First in human study BIOMAG-I: 12 months results of the sirolimus eluting resorbable coronary magnesium scaffold system (DREAMS 3G) in the treatment of subjects with de novo coronary artery lesions

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Background/Introduction: Biodegradable scaffolds have emerged as an attractive alternative to polymeric scaffolds. A 3rd generation drug-eluting resorbable magnesium scaffold (DREAMS 3G) was developed to enhance the performance of previous scaffold generations and achieve angiographic outcomes comparable to those of contemporary drug-eluting stents.

Purpose: The aim of the BIOMAG-I first-in-human (FIM) study was to assess the angiographic, clinical and safety performance of DREAMS 3G in patients with de novo coronary artery lesions. We assessed the 12-month safety and performance of this novel device as well intravascular imaging data at baseline, 6- and 12-month follow-up.

Methods: In this prospective, multicentre, non-randomized, first-in-human study 116 subjects with 117 coronary artery lesions were enrolled at 14 centers in Europe. Clinical follow-up was scheduled at 1, 6 and 12-months and annually thereafter until 5 years. Invasive imaging assessments were scheduled 6 and 12-months post-procedure. Vasomotion was assessed in a subgroup of subjects during the 12 months follow-up. The primary endpoint was in-scaffold LLL at six months. Secondary endpoints include in-segment LLL, TLF, clinically driven target lesion revascularization (TLR), cardiac death, target-vessel myocardial infarction (TV-MI) and scaffold thrombosis.

Results: Preliminary in-scaffold LLL (n=89 subjects) remained stable from 6 months (0.20 ± 0.28 mm) to 12 months (0.24 ± 0.35 mm). Interim intravascular ultrasound assessments and optical coherence tomography findings corroborated the QCA results with a preservation of the lumen area from 6 (IVUS: 7.0 ± 2.5 mm²; OCT: 8.1 ± 2.7 mm²) to 12 months (IVUS: 7.2 ± 2.6 mm²; OCT: 7.8 ± 2.6 mm²). Vasomotion assessment in a subgroup of subjects confirmed the mobility of the scaffolded segment at 12 months follow up: after Acetylcholine administration: 12.5% ± 7.5 (n=27); after nitro administration: 10.7% ± 9.2 (n=22). Up to 12-months follow up, 3 clinically driven TLR were reported (3.4%). No cardiac death, no TV-MI and no scaffold thrombosis were reported up to 12 months. Full data set of the 116 subjects will be available upon presentation.

Conclusions: The novel third-generation drug-eluting magnesium scaffold, DREAMS 3G, showed a continuous favorable safety and efficacy profile up to 12 months and stable angiographic parameters between 6 and 12 months. Intravascular imaging assessment showed a preservation of the lumen area between 6 and 12 months.