Conclusions: In this first interim post-hoc analysis, diabetic patients treated with the Absorb IVUS showed similar incidence of 1-year MACE when compared to non-diabetic patients.

TCT-37

Prospective, Multi-Center Evaluation of the DESolve Ns Novolimus-Euting Biosorbable Coronary Scaffold: First Report of One Year Clinical and Imaging Outcomes

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Background: Biosorbable vascular scaffolds represent an exciting advance in percutaneous coronary intervention (PCI), providing an initial coronary scaffold which are eventually resorbed by the body. The DESolve Ns Novolimus-Euting Coronary Scaffold System (BCSS) is a novel drug eluting biosorbable scaffold that is composed of a PLLA-based scaffold coated with a biodegradable polylactide-based polymer and the drug Novolimus, a macrocyclic lactone mTOR inhibitor which has demonstrated potent anti-proliferative properties in previous clinical trials using Elixis's metallic Novolimus-Euting (NEB) coronary stents. The DESolve Ns study is a prospective, multicenter evaluation of the safety and efficacy of the DESolve Ns NEBCSS in patients with single de novo native coronary artery lesions through clinical endpoints and multiple imaging modalities.

Methods: 126 patients with single, de novo coronary artery lesions were enrolled in this prospective, multi-center, single-arm study. Those patients receiving the study device are being analysed for multiple clinical endpoints including: Major Adverse Cardiac Events (MACE), a composite endpoint of cardiac death, target vessel MI, or clinically-indicated target lesion revascularization (CI-TLR); Clinically-indicated Target Lesion and Target Vessel Revascularization (CI-TVR) and Stent Thrombosis assessed at 1, 6 and 12 months and annually to 5 years. All patients underwent angiographic assessment at 6 months and a subset of patients underwent IVUS and OCT assessment at 6 months and MSCT at 12 months.

Results: At baseline, the patient population had a mean age 62 years, 32% were females, 21% were diabetic. Pre-procedure mean lesion length was 11.2 mm, RVD was 3.06 mm. Serial QCA imaging at 6 months demonstrated low mean in-scaffold late lumen loss (0.21mm).IVUS and OCT imaging indicated early vessel restoration at 6 months. Clinical events remained low (MACE = 3.25% at 6 months) with no reports of definite stent thrombosis.

Conclusions: The DESolve Ns NEBCSS demonstrated safety and efficacy in treating de novo coronary artery lesions with low clinical event rate and evidence of low late lumen loss at 6 months. A first report of results through 12 months will be presented.

TCT-38

Three-year clinical data of the BIOSOLVE-I Study with the paclitaxel-eluting bioabsorbable magnesium scaffold (DREAMS) and multi-modality imaging analysis

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Background: In order to assess the intermediate term safety, clinical performance and the bioabsorption process of the Paclitaxel-Eluting Bioabsorbable Magnesium Scaffold (DREAMS) 3-year clinical data of cohort 1 and multi-modality imaging outcomes are reported.

Methods: Forty-six subjects were enrolled in the first-in-man BIOSOLVE-I study in two different cohorts with clinical follow-up at 1, 6, 12, 24 and 36 months; angiographic and IVUS follow-up for cohort 1 at 6-month and for cohort 2 at 12-month. A subgroup of patients underwent OCT and vasmotion testing. The primary endpoint is Target Lesion Failure (TLF) at 6-month for cohort 1 and at 12-month for cohort 2. For some patients also 18-month and 24-month imaging data are available.

Results: TLF rate at 24-month was 6.8% including 2 TLRs and 1 peri-procedural MI occurring at the 12-month follow-up angiography: no events emerged from 12- to 24-month. No cardiac death or scaffold thrombosis was observed. 36-month clinical data of Cohort 1 will be available upon presentation. Vasostenstriction after acetylcholine at 6-month (Delta=-10.04%; p=0.008 versus baseline) followed by vasodilatation after nitroglycerine (Delta=-8.69%; p<0.0001 versus baseline) demonstrates the uncaging aspect of the absorption process with no further change at the 12-month follow-up. Six-month virtual histology (VH) data showed a significant decrease in the dense calcium by 39.5% (p<0.0015) remaining stable from 6- to 12-month follow-up. This decrease is interpreted as a surrogate assessment for the bioabsorption process of the scaffold material. Preliminary echogenicity data using the decrease in intensity of the ultrasound signal to quantify the change in strut structure demonstrate a relatively large decrease of hyperechogenicity (28.5%) in the first 6-month, followed by lower decrease (18.4%) in the 6 months thereafter, with indications that the hyperechogenicity at 18-month returns to the values seen pre-implantation.

Conclusions: DREAMS shows excellent safety and efficacy data with no death and no scaffold thrombosis up to 3 years in the BIOSOLVE-I trial. Multi-modality imaging documented the absorption process and the uncaging aspect of this device already at 6 months.

TCT-39

12-Month Angiographic and Clinical Results of the ReZolve® Sirolimus-Eluting Biosorbable Coronary Scaffold: The RESTORE trial

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Background: ReZolve is a novel scaffold incorporating a unique slide & lock expansion technology and a proprietary biosorbable stent material that is a polycarbonate co-polymer of tyrosine analogs. The aim of this study was to evaluate, for the first time, the safety and performance of the ReZolve sirolimus-eluting biosorbable coronary scaffold in non-complex human coronary lesions.

Methods: The RESTORE trial is a prospective, multi-center and multi-national trial enrolling patients with single, de novo lesions in native coronary arteries with an average reference diameter between 2.9 mm to 3.3 mm and lesion length up to 12 mm. The primary study endpoint was freedom from ischemic-driven target lesion revascularization (TLR) at 6-months and 12-month in-scaffold late loss. Serial IVUS evaluation (post procedure and at 12 months) was also performed in a subgroup of patients. All imaging analyses were performed by independent core labs.

Results: A total of 26 patients were enrolled in this trial and the device was successfully implanted in 22 cases. Most patients were male (76%) and 36% of all patients had diabetes. Mean reference vessel diameter and lesion length were 2.72 mm and 11.1 mm, respectively. Acute recoil was minimal at 3.8% ± 6.7%. Through 6 months post-implant there were 2 focal in-scaffold TLRs. The 12-month QCA evaluation was completed for the first 8 patients and resulted in a late loss of 0.20 ± 0.19 mm. Of note, the mean stent diameter at implant in this initial group of patients was 3.1 mm ± 0.1 mm. At the time of the meeting.

Conclusions: In this preliminary assessment, the ReZolve scaffold showed excellent acute performance with minimal acute recoil. Complete 12-month QCA and IVUS data is required to confirm the performance of this novel device.