Eurocor announces interim results of the Freeway™ Stent Study at IROS Congress

- Freeway™ drug-eluting balloon for treatment of de novo lesions in the SFA or popliteal arteries
- The trend shows a low TLR rate of 2.5% for Freeway™

India | January 18, 2013 – Eurocor GmbH, an Opto Circuits group company, unveiled interim results of the ongoing Freeway Stent Study on January 17th, 2013 at IROS (Interventionell Radiologische Olbert Symposium), Berlin, Germany. The study was presented during the Free Paper Session 2 by Prof. Dr. Josef Tacke, Klinikum Passau, Germany. The multicenter, open, prospective randomized trial investigates the prevention of restenosis by drug-eluting balloon (DEB) dilatation (Freeway™) after stenting with a Nitinol stent versus, dilatation with standard balloon (POBA) after stenting with a Nitinol stent in the treatment of Superficial Femoral Artery (SFA) or Popliteal artery (PI-segment) lesions in the legs.

Interim Results

The trend shows a very low target lesion revascularization (TLR) rate of 2.5%, whereas the second group of 39 patients that have been treated with the Nitinol stent and POBA are showing a TLR rate of 10.2 %. Also a higher rate of primary patency for the DEB arm compared to the POBA arm (86.1% vs. 75.7%, respectively) has been found. These findings are reflected in a significant better clinical outcome regarding Rutherford classification (0.25±0.66 vs. 0.69±0.97, respectively; p=0.02).

About the Trial

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 are enrolled and are randomized in a 1:1 ratio. Both groups will be treated with Nitinol stent implantation following postdilatation with a drug-eluting balloon (Freeway™ DEB) or a standard balloon (POBA), randomized in a 1:1 ratio. The Primary Endpoint is the rate of clinically driven target lesion revascularization (TLR) at 6 months. After 6th and 12th month, the patients will undergo a duplex follow-up or an angiographic follow-up (a clinical FU at 12 month will finalize the study). The analysis is performed by an independent core lab.
Currently 111 patients have been enrolled, whereof a 6 month follow-up is now available for 79 patients. 40 of them have been treated with a Nitinol stent and a DEB.

Prof. Dr. Josef Tacke commented: "In-stent restenosis is a serious problem in the SFA and PI-segment. Drug-eluting balloons might be an option to prevent restenosis at an early stage for patients that need to be stented. The interim results 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-eluting balloon Freeway™. Especially the already significant outcome regarding the Rutherford Classification is good news. We trust that our DEB technology platform used in the Freeway™ Stent Study will offer treatment options and significant therapeutic advantages for the patients," said Dr. Rembert Pogge von Strandmann, Director Clinical Department, Eurocor.

About Eurocor GmbH

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 Europe. 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™. Eurocor GmbH is a wholly owned subsidiary of Opto Eurocor Healthcare Limited and is part of the Opto Circuits Group.

For more information, please visit eurocor.de and optocircuits.com

About: Opto Circuits (India) Limited
Website: www.optocircuits.com

Opto Circuits (India) Ltd. (OCI) is an MNC in the business of design, development, manufacture and marketing of healthcare equipment and medical interventional products. The product profile includes USFDA-listed, CE-marked cardiac and vital signs monitoring systems, anesthesia and respiratory care equipment, automated external defibrillators, stents, catheters, body implants and consumables. Some of OCI's well-known brands are Cardiac Science, Criticare, Devon, Eurocor, Ormed, Mediaid and Unetixs. The company's key markets are North America, Europe and BRIC countries.

Contact Us:
Opto Circuits (India) Ltd.
E: Media - media@optoindia.com | Investors - ir@optoindia.com
T: +91 80 2852 1040/41/42