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

M. Haude1, A. Wlodarczak2, R. Van Der Schaaf3, J. Torzewski4, B. Ferdinande5, J.F. Iglesias6, J. Bennett6, G. Toth9, M. Joner10, R. Toelg11, M. Wiemer12, G. Olivecrona13, P. Vermeersch14, R. Waksman15

1Rheinland hospital, Medicinal Clinic I, Neuss, Germany
2Miedziowe Centrum Zdrowia SA, Department of Cardiology, Lubin, Poland
3Hospital Onze Lieve Vrouwe Gasthuis, Department of Interventional Cardiology, Amsterdam, Netherlands (The)
4Clinic Kempten-Oberallgäu, Cardiovascular Centre, Kempten, Germany
5Hospital Oost-Limburg (ZOL), Department of Cardiology, Genk, Belgium
6Hospital Clinico San Carlos, Division of Cardiology, Madrid, Spain
7University Hospital of Geneva, Cardiology Division, Geneva, Switzerland
8University Hospitals (UZ) Leuven, Department of Cardiovascular Medicine, Leuven, Belgium
9Medical University of Graz, Division Cardiology, Graz, Austria
10German Heart Center of Munich, Klinik für Herz- und Kreislaferkrankungen, Munich, Germany
11Heart Center Bad Segeberg, Cardiology Department, Bad Segeberg, Germany
12Mill district clinics - Johannes Wesling Clinic Minden, Department of Cardiology and Intensive Care, Minden, Germany
13Skane University Hospital, Department of Cardiology, Lund, Sweden
14Interventional Cardiology ZNA Middelheim, Antwerpen, Belgium
15MedStar Washington Hospital Center, Interventional Cardiology, Washington DC, United States of America

Funding Acknowledgements: Type of funding sources: Private company. Main funding source(s): BIOTRONIK AG

Background/Introduction: Bioresorbable 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 motility 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.