus P2Y\textsubscript{12} inhibitor) might be considered for the first 1 or 3 months

† “Event-free” defined as free from MI, repeat revascularization, stroke, or ST and compliant with DAPT in the first 1 or 3 months
Patient Disposition

**XIENCE 90**

Total enrolled
N = 2047

Follow-up at 3 months
N = 1923/2047 (93.9%)

“3-month clear” patients
N = 1693/1923 (88.0%)

Follow-up at 12 months
N = 1653/1693 (97.6%)

37 Deaths
44 Missed Visit
43 Withdrawn by patient or site/physician

230 (12.0%) not 3-month clear:
54 AE before 3 mo
109 DAPT non-compliance
73 Continued P2Y₁₂ after 3 mo
1 Withdrawn by patient

18 LTFU/Missed Visit
22 Withdrawn by patient or site/physician

**XIENCE 28**

Total enrolled
N = 1605

Follow-up at 1 months
N = 1546/1605 (96.3%)

“1-month clear” patients
N = 1392/1546 (90.0%)

Follow-up at 6 months
N = 1375/1392 (98.8%)

11 Deaths
12 LTFU/Missed visit
1 Duplicate subject enrollment
35 Withdrawn by patient or site/physician

154 (10%) not 1-month clear:
25 With AE before 1 mo
35 DAPT Non-Compliance
134 Physician’s Concern
6 Continued P2Y₁₂ after 1 mo

**“Clear” defines patients who are event free (MI, repeat revascularization, stroke, or ST) and compliant with DAPT within 1 month (XIENCE 28) or 3 months (XIENCE 90) of index PCI**
HBR Criteria Distribution

All Registered Patients

**XIENCE 90**

- Age ≥ 75 years: 65.6%
- Age ≥ 75 years (only): 35.5%
- Chronic OAC therapy: 40.8%
- Hemoglobin < 11 g/dL: 16.2%
- History of stroke: 11.3%
- Creatinine ≥ 2.0 mg/dL: 8.0%
- Platelet < 100,000/mm3: 3.0%
- History of major bleeding: 2.9%

AVERAGE NUMBER OF CRITERIA MET: \(1.5 \pm 0.7\)

**XIENCE 28**

- Age ≥ 75 years: 69.3%
- Age ≥ 75 years (only): 35.1%
- Chronic OAC therapy: 43.9%
- Hemoglobin < 11 g/dL: 15.2%
- History of stroke: 10.8%
- Creatinine ≥ 2.0 mg/dL: 8.6%
- Platelet < 100,000/mm3: 3.9%
- History of major bleeding: 3.6%

AVERAGE NUMBER OF CRITERIA MET: \(1.6 \pm 0.8\)
## Baseline Characteristics

### “Clear” Patients

<table>
<thead>
<tr>
<th>Variable</th>
<th><strong>XIENCE 90 (N = 1693)</strong></th>
<th><strong>XIENCE 28 (N = 1392)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years (Mean ± SD)</td>
<td>75.25 ± 9.29 (1693)</td>
<td>75.97 ± 8.37 (1392)</td>
</tr>
<tr>
<td>Female</td>
<td>35.2% (596/1693)</td>
<td>32.5% (453/1392)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>89.5% (1516/1693)</td>
<td>84.7% (1179/1392)</td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td>82.8% (1401/1693)</td>
<td>67.5% (939/1392)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>39.2% (663/1692)</td>
<td>37.0% (512/1382)</td>
</tr>
<tr>
<td>CKD (eGFR &lt; 60 mL/min)</td>
<td>40.2% (677/1682)</td>
<td>47.4% (631/1330)</td>
</tr>
<tr>
<td>Prior MI</td>
<td>15.8% (264/1669)</td>
<td>16.4% (227/1382)</td>
</tr>
<tr>
<td>Prior CABG</td>
<td>12.1% (205/1693)</td>
<td>8.0% (112/1392)</td>
</tr>
<tr>
<td>ACS</td>
<td>34.7% (588/1693)</td>
<td>34.1% (475/1392)</td>
</tr>
<tr>
<td>NSTEMI</td>
<td>7.1% (120/1693)</td>
<td>17.6% (245/1392)</td>
</tr>
<tr>
<td>Unstable Angina</td>
<td>28.7% (486/1693)</td>
<td>16.5% (230/1392)</td>
</tr>
<tr>
<td>PARIS Score (Median, IQR)</td>
<td>6.0 (4.0, 8.0) (1693)</td>
<td>6.0 (4.0, 8.0) (1392)</td>
</tr>
<tr>
<td>PRECISE-DAPT Score (Median, IQR)</td>
<td>25.0 (19.0, 32.0) (1606)</td>
<td>27.0 (20.0, 34.0) (1295)</td>
</tr>
</tbody>
</table>
# Procedural Characteristics

## “Clear” Patients

<table>
<thead>
<tr>
<th>Variable</th>
<th>XIENCE 90 (N = 1693)</th>
<th>XIENCE 28 (N = 1392)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multivessel Disease</td>
<td>46.0% (779/1693)</td>
<td>41.2% (573/1392)</td>
</tr>
<tr>
<td>Radial Access</td>
<td>52.2% (883/1693)</td>
<td>70.8% (986/1392)</td>
</tr>
<tr>
<td>B2/C Lesion</td>
<td>33.8% (573/1693)</td>
<td>35.8% (498/1392)</td>
</tr>
<tr>
<td>Bifurcation</td>
<td>7.6% (129/1693)</td>
<td>11.6% (161/1392)</td>
</tr>
<tr>
<td>Total Stent Length, mm (Mean ± SD)</td>
<td>25.5 ± 13.8 (1693)</td>
<td>27.2 ± 14.4 (1389)</td>
</tr>
<tr>
<td><strong>N = 2078 Lesions</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Target Lesion Location</th>
<th>XIENCE 90 (N = 2078)</th>
<th>XIENCE 28 (N = 1700)</th>
</tr>
</thead>
<tbody>
<tr>
<td>LAD</td>
<td>43.2% (898/2078)</td>
<td>45.9% (781/1700)</td>
</tr>
<tr>
<td>LCX</td>
<td>24.7% (513/2078)</td>
<td>24.1% (409/1700)</td>
</tr>
<tr>
<td>RCA</td>
<td>32.0% (665/2078)</td>
<td>29.9% (509/1700)</td>
</tr>
<tr>
<td>Pre-procedure RVD, mm (Mean ± SD)</td>
<td>2.99 ± 0.49 (2078)</td>
<td>2.99 ± 0.50 (1700)</td>
</tr>
<tr>
<td>Pre-procedure DS, % (Mean ± SD)</td>
<td>83.7 ± 10.3 (2078)</td>
<td>82.47 ± 10.80 (1699)</td>
</tr>
<tr>
<td>Target Lesion Length, mm (Mean ± SD)</td>
<td>16.0 ± 7.1 (2078)</td>
<td>18.01 ± 8.43 (1700)</td>
</tr>
</tbody>
</table>
Antiplatelet Usage

Primary Analysis Population

**XIENCE 90**
Between 3 and 12 Months

- ASA: 100%
- DAPT: 90.6%
- P2Y₁₂ inh.: 2.6%

**XIENCE 28**
Between 1 and 6 Months

- ASA: 86.15%
- DAPT: 8.73%
- P2Y₁₂ inh.: 5.12%

Note: Patients with adverse events during follow-up are included in the curves

ASA: includes subjects on ASA only or ASA + OAC
DAPT: includes subjects on DAPT only or DAPT + OAC
P2Y₁₂ inh.: includes subjects on P2Y₁₂ inh. and/or OAC

**CRF**
Study Endpoints

Primary endpoint
- All-cause death or all MI (non-inferiority)

Key secondary endpoints
- BARC 2-5 bleeding (superiority)
- Definite/probable ST (performance goal)

XIENCE 90 vs control
XIENCE 28 vs control

XIENCE 90 vs control
XIENCE 28 vs control

XIENCE 90 only
XIENCE V USA: Historical Control

A prospective, multicenter, post-approval study to evaluate the safety and effectiveness of the XIENCE stent in real-world settings between 2008-2011

8,061 patients from 192 sites in the US

A Real-World Population

- Age 64.6±10.8 y
- Diabetes 35.8%
- Renal Insufficiency 10.5%
- Prior MI 29.7%
- Male 69.6%
- AMI on Presentation 14.8%
- Restenosis 8.8%
- Bifurcation Lesion 9.7%
- LVEF <30% 3.4%
- Prior CABG 16.4%
- B2/C Lesion 49.9%
- Prior PCI 39.1%
- Multivessel Disease 39.8%
- Graft Lesion 4.6%

DAPT Usage in XV USA

<table>
<thead>
<tr>
<th>Visit</th>
<th>Usage (%)</th>
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</thead>
<tbody>
<tr>
<td>30-day Visit</td>
<td>94.2%</td>
</tr>
<tr>
<td>180-day Visit</td>
<td>90.5%</td>
</tr>
<tr>
<td>1-Year Visit</td>
<td>85.6%</td>
</tr>
</tbody>
</table>

Naidu S.N. et al., J Am Coll Cardiol Intv 2012;5:626–35
Propensity Score

POPULATIONS

XIENCE 90 (3-mo DAPT)

Investigational Arm

XIENCE V USA (12-mo DAPT)

Historical Control

SINGLE-ARM STUDIES

Stratification: XIENCE 90

PROPENSITY STRATIFICATION

Patients sorted by propensity score using baseline characteristics

Stratification in 5 quintiles

<table>
<thead>
<tr>
<th></th>
<th>XIENCE 90</th>
<th>XV USA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q2</td>
<td></td>
<td></td>
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<tr>
<td>Q3</td>
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<tr>
<td>Q4</td>
<td></td>
<td></td>
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<tr>
<td>Q5</td>
<td></td>
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</tbody>
</table>
Propensity Score Stratification: XIENCE

**POPULATIONS**

- **XIENCE 28** (1-mo DAPT)
  - Investigational Arm

- **XIENCE V USA** (6-mo DAPT)
  - Historical Control

**SINGLE-ARM STUDIES**

**PROPENSITY STRATIFICATION**

Patients sorted by propensity score using baseline characteristics

- **XIENCE 28**
  - Q1
  - Q2
  - Q3
  - Q4
  - Q5

- **XV USA**
  - Stratification in 5 quintiles
# Sample Size and Power Calculations

## Primary Endpoint: All Death or MI

<table>
<thead>
<tr>
<th></th>
<th><strong>XIENCE 90</strong></th>
<th><strong>XIENCE 28</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Control group</td>
<td>3-month clear HBR patients from XIENCE V USA</td>
<td>1-month clear HBR patients from XIENCE V USA</td>
</tr>
</tbody>
</table>
| Primary hypothesis   | Non-inferiority for all death or MI  
  • Margin (Δ) = 2.8% | Non-inferiority for all death or MI  
  • Margin (Δ) = 2.5% |
| Expected rate        | 6.1% between 3 and 12 months | 4.3% between 1 and 6 months |
| Statistical model    | Propensity stratification | Propensity stratification |
| Test significance level (α) | 0.025 (1-sided) | 0.025 (1-sided) |
| Attrition rate       | 15% | 10% |
| Power (1-β)          | 87% | 90% |
| Sample size (N patients) | 2000 | 1600 |
XIENCE 90: All Death or MI
Between 3 and 12 Months

PS Stratified Mean

<table>
<thead>
<tr>
<th>Quintile</th>
<th>XIENCE 90 (N = 1693)</th>
<th>XIENCE V USA (N = 1280)</th>
</tr>
</thead>
<tbody>
<tr>
<td>10%</td>
<td>5.4%</td>
<td>5.4%</td>
</tr>
</tbody>
</table>

Non-inferiority Analysis

One-sided 97.5% UCL: 2.23%

Non-inferiority margin: 2.8%

\[ P_{\text{non-inferiority}} = 0.0063 \]

Non-inferiority tested with the stratified Farrington-Manning method
**XIENCE 28: All Death or MI**

Between 1 and 6 Months

**PS Stratified Mean**

Mean rate across 5 quintiles (%)

<table>
<thead>
<tr>
<th>Quintile</th>
<th>XIENCE 28 (N = 1392)</th>
<th>XIENCE V USA (N = 1411)</th>
</tr>
</thead>
<tbody>
<tr>
<td>10%</td>
<td>3.5%</td>
<td>4.3%</td>
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<tr>
<td>8%</td>
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<tr>
<td>6%</td>
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</tr>
<tr>
<td>4%</td>
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<tr>
<td>2%</td>
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<tr>
<td>0%</td>
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</table>

**Non-inferiority Analysis**

One-sided 97.5%

UCL: 0.97%

\[ P_{non-inferiority} = 0.0005 \]

Non-inferiority margin: 2.5%

Non-inferiority tested with the stratified Farrington-Manning method
BARC 2-5 Bleeding
Powered Secondary Endpoint

**XIENCE 90**
Between 3 and 12 Months

<table>
<thead>
<tr>
<th></th>
<th>XIENCE 90 (N = 1693)</th>
<th>XIENCE V USA (N = 1280)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PS Stratified Mean (%)</td>
<td>5.1%</td>
<td>7.0%</td>
</tr>
</tbody>
</table>

\[ P_{\text{superiority}} = 0.0687 \]

**XIENCE 28**
Between 1 and 6 Months

<table>
<thead>
<tr>
<th></th>
<th>XIENCE 28 (N = 1392)</th>
<th>XIENCE V USA (N = 1411)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PS Stratified Mean (%)</td>
<td>4.9%</td>
<td>5.9%</td>
</tr>
</tbody>
</table>

\[ P_{\text{superiority}} = 0.19 \]

Note: XIENCE V USA protocol did not mandate collection of BARC 2 bleeding events

An assumed ~50% reduction in BARC 2-5 bleeding provided XIENCE 90 with 95% power and XIENCE 28 with 90% power

Superiority tested with the stratified Farrington-Manning method using a one-sided significance level of 0.025
The PS stratified analysis for BARC 3-5 bleeding was not pre-specified.
XIENCE 90: Stent Thrombosis

Powered Secondary Endpoint (3-12 Months)

ARC Definite/Probable ST

Performance Goal: 1.2%

2-sided 95% UCL: 0.63%

P < 0.0001

An assumed 0.5% rate of definite/probable ST provided XIENCE 90 with 85% power (Exact test)
Definite/probable ST was *not* a powered secondary endpoint in XIENCE 28
Limitations

- The XIENCE 90 and XIENCE 28 studies present limitations inherent to the non-randomized design, despite statistical compensation using a propensity-adjusted analysis.

- Findings may not be generalizable to patients who do not meet the XIENCE Short DAPT Program inclusion and exclusion criteria.

- The observed treatment effect applies only to patients “free” from adverse events and adherent to the DAPT regimen in the first 1 or 3 months post-PCI.

- Given that XIENCE V USA was performed approximately one decade before the XIENCE Short DAPT Program, confounders related to changes in clinical practice cannot be excluded.
Conclusions

Among HBR patients undergoing PCI with the XIENCE stent, a short DAPT regimen of 1 or 3 months compared with standard DAPT up to 12 months resulted in:

- non-inferior ischemic outcomes
- similar rates of clinically relevant (BARC 2-5) bleeding, with a significant reduction in major (BARC 3-5) bleeding
- very low incidence of stent thrombosis
<table>
<thead>
<tr>
<th>XIENCE 90</th>
<th>XIENCE 28 USA</th>
<th>XIENCE 28 Global</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kansas Heart Hospital</td>
<td>Royal Jubilee Hospital</td>
<td>Segeberger Kliniken GmbH</td>
</tr>
<tr>
<td>(Cardiovascular Research Institute of Kansas)</td>
<td>PI: Aziz Maksoud</td>
<td>PI: Dr. Ralph Toelg</td>
</tr>
<tr>
<td></td>
<td>RC: Lindsey Steele</td>
<td>RC: Friederike Geyer</td>
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