Disclosures for W. Wijns

- Consulting Fees and honoraria on my behalf go to the Cardiovascular Research Center Aalst

- Contracted Research between the Cardiovascular Research Center Aalst and several pharmaceutical and device companies, including MiCell and Medtronic
- Ownership Interest: Co-founder and Board member of Argonauts, Genae and Cardio^{3}BioSciences (cell-based regeneration cardiovascular therapies)

DESSOLVE II Trial Results

2-Year Follow-up of a Crystalline Sirolimus-Eluting Stent with Rapid Bioabsorbable Polymer

William Wijns, MD, PhD
Cardiovascular Center, Aalst, Belgium
on behalf of the DESSOLVE Investigators

DES with Bioabsorbable Coatings

Components and Device Formulation

The designs of new bioabsorbable DES are varied and the device mechanism of action and patient outcomes are dependent on the combination of components

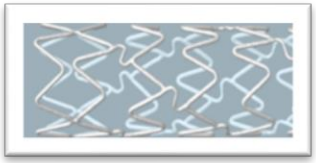
Optimize **POLYMER** - for fast elimination

MiStent SES polymer is eliminated within 90 days from the tissue[1]

Optimize **DRUG** - controlled prolonged elution

MiStent SES has crystalline sirolimus for drug elution up to 9 months[1]

Long-term Drug Delivery without Coating



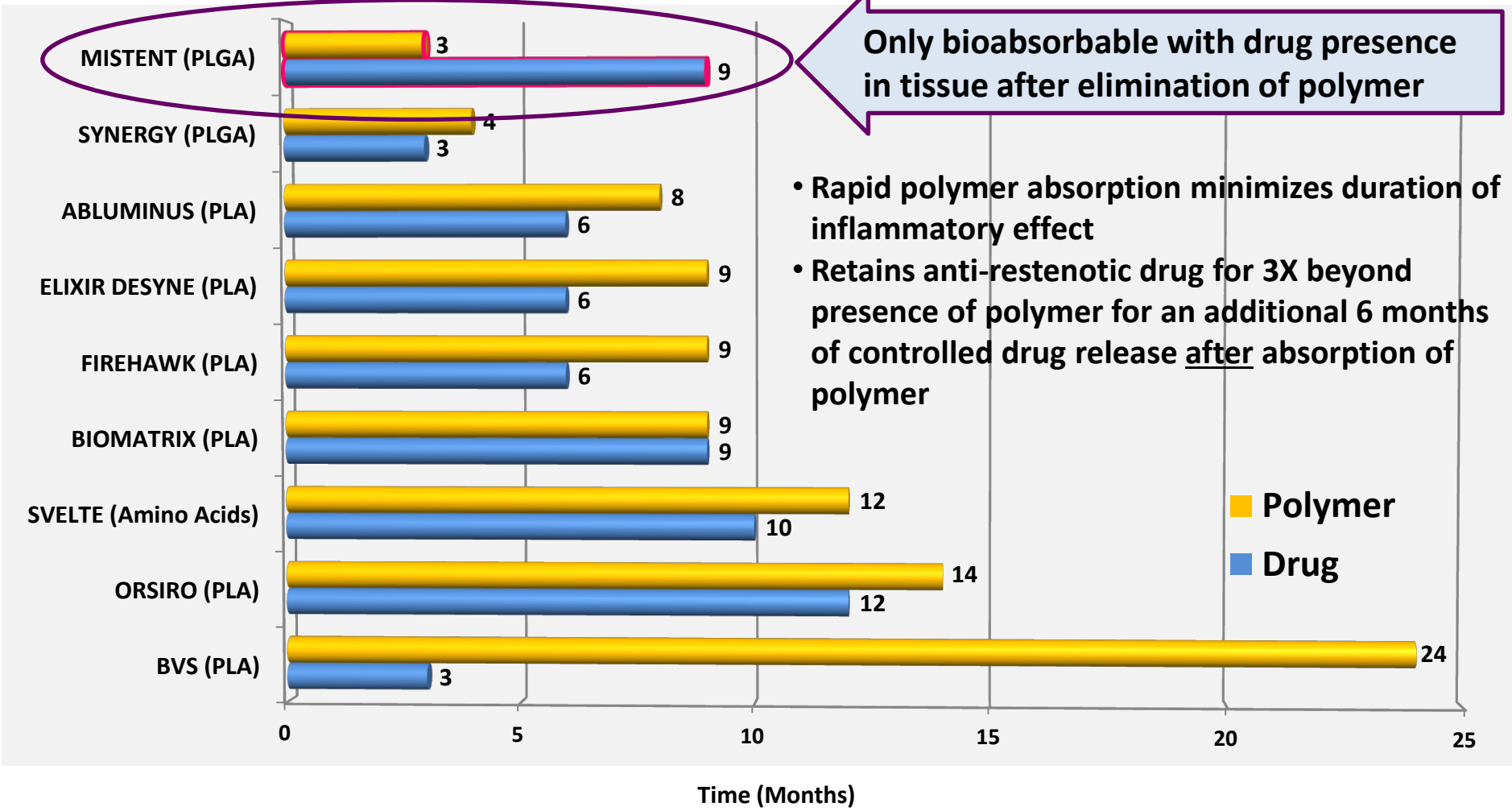
Optimize **STENT** - MiStent SES is a thin strut (64 µm) CoCr stent

Thinner struts are associated with earlier strut coverage and healing[2] and demonstrate lower evidence of acute thrombogenicity[3]

1. Carlyle WC et al, *J Control Release* 2012.
2. Soucy N, Feygin J et al, *EuroIntervention* 2010.
3. Kolandaivelu K et al. *Circ* 2011.

Mechanism of Action

Time Course for Drug Delivery & Polymer Dissolution



Ref: MiStent data on file.
Information adapted from K. Dawkins CRT2013.

DESSOLVE I First-In-Human Trial

Demonstrated BMS-type Vessel Healing with Effective Suppression of NIH

- Mean in-stent LLL of 0.1 mm at 6/8 months
- No progression of LLL over 18 months

- No positive remodeling (IVUS)
- 95% strut coverage at 6 months (OCT)
- No definite neoatheroma formation through 18 months (OCT)

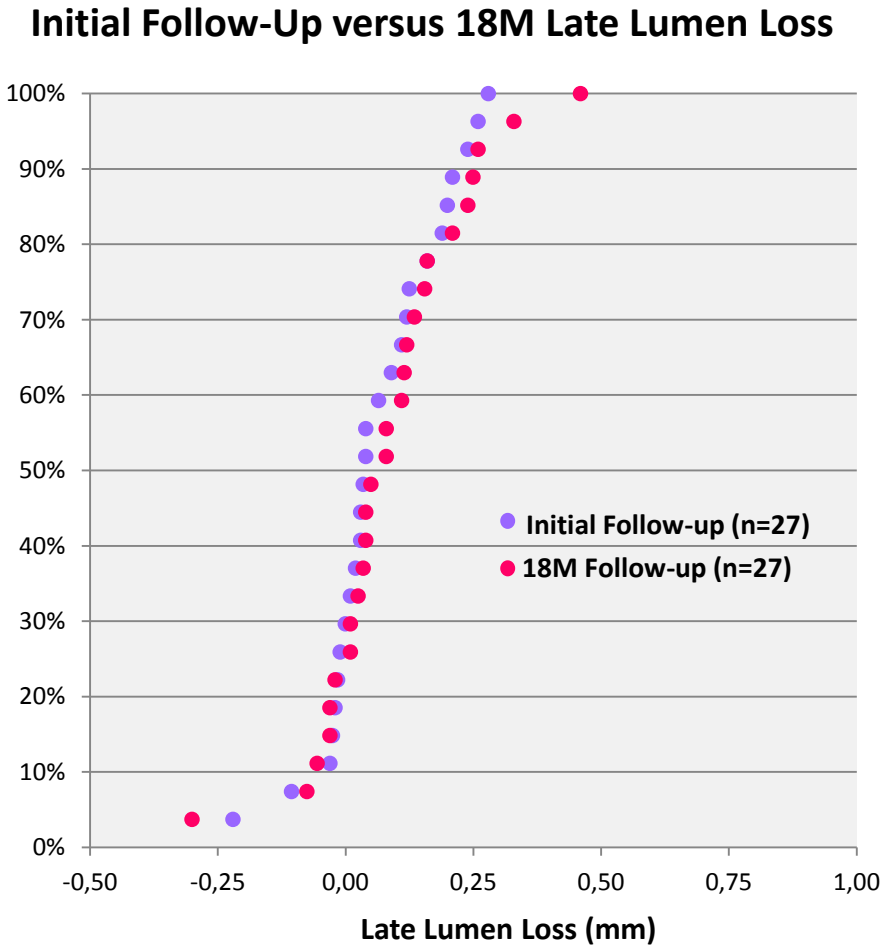
MACE at 3 Years

No Target Vessel Related MACE

No Stent Thrombosis

MACE 6.9% (2/29) - 2 non-target vessel MI:

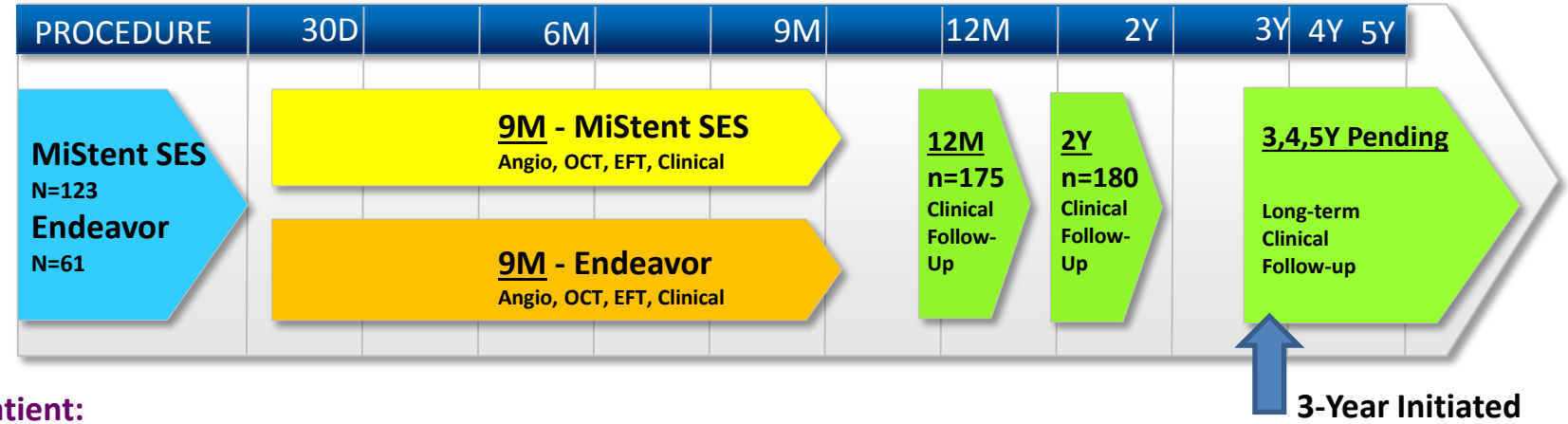
- 44 days during diagnostic angio for a non-TV
- 732 days due to ST in XIENCE stent in a non-TV implanted at index procedure



Ref: Ormiston J, et al. *JACC CI* 2013.
Attizzani G, et al. *AmJCard* 2013.

DESSOLVE II Design & Enrollment Criteria

2:1 RCT design, 184 patients at 26 sites
Superiority of in-stent LLL at 9 months with Endeavor
Angiography, OCT, EFT evaluations at 9 months



Patient:

- **Stable or unstable angina pectoris** (Class I, II, III or IV), documented ischemia, or documented silent ischemia
- No recent MI (< 72 hours) or elevated cardiac biomarkers

Target Lesion:

- **Planned single[1], de novo, types A, B1 or B2 coronary lesions** in a native coronary artery with > 50% diameter stenosis
- **Vessel diameter and lesion length suitable for 2.5-3.5 mm x 9-30 mm stent[2]**
- Exclusion if highly calcified, tortuous, thrombus present, proximal angulation
- Exclusion if located at side branch > 2.5 mm, ostial location, previously treated vessel

[1]Treatment of a non-target vessel lesion permissible before target lesion PCI if no procedural complications
[2]DESSOLVE I max stent length limited to 23 mm

DESSOLVE II – 9 Month Results

Angiography

The MiStent SES was **superior** to Endeavor for the primary endpoint analysis of late lumen loss

Measure (Mean)	MiStent SES (N=103)	Endeavor ZES (N=52)	
Late Lumen Loss	0.27 ± 0.46	0.58 ± 0.41	P < 0.001

OCT

The proportion of uncovered struts and % strut malapposition was remarkably low in both groups

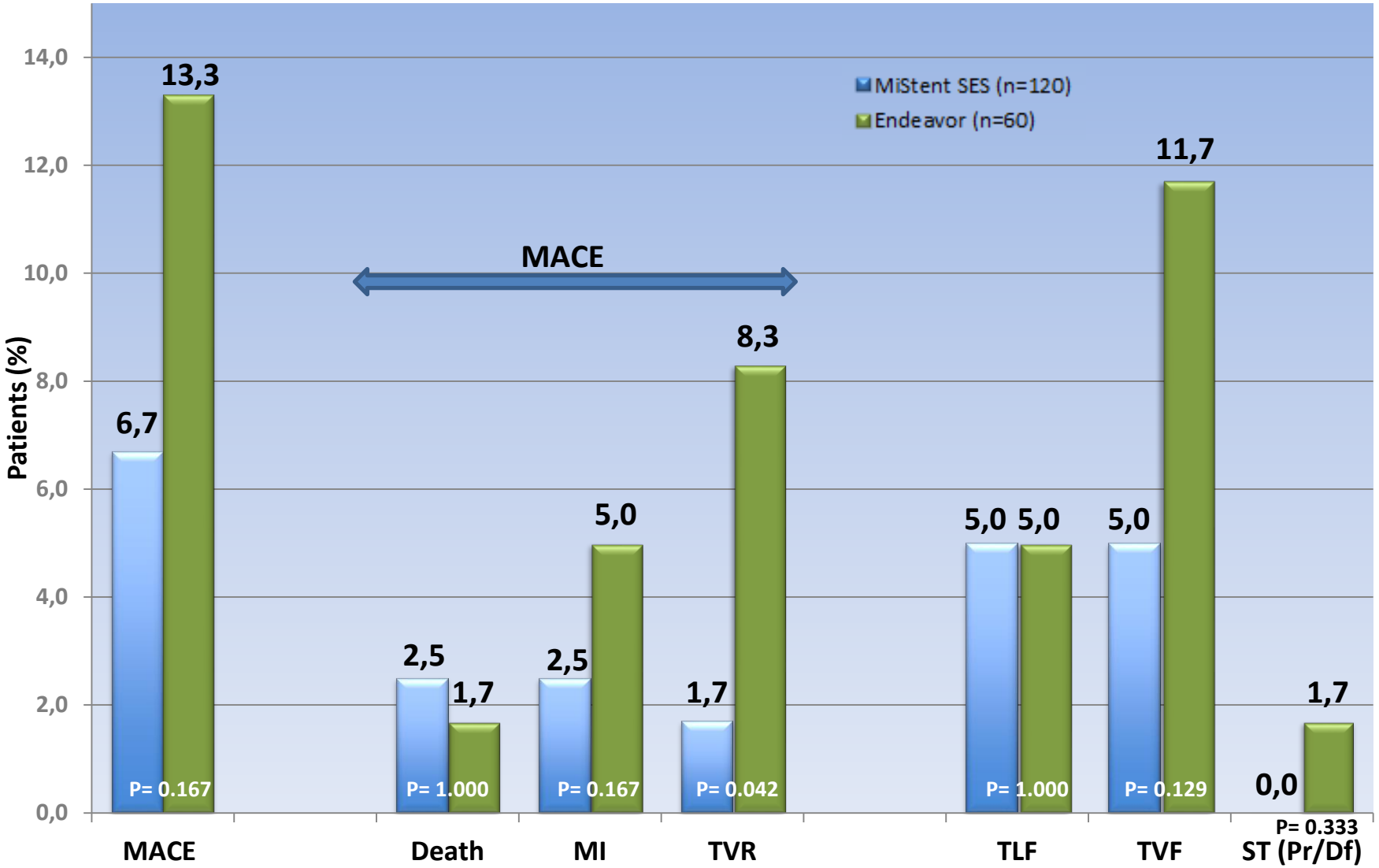
Measure (Median)	MiStent SES (N=24)	Endeavor ZES (N=14)
% Uncovered Struts	0.34	0.00
% Strut Malapposition	0.00	0.00

Endothelial Function Testing

Dilation of the reference vessel segments after pacing indicating normal endothelial function for both MiStent SES and Endeavor at 9 months

Measure (%)	MiStent SES (N=19)	Endeavor ZES (N=10)
Responders	100%	100%
Non-Responders	0%	0%
Vasoconstrictors	0%	0%

DESSOLVE II – 2Y Clinical Outcomes



Summary of MiStent SES Design and Performance

MiStent Design

- Rapid elimination of polymer from the tissue within 90 days
- While using crystalline sirolimus to maintain low drug tissue level for up to 9 months

Detailed Imaging Shows BMS-like Healing

- High rates of strut coverage by OCT
- Minimal progression of NIH through 18 months
- No positive remodeling by IVUS
- Maintenance of endothelial function at 9 months
- No definite neoatheroma formation by OCT at 18 months

Long-Term Safety Profile

- DESSOLVE I 3 yr f/u: No TV MACE events, no ST, 2 non-TV non-Q-wave MIs
- DESSOLVE II 2 yr f/u: 6.7% MACE, no probable or definite ST, 1.7% TLR