BIOFLOW-II

Orsiro – BIOFLOW-II

Conclusions

- **Target Lesion Failure (TLF) comparable to Xience Prime* although separating over time in favor of Orsiro out to 48 months**
- Absence of definite or probable stent thrombosis also in high risk populations such as diabetic and small vessel subgroup out to 48 months
- The results of this prospective, randomized study confirms the safety and efficacy of Orsiro

Study design

A prospective, multi-center, randomized, controlled trial comparing the Orsiro DES to Xience Prime

Coordinating clinical investigators

- Prof. Stephan Windecker, Bern, Switzerland
- Dr. Thierry Lefèvre, Massy, France

Endpoints

Primary endpoint

- In-Stent Late Lumen Loss (LLL) at 9 months

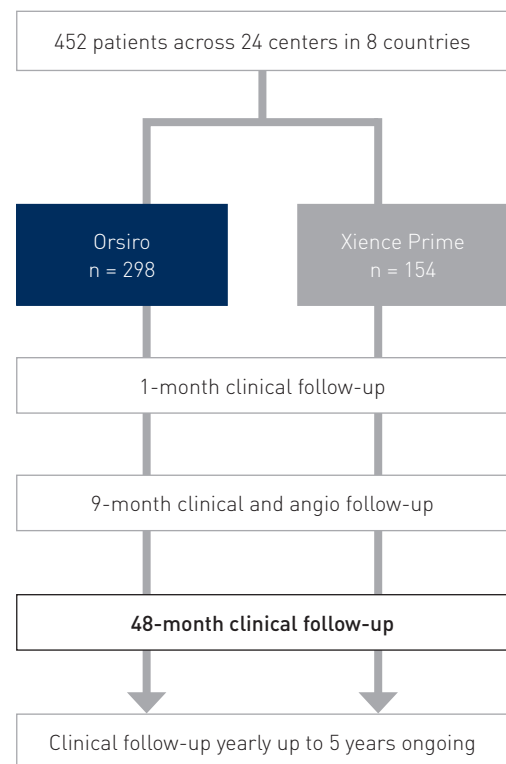### Secondary clinical endpoints (selected)

- Target Lesion Failure (TLF)
- Definite stent thrombosis

Intra vascular imaging subgroups

- OCT at baseline and at 9 months (n = 65)
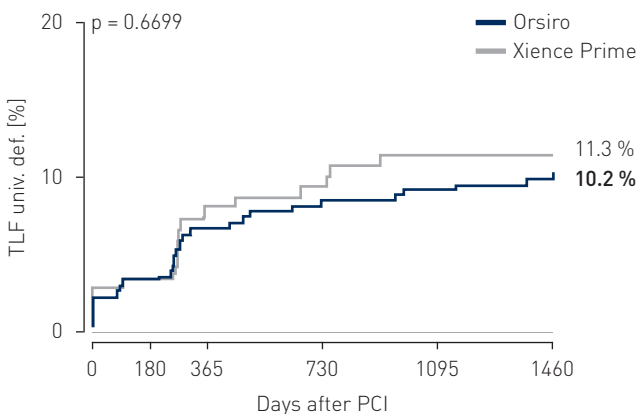- IVUS at baseline and at 9 months (n = 66)

Patients

Inclusion of up to two de novo lesions
with a maximal length of 26 mm each.

452 patients across 24 centers in 8 countries

| Orsiro n = 298 | Xience Prime n = 154 |

1-month clinical follow-up

9-month clinical and angio follow-up

48-month clinical follow-up

Clinical follow-up yearly up to 5 years ongoing

Results at 48 months

TLF rate – All subjects

p = 0.6699

11.3 %
10.2 %

Target Lesion Failure Composites [%]	Orsiro n = 298	Xience Prime n = 154	p-value
Cardiac death	1.4	2.0	**0.6249**
Target vessel MI	3.5	2.6	**0.6624**
TLR (clinically-driven)	6.4	6.7	**0.8482**
CABG (emergent)	0	0	**> 0.9999**

Clinical event rates were comparable between Orsiro and Xience Prime up to 48 months

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TLF rate – Small vessel population
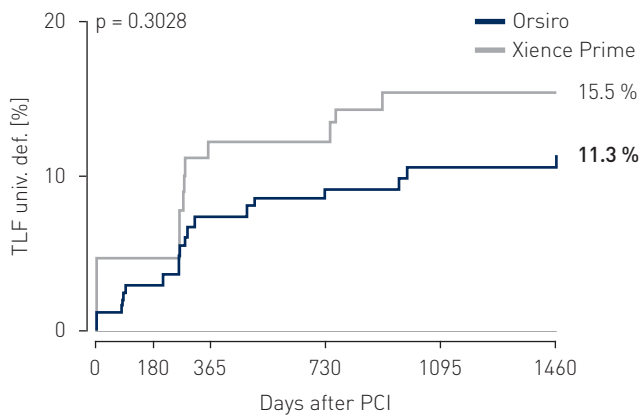
Target Lesion Failure Composites [%]	Orsiro n = 168	Xience Prime n = 91	p-value
Cardiac death	0.6	2.2	0.2652
Target vessel MI	3.9	4.4	0.7380
TLR (clinically-driven)	8.9	8.9	0.9448
CABG (emergent)	0	0	> 0.9999

TLF defined as composite of cardiac death, target vessel Q-wave or non Q-wave Myocardial Infarction (MI), Coronary Artery Bypass Grafting (CABG) and clinically-driven TLR.

All subject stent thrombosis results at 48 months

- **No definite and no probable stent thrombosis** occurred in either arm through 48 months
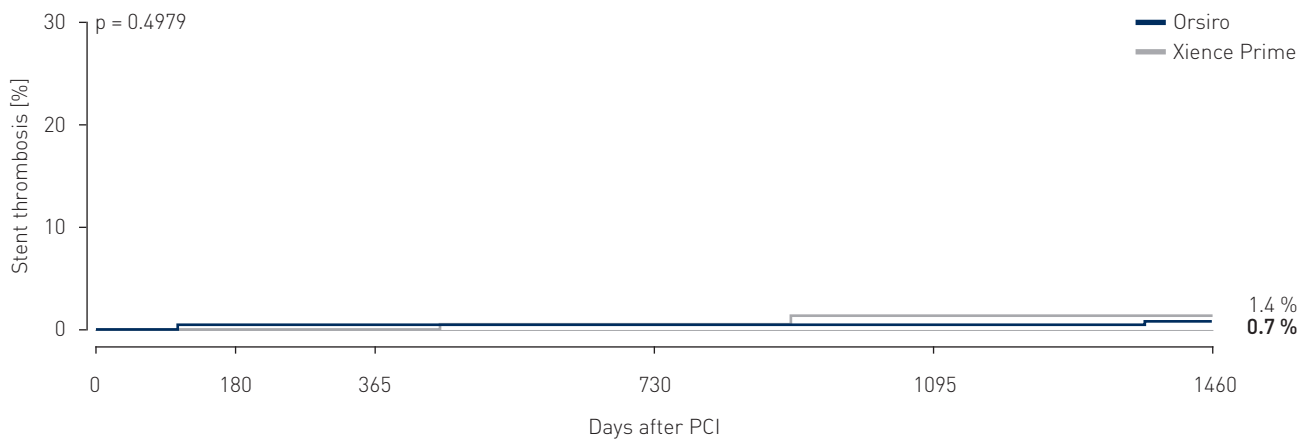
Reference: Ton Slagboom on behalf of the BIOFLOW-II Investigators, Poster, euroPCR 2017

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