TNT session

2018 euro PCR

"Amphilimus™ Eluting Stent: leveraging on innovative technology to go beyond current PCI clinical boundaries in diabetic and HBR patients"

Session evaluation and key learnings

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EAPCI European Society of Cardiology PCR

Potential conflict of interest

Speaker's name: **Roxana Mehran**

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

Receipt of grants / research supports:	The Medicines Co., BMS, Astra Zeneca, Lilly/Daiichi Sankyo/Orbus Niche,
Receipt of honoraria or consultation fees:	Abbott Vascular, AstraZeneca, Boston Scientific, Covidien, CSL Behring, Janssen, Merck,
Advisory Board:	Janssen (J+J),

GOALS of PCI

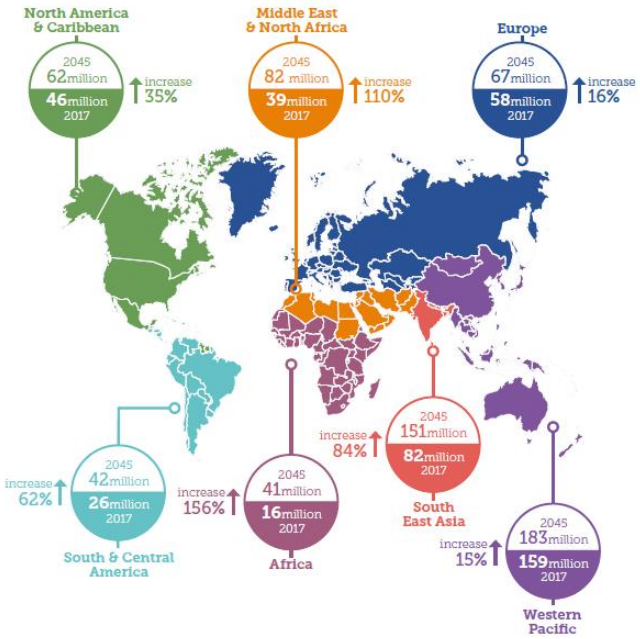
Maximization of Efficacy, coupled with excellent Safety, are key elements to improve clinical outcome of complex patients

Reduction of both ischemic and bleeding events

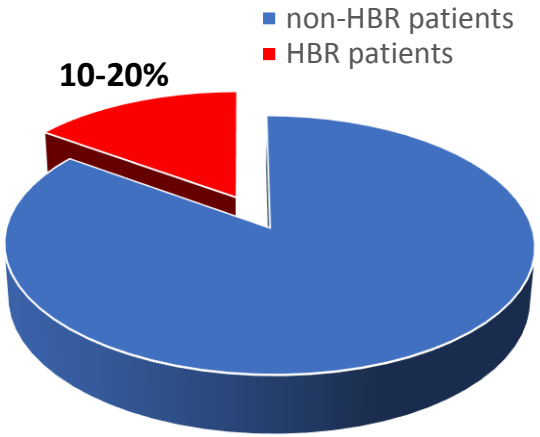
Diabetic and HBR pts = Complex pts

Diabetic patients and HBR patients represent clinical scenarios in which maximum Efficacy and Safety are key to advance PCI outcome.

Diabetic population



Estimated range of HBR patients undergoing PCI



Cre8™ EVO

Cre8™ EVO, leveraging on its polymer-free Abluminal Reservoirs which slowly elute the Amphilimus™ formulation, has potential to maximize device efficacy in diabetic patients and reduce DAPT duration when clinically needed (HBR pts).

Abluminal RESERVOIRS

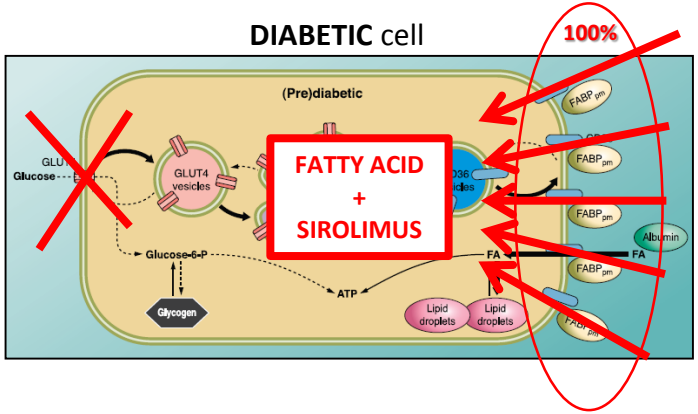
ARTERIAL WALL

Drug elution is controlled and directed exclusively towards the vessel wall

BLOOD FLOW

Lack of polymer
Lack of drug

AMPHILIMUS™ formulation



Membrane protein overexpression leads to higher fatty acids bindings/ translocation

Membrane Fatty Acid Transporters as Regulators of Lipid Metabolism: Implications for Metabolic Disease - Glatz J; 2010 Physiol Rev 90: 367–417

ReCre8 randomized trial*

All-comer patients requiring PCI stratified by DM and troponin status.
- 1 month DAPT in troponin-negative patients
- 12 months DAPT in troponin-positive patients

Cre8™

1532 patients
3 European Sites
Randomization 1:1

Resolute Integrity

PI: P. Stella – The Netherlands

Primary Endpoint
- 12 months Target Lesion Failure (TLF: Cardiac Death + lesion related MI + TLR)

Secondary Endpoint
- 12 months Net Adverse Clinical Events (NACE: any Death + any stroke + any MI + any Revasc. + any Bleeding BARC≥3)

Clinical FU

1month	1Y	3Y

***Enrollment completed**

Diab8 randomized trial

All-comer patients with diabetes mellitus undergoing PCI

Cre8™ EVO

3040 patients
55 International Sites
Randomization 1:1

Everolimus Eluting Stent (EES)

PI: Antonio Colombo

Primary Endpoint

- **EFFICACY** = 12 months Target Lesion Revascularization (TLR)
  Sequential check for Non-inferiority (first step) and then for **Superiority** (second step)

Secondary main Endpoints

- **EFFICACY** = 24 months TLR for **Superiority**
- SAFETY = 12 months Cardiac Death + Target Vessel MI (CD + TVMI)

Clinical FU

1 year | **2 years** | **3 years**

Current DES platforms have shown improved results and excellent outcomes, however we are still met with the need to enhance outcomes in most complex patients

Cre8™ EVO has today the potential to set a new DES benchmark in complex patients like diabetics and HBR pts