

BIOFLOW-II

Results for total population out to 5 years

Conclusions

- Target Lesion Failure (TLF) comparable to Xience Prime* although separating over time in favor of Orsiro™ out to 5 years
- Absence of definite or probable Stent Thrombosis (ST) also in high risk populations such as diabetic and small vessel subgroups out to 5 years
- The results of this prospective, randomized study confirm the long term safety and efficacy profile of Orsiro™

Study design

A prospective, multi-center, randomized, controlled trial comparing Orsiro™ to Xience Prime.

Patients

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

Endpoints

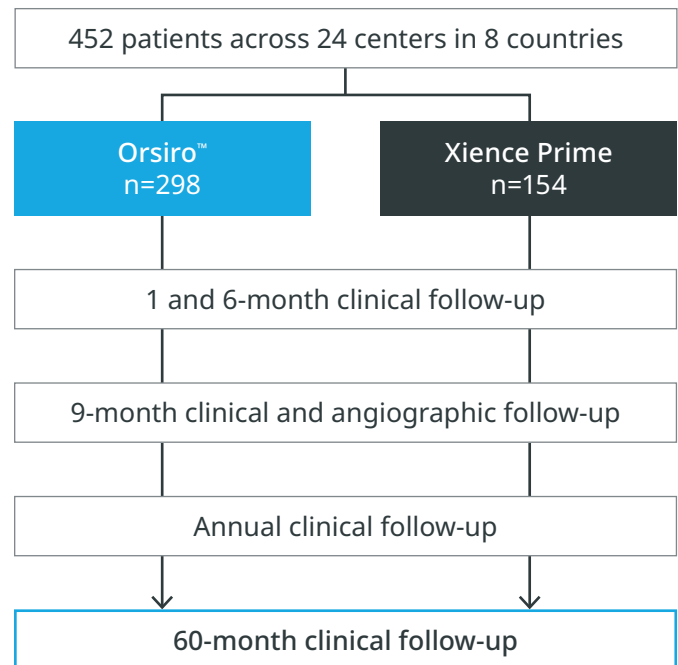
Primary endpoint

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

Selected secondary endpoints

- TLF^Δ
- Definite ST[§]

PATIENT AND LESION CHARACTERISTICS ¹	ORSIRO N=298	XIENCE PRIME N=154
Age, yrs ^{***}	62.7±10.4	64.8±9.2
Male	78.2 %	74.7 %
Hypertension	77.5 %	77.3 %
Hypercholesterolaemia	67.8 %	73.4 %
History of MI	30.2 %	20.1 %
Diabetes	28.2 %	28.6 %
Insulin dependent	21.4 %	34.1 %
Non-insulin dependent	78.6 %	65.9 %
Average number of lesions per patient ^{**}	13.36±6.82	13.65±5.58



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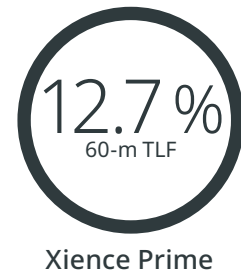
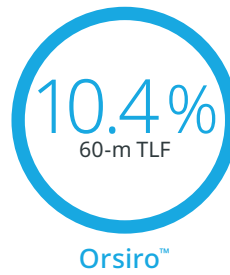
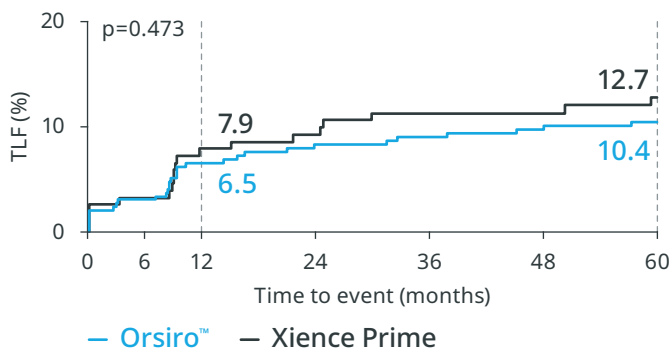
** Data shown as mean ±SD

† p=0.0344

Δ Composite of cardiac death, target vessel Q-wave or non-Q wave Myocardial Infarction (MI), Emergent Coronary Artery Bypass Graft (CABG), clinically driven Target Lesion Revascularization (TLR).

§ ST as per ARC definition

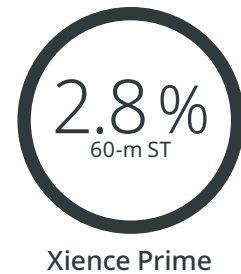
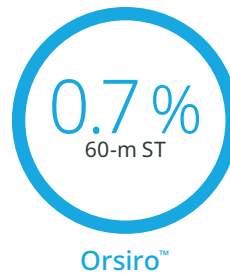
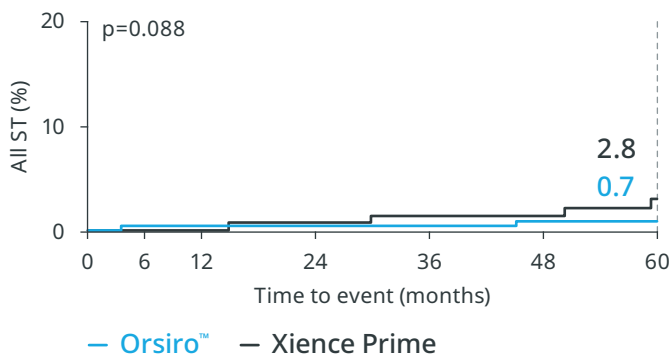
TLF rates - Total population out to 5 years¹



TLF COMPONENTS ¹	ORSIRO N=298	XIENCE PRIME N=154	P-VALUE
Cardiac death	1.7 %	2.8 %	0.504
TV-MI	3.4 %	3.3 %	0.953
CD-TLR	6.3 %	6.7 %	0.850

No definite or probable ST occurred in the Orsiro arm out to 5 years¹

	ORSIRO	XIENCE PRIME	P-VALUE
ST	0.7 %	2.8 %	0.088
Definite ST	0.0 %	0.7 %	0.341
Probable ST	0.0 %	0.0 %	—



Coordinating clinical investigators: Prof. Stephan Windecker, Bern, Switzerland; Dr. Thierry Lefèvre, Massy, France

Reference:

¹ Lefèvre T et al. Comparison of a novel biodegradable polymer sirolimus-eluting stent with a durable polymer everolimus-eluting stent: 5-year outcomes of the randomized BIOFLOW-II trial. JACC: Cardiovascular Interventions 2018;11(10):995-1002; ClinicalTrials.gov: NCT01356888.

Clinical data conducted with Orsiro, Orsiro Mission's predecessor device can be used to illustrate Orsiro Mission clinical outcomes.

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BIOFLOW-II

Diabetic subgroup

Conclusions

- Target Lesion Failure (TLF) comparable to Xience Prime* although separating over time in favor of Orsiro™ out to 5 years
- Absence of definite or probable Stent Thrombosis (ST) also in high risk populations such as diabetic and small vessel subgroups out to 5 years
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Diabetic subgroup demographics & lesion characteristics¹

SUBJECTS	ORSIRO N=84	XIENCE PRIME N=44
Age, yrs**	63.7±9.2	64.8±7.5
Hypertension	91.7 %	88.6 %
Hyperlipidemia	76.2 %	77.3 %
History of MI	28.6 %	15.9 %
Congestive heart failure [†]	13.1 %	27.3 %
Insulin dependent	21.4 %	34.1 %
Non-insulin dependent	78.6 %	65.9 %
Lesions	n=93	n=49
Lesion length (mm)**	12.58±5.22	14.37±6.21
Reference vessel diameter (mm)**	2.71±0.53	2.73±0.51
Diameter stenosis (%)	67.6±14.36	67.83±14.45

[†]p=0.047

TLF ^a COMPONENTS ²	ORSIRO N=84	XIENCE PRIME N=44	P-VALUE
Cardiac death	1.3 %	6.9 %	0.089
TV-MI	2.5 %	0.0 %	0.545
CD-TLR	13.5 %	4.5 %	0.138

References:

- 1 Sabatè M et al. BIOFLOW-II – 1 year substudy results of the diabetic and small vessel cohorts; Presented at: EuroPCR 2014; May 20, 2014; Paris, France; ClinicalTrials.gov: NCT01356888.
- 2 Lefèvre T et al. Comparison of a novel biodegradable polymer sirolimus-eluting stent with a durable polymer everolimus-eluting stent: 5-year outcomes of the randomized BIOFLOW-II trial. JACC: Cardiovascular Interventions. 2018 May 21;11(10):995-1002.

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^a Composite of cardiac death, target vessel Q-wave or non-Q wave Myocardial Infarction (MI), Emergent Coronary Artery Bypass Graft (CABG), clinically driven Target Lesion Revascularization (TLR).

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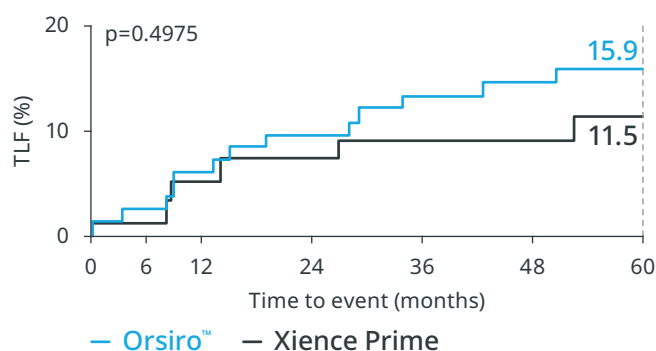
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Diabetic subgroup TLF rates out to 5 years²



BIOFLOW-II

Small vessel subgroup

Conclusions

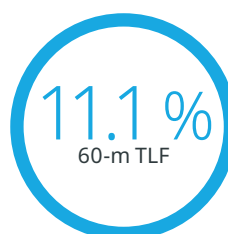
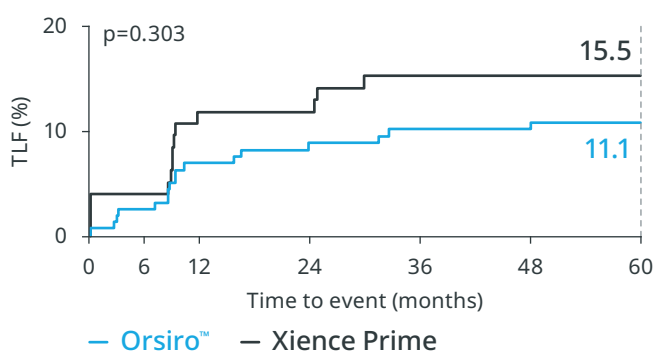
- Target Lesion Failure (TLF) comparable to Xience Prime* although separating over time in favor of Orsiro™ out to 5 years
- Absence of definite or probable Stent Thrombosis (ST) also in high risk populations such as diabetic and small vessel subgroup out to 5 years
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Small vessel subgroup demographics & lesion characteristics¹

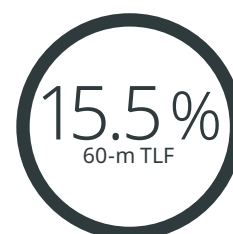
SUBJECTS	ORSIRO N=168	XIENCE PRIME N=91
Age, yrs**	62.9±10.2	65.5±9.0
Hypertension	80.4%	76.9%
Hyperlipidemia	69.6%	68.1%
History of MI	33.9%	26.4%
Diabetes	33.9%	28.6%
Insulin dependent	29.8%	30.8%
Non-insulin dependent	70.2%	69.2%
Lesions	n=195	n=109
Lesion length (mm)**	13.93±6.88	13.08±5.22
Reference vessel diameter (mm)**	2.49±0.37	2.49±0.33
Diameter stenosis (%)	67.55±13.70	65.56±14.47

TLF COMPONENTS ²	ORSIRO N=84	XIENCE PRIME N=44	P-VALUE
Cardiac death	0.6%	2.2%	0.265
TV-MI	3.7%	4.4%	0.738
CD-TLR	8.7%	8.9%	0.948

Small vessel subgroup TLF rates out to 5 years²



Orsiro™



Xience Prime

References:

- 1 Sabaté M et al. BIOFLOW-II – 1 year substudy results of the diabetic and small vessel cohorts; Presented at: EuroPCR 2014; May 20, 2014; Paris, France; ClinicalTrials.gov: NCT01356888.
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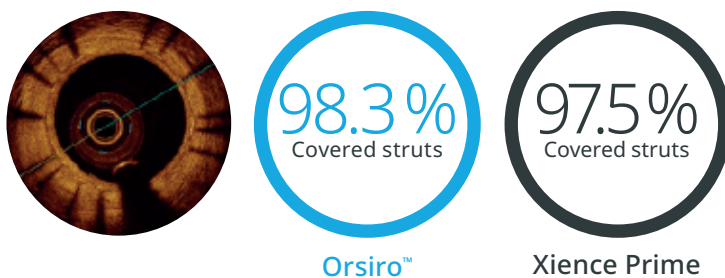
Imaging data

Conclusions

- The BIOFLOW-II OCT/IVUS subgroup analysis showed similar results between the Orsiro™ and Xience Prime*
- Safe inhibition of neointimal hyperplasia was seen in both arms at 9 months with struts well covered with a thin, uniform neointima
- Orsiro™ was associated with a significantly lower area of neointimal hyperplasia than Xience Prime and achieved excellent strut coverage

Intravascular imaging subgroups¹

OCT imaging was performed in a pre-specified subgroup to assess strut coverage at 9 months.



	ORSIRO	XIENCE PRIME	P-VALUE
Apposed struts	98.9%	99.2%	0.43
Covered struts	98.0%	97.29%	0.48
Neointimal area (mm ²)**	0.75±0.40	1.00±0.44	0.03
Neointimal thickness (mm)**	0.10±0.04	0.11±0.04	0.37

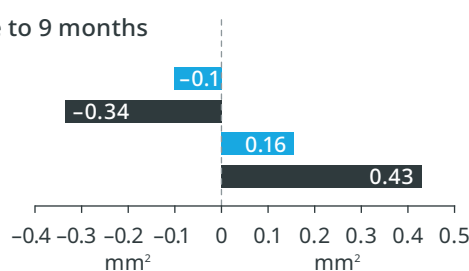
Neointimal hyperplasia at 9-month follow-up¹

IVUS imaging was performed in a pre-specified subgroup to evaluate potential neointimal hyperplasia at 9 months.

Change from baseline to 9 months

Δ Mean lumen area

p=0.34



Neointimal area

p=0.04

■ Orsiro™
n=31

■ Xience Prime
n=25

Reference:

1 Windecker S et al. Comparison of a novel biodegradable polymer sirolimus-eluting stent with a durable polymer everolimus-eluting stent: results of the randomized BIOFLOW-II trial. *Circulation: Cardiovascular Interventions*. 2015 Feb 1;8(2):e001441.

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