The SYNERGY Stent: Complete Revascularisation Solutions in Complex PCI

Sponsored by Boston Scientific

Chairpersons: Adrian Banning and Franz-Josef Neumann
Potential conflicts of interest

Speaker's name: Adrian Banning

- I have the following potential conflicts of interest to report:

Receipt of grants / research supports:
Boston Scientific

Receipt of honoraria or consultation fees:
Abbott, Medtronic, Philips/Volcano, Miracor
Session objectives:

• To discuss the potential benefits of bioabsorbable polymer DES in high-bleeding risk patients

• To understand how PCI guidance can optimise coronary procedures

• To learn how the Synergy stent is being used in complex patient subsets
SYNERGY 48mm Stent Technology Design

Current Platform

- Everolimus Drug
  - 100μg/cm²
  - 3 month release
- Bioabsorbable PLGA Coating
  - Abluminal
  - 4μm thick
  - < 4 month absorption time
- Platinum Chromium Platform
  - 74μm (0.0029 in)

New Features

- 48 mm length
  - Small vessel diameter: 2.50, 2.75mm
  - Workhorse diameter: 3.00, 3.50mm
  - Large vessel diameter: 4.00mm
- Adjustments to accommodate longer balloon and stent
  - Markerband to markerband spacing
  - Balloon body length
  - Crimped stent length
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• Transition from

  *Can we treat*.... (early stent era)

• to

  *Should we treat* – *Syntax*

• to

  *How do we treat*
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- **Predictability**
  - of procedural performance
  - In the long term

- **Safety**

  - Confirmation of existing indications for stents
  - Move into new indications
    - Alternative to CABG and untreatable
<table>
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<th>Study</th>
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| TIMELESS | Healing/Endothelial Coverage at 3m with 3m DAPT  
Single arm registry 50 patients. Primary endpoint technical and clinical success (absence in hospital MACE) |
| TRANSFORM OCT | Endothelial coverage and neo-atherosclerosis compared to RI.  
90 patients. Primary endpoint:% struts uncovered at 3m +18m, neo-atherosclerosis at 18m |
| SENIOR | Reduced DAPT in elderly.  
SYNERGY vs. BMS , 1200 pts 40 sites  
1m DAPT in elective patients and 6m DAPT in ACS patients (RCT 1:1), |
| BIORESORT | All comers with diabetes substudy.  
3450 patients, RCT 1:1:1 SYN vs. RI vs. Orsiro.  
Primary endpoint TVF 1year |
| CONSISTENT | Safety and efficacy of sub-intimal stenting w/SYNERGY in CTO.  
Prospective, multi-center, single arm, 200 patients |
| SYNTAX II | Multi-vessel disease.  
Single arm, n=400. Compared to historical CABG population.  
IVUS and FFR |
| Platelet adrenergic receptors following stent implantation | Platelet activation and evaluation of platelets α2A-Ars and α2B-Ars  
Single center, prospective study in 150 patients with CAD before and after stent implantation (baseline and every 2 months for up-to 12 months |

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Synergy: Investigator Sponsored Research (2 of 3)

- IDEAL LEFT MAIN
  - Enrollment Complete
  - SYNERGY vs Xience in LMS
    - 818 patients, 1:1 RCT, SYNERGY vs Xience
    - Primary endpoint MACCE at 2 years. OCT healing substudy at 3m

- SORT OUT VIII
  - Enrollment Complete
  - Real World, All comers.
    - 1:1 RCT vs. Biomatrix; 2800 patients, 3 sites, OCT Healing substudy.
    - Primary endpoint TVF at 1 year, clinical FU yearly for 5 years

- SORT OUT VIII Imaging
  - Enrollment Complete
  - Real World, All comers Early Vessel Healing
    - 1:1 RCT vs. Biomatrix; 160 patients, 1M and 3M OCT.

- SWEET
  - Enrollment Complete
  - Real world SYNERGY Registry
    - Assess performance of SYNERGY in complex patients
    - 12 month clinical follow-up

- MOVES
  - Enrollment Complete
  - Vascular Healing and Vasomotion
    - SYNERGY and BVS, OCT imaging and vasomotion testing at 14 months

- OCT Resorbable Polymer and BVS
  - Enrollment Complete
  - SYNERGY vs BVS
    - 100 patients, OCT assessment at 6 + 12 months (% strut coverage, neointimal thickening, & stent malapposition)

- CELTIC BIFURCATION
  - Enrollment Complete
  - SYNERGY vs Xience in Bifurcation
    - 170 patients, Medina 1:1:1, 2 Stent Strategy, SYNERGY vs Xience

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SYNERGY: Investigator Sponsored Research (3 of 3)

Enrollment Complete

SYNERGY vs BVS in clinical practice

100 patients, single site registry excluding LMS
Clinical practice implications, procedural resources, acute performance and complications

ISAR RESORB

1:1 RCT, N=230, 2 sites, de-novo lesions (excluding LM & AMI)
% diameter stenosis (in stent) at 6-8m, DOCE at 12m

Enrollment Complete

SCAAR

SYNERGY vs BVS

~4,000 patients in 50,000 patient cohort, comparison to other DES
Clinically driven restenosis & TLR at 12m, Early/late ST

Enrollment Complete

SYNERGY in Real World National Registry

SYNERGY vs BVS

Multitargeted, non-blinded study, N=1200
S&E of immediate complete primary PCI of all target vessels vs PCI of culprit vessel only followed by staged PCI (19-30 days) of all target vessels

Enrolling

MULTISTARS AMI

STEMI & MVD Patients with SYNERGY

1:1 RCT, N=230, 2 sites, de-novo lesions (excluding LM & AMI)
% diameter stenosis (in stent) at 6-8m, DOCE at 12m

Enrolling

POEM

1-Month DAPT in High-Bleeding Risk Patients

Stable & ACS Patients with CAD N=1023
Primary Outcome: Composite of cardiac death, MI, def/prob ST at 1 year

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SYNERGY Clinical Trials
Ongoing and Upcoming Trials

SYNERGY research program studying >30,000 patients.

Addressing full spectrum of cardiovascular disease complexity
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Thanks to Sponsor, Co-chair, Speakers and audience