

## Orsiro – BIOFLOW-I

### Conclusions

- In BIOFLOW-I, the Orsiro hybrid DES showed excellent Late Lumen Loss (LLL) results in the overall patient population.
- BIOFLOW-I has a high rate of diabetic patients and complex lesions, atypical for a FIM study.
- There was no late catch-up in LLL values at 9-month follow-up. This combined with a narrow standard deviation suggests robust study results.

### Study design

Prospective, multi-center, non-randomized, first-in-man trial

### Objective

To assess the safety and clinical performance of the Orsiro hybrid drug-eluting stent in patients with single de novo coronary artery lesions

### Coordinating clinical investigator

- Prof. Martial Hamon  
University Hospital of Caen, France

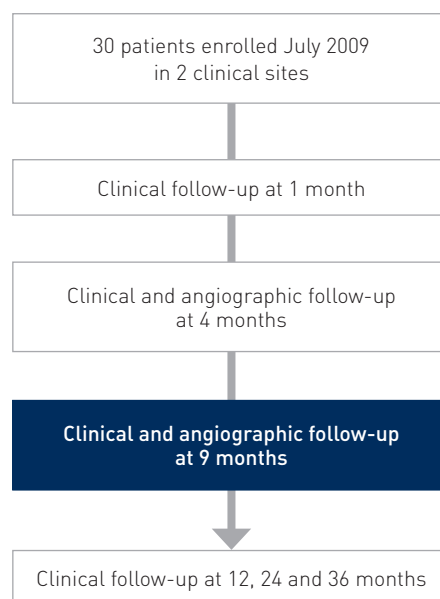
### Principal investigators

- Dr. Rodica Niculescu
- Dr. Dan Deleanu

### Endpoints

#### Primary endpoint

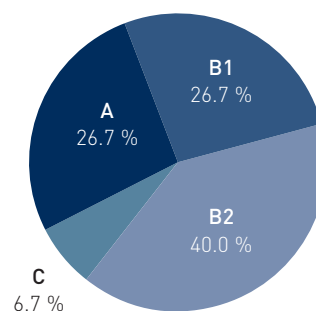
- In-stent late lumen loss at 9 months by QCA



### Baseline clinical characteristics

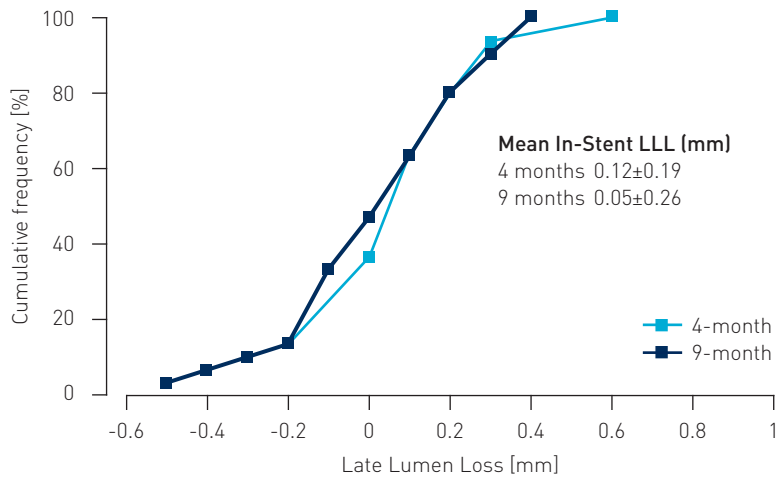
| n = 30                |            |       |
|-----------------------|------------|-------|
| Age (years)           | 58.1 ± 9.8 |       |
| Male sex              | 60 %       | 18/30 |
| Hyperlipidemia        | 93.3 %     | 28/30 |
| History of MI         | 73.3 %     | 22/30 |
| Hypertension          | 66.6 %     | 20/30 |
| Smoker                | 53.3 %     | 16/30 |
| Diabetes              | 23.3 %     | 7/30  |
| Chronic heart failure | 20.0 %     | 6/30  |

### AHA / ACC lesion classification



## Primary endpoint

### Cumulative frequency of in-stent Late Lumen Loss at 4 and 9 months



## Secondary endpoint

### MACE rate at 12 months

| 12-month clinical results | n | %    |
|---------------------------|---|------|
| MACE                      | 3 | 10.0 |
| Cardiac death             | 1 | 3.3  |
| MI                        | 0 | 0.0  |
| Stent thrombosis          | 0 | 0.0  |
| TLR (clinically driven)   | 2 | 6.7  |

MACE defined as composite of cardiac death, MI attributed to the target vessel, stent thrombosis and clinically driven target lesion revascularization. Stent thrombosis was defined according to the Academic Research Consortium definitions.

Source:

Hamon M et al. Clinical and angiographic experience with a third-generation drug-eluting Orsiro stent in the treatment of single de novo coronary artery lesions (BIOFLOW-I): a prospective, first-in-man study. EuroIntervention. 2013; 8: 1006-1011.