Press Release

Eurocor announces 6 and 12 months interim results of the Freeway Stent Study at TCT Congress in San Francisco

- **Freeway™ drug-coated balloon for treatment of stenotic or occluded lesions in the SFA or proximal popliteal arteries**

Bonn, Germany – November 22, 2013 – Eurocor GmbH, an Opto Circuits group company, unveiled 6 and 12 months insights of the ongoing Freeway Stent Study during the TCT Congress in San Francisco on October 29th. The study is lead-managed by Prof. Dr. Josef Tacke, Klinikum Passau, Germany. The multicenter, open, prospective randomized trial investigates the prevention of restenosis by the usage of a drug-coated balloon (DCB) Freeway or plain old balloon angioplasty (POBA) after Nitinol Stent implantation in the treatment of Superficial Femoral Artery (SFA) or Popliteal artery (PI-segment) lesions in the legs.

The randomized, prospective clinical study is being conducted in 15 European sites to investigate the rate of clinically driven target lesion revascularization (TLR). 200 patients suffering from *de novo* lesions that need to be stented will be enrolled and are randomized in a 1:1 ratio. Both groups will be treated with Nitinol stent implantation first following randomization in a 1:1 ratio to postdilatation with a drug-coated balloon (Freeway DCB) or a plain old balloon (POBA). During the 6th and 12th month, the patient will undergo a Duplex follow-up as well as an angiographic follow-up in a subgroup at 6 month. The analysis will be performed by an independent core lab.

The Results at 6 and 12 months

Currently 142 patients have been enrolled, whereof a 6 month follow-up is now available for 100 patients. 52 of them have been treated with a Nitinol stent and a DCB. The trend shows a very low target lesion revascularization (TLR) rate of 1,9% in the Freeway DCB group, whereas the second group of 48 patients that have been treated with the Nitinol stent and POBA are showing a TLR rate of 8,5%.

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The 12 months FU results in 69 patients also shows a positive trend in the TLR rate of 5.7% for the DCB group (N=35) and 14.7% (N=34) for the POBA group.

Conclusion

The TLR rate for the subgroup of patients treated with Freeway DCB shows a sigificant better outcome at 6 months and positive trend at 12 months for the patients. The results furthermore show a significant better clinical result regarding Rutherford Classification after stent postdilatation with Freeway DCB vs POBA after 6 and 12 months as well as a siginificant better primary patency rate with Freeway DCB compared to POBA at 6 months. Also the Ankle-Brachial-Index (ABI Index) shows a sigificant better clinical result for Freeway DCB compared to the POBA group at 6 months.

Prof. Dr. Josef Tacke commented: “In-stent restenosis is a serious problem in the SFA and PI-segment. Drug-coated balloons might be an option to prevent restenosis at an early stage for patients that need to be stented. The first insights are very promising and we are looking forward to the final results of the study.”

“The trend so far shows a good and safe performance of our drug-coated balloon Freeway. We trust that our DCB technology platform used in the Freeway Stent Study will offer better treatment options and significant therapeutic advantages for the patients,” said Dr. Rembert Pogge von Strandmann, Director Clinical Department, Eurocor.

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The Company:
Eurocor is a rapidly growing European Life Sciences Technology Corporation specializing in the research, development and manufacture of cardiovascular and endovascular products. Eurocor provides interventional physicians with innovative coronary stent technologies and special cardiovascular and endovascular devices, manufactured in Bonn. Products are indicated for minimally invasive cardiovascular and peripheral surgery and comply with biological and biomechanical principles to offer highly flexible, adaptable solutions. Extensive research and development, close clinician collaboration, outstanding quality standard philosophy and global scientific alliances lead to optimization of clinically effective technologies. Eurocor has designed an innovative method for balloon catheter drug delivery with high patient compliance. One heartbeat ahead® – with innovative products such as DIOR® and FREEWAY™.
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