**TCT-12**

Short Versus Long-Term Clinical Outcomes In A Randomised Comparison Of Zotarolimus- and Sirolimus-Eluting Coronary Stents

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1E-ECS, n=1192 or sirolimus-elyuting Cypher™ stent (C-SES; n=1170) implantation. Endpoints included a composite of cardiac death, myocardial infarction or target vessel revascularization (MACCE) and definite stent thrombosis. This trial is registered with ClinicalTrials.gov, number NCT00604786.

Methods: A 5-year follow-up, MACCE rates were similar in patients treated with E-ZES and C-SES (97% vs. 18% [0.07]; odds ratio [OR] = 1.10, 95% confidence interval [CI]: 0.88-1.37; p = 0.35). Definite stent thrombosis was more frequent after E-ZES than C-SES implantation at 1 year (93/1% vs. 46% [0.01]; OR = 2.13, 95% CI: 1.48-3.07; p < 0.001) and year 5 (OR = 2.13, 95% CI: 1.39-3.28, p < 0.001). Definite stent thrombosis was more frequent after implantation of DES. Prolonged and more powerful DAPT regimens have shown out to 3 years. An ongoing trial is studying the possibility of using this stent in patients with high bleeding risk, unable to tolerate a prolonged course of DAPT. The BioFreedom FIM 4-year follow-up will be reported for the 1st time during this presentation.

**TCT-14**

Very Long-term Results of BioFreedom First-In-Man, a Randomized Trial comparing Polymer-Free BioFreedom™ stents with Durable Polymer Taxus™ Eluting Stents

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Background: US guidelines currently recommend 12 months of uninterrupted DAPT after implantation of DES. Prolonged and more powerful DAPT regimens have offered benefit by reducing VLS, but at the cost of increased risk of bleeding. There is an emerging need for new stents that are less dependent on prolonged DAPT. The BioFreedom™ stent (BFD) releases Biolimus A9™, without using a polymer or binder. Based on an animal model, 98% of the drug diffuses to the vessel wall within 1 month, leaving a BMS in place. It is reasonable to therefore to consider that the stent offers a potential safety advantage and a reduced need for prolonged DAPT compared to a polymer based DES. This First-In-Man trial aims to demonstrate the safety and effectiveness of the BFD compared to the Taxus Liberte™ paclitaxel-eluting stent (PES).

Conclusions: The BioFreedom FIM is a prospective, multi-center, randomized trial. 1,162 patients were enrolled and randomized to BFD Standard Dose (SD, 15.6 μg/mm), or BFD Low Dose (LD, 7.8 μg/mm), or Taxus Liberte™ PES. The primary endpoint was in-stent Late Loss (LL) at 12 months. The main secondary endpoints are IVUS determined vessel volume, 13% 4 and 12 months; MACE (death, MI, emergent bypass of clinically-driven TLR) and ST rates (ARC defined) at 30 days, 4, and 12 months, and thereby up to 5 years.

Results: The in-stent LL was non inferior in BFD SD (p non-inferiority = 0.001) and trended towards superiority with medians of 0.17mm (0.09, 0.39) vs. 0.35mm (0.22, 0.57) compared to PES (p = 0.11) at 12 months. At 3 years, the clinical FU was shown out to 3 years. There was a significant difference in adherence to DAPT between the groups (BFD SD 5.2% vs. PES 19% p<0.05) which disappeared at 3 years.

Conclusions: The safety and efficacy of the polymer free BioFreedom has been shown out to 3 years. An ongoing trial is studying the possibility of using this stent in patients with high bleeding risk, unable to tolerate a prolonged course of DAPT. The BioFreedom FIM 4-year follow-up will be reported for the 1st time during this presentation.

**TCT-15**

Results of the Primary Endpoint of the PLATINUM PLUS Trial: A Prospective, Randomized, Multi-center Trial to Assess the Everolimus-Eluting Coronary Stent System (PROMUS Element) for Coronary Revascularization in a Population of Unrestricted Patients

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Background: A drug-eluting stent consists of 3 components of equal importance: a metallic platform, a polymer and a drug, all influencing acute and long term results brought to you by CORE

Conclusions: COMPARE is the first trial that will show adjudicated long-term data of EES and in comparison to PES. These 5 year results may have clinical implications, specifically for those patients with high SYNTAX scores.

Methods: The trial was designed as a non-inferiority single blind randomized 2:1 trial (PROMUS Element™) and recruited from October 2010 to February 2012 2979 consecutive, all-comer patients in 48 European centers. The primary endpoint was Target Vessel Failure (TVF: ischemia-driven target vessel revascularization (TVR), any MI or cardiac death related to the target vessel) at 1 year.