



News Release

Opto Circuits' group company, Eurocor's partner - Micell Technologies Receives CE Mark Approval for MiStent SES

--Unique safety profile could benefit patients with coronary artery disease--

Bonn, Germany | Bengaluru, India | June 14, 2013: Eurocor GmbH, a group company of Opto Circuits (India) Ltd. (Bloomberg: OPTC IN; Reuters: OPTO. NS; NSE: OPTOCIRCUI; BSE: 532391), is pleased to announce that their partner Micell Technologies, Inc. received CE (Conformité Européenne) Mark approval for its MiStent® Sirolimus Eluting Absorbable Polymer Coronary Stent System (MiStent SES®) introducing a thin-strut stent that features elimination of the coating from the stent in 45-60 days and the complete absorption of the polymer coating within 90 days. The MiStent SES® is unique in providing local drug delivery both during and after the period of polymer absorption, thereby eliminating long-term polymer exposure, a potential cause of delayed healing and late adverse events.

Micell's Chief Executive Officer, Arthur J. Benvenuto, commented, "The MiStent SES® brings a new paradigm of safety without compromise to efficacy or deliverability. With polymer absorption faster than any other DES currently available, we believe the MiStent SES provides a long-term safety profile of a highly deliverable bare metal stent."

The MiStent SES® approval is supported by in-depth clinical analysis from the DESSOLVE I and DESSOLVE II clinical trials. The DESSOLVE II trial met its primary end point: superiority of MiStent SES in minimizing in-stent late lumen loss (LLL) at nine months as compared to Medtronic's Endeavor® Sprint DES (p<0.001). The trial was a randomized, multi-center study of 184 patients with documented stable or unstable angina pectoris. At nine months' follow-up, in-stent LLL was 0.27 mm with a target lesion revascularization rate of 0.9%. The major adverse cardiac events (MACE) rates were 4.3% for MiStent SES and 6.7% for Endeavor. In a sub-group of patients, optical coherence tomography (OCT) and endothelial function testing confirmed good vessel healing with excellent strut coverage and normal endothelial function.

The DESSOLVE I first-in-human study provides additional evidence for the potential clinical advantages of MiStent SES's unique features, with serial angiographic, intravascular ultrasound (IVUS) and OCT assessment of patients at early (6/8 month) and late (18 month) time points. Data analysis of the groups using matched pairs shows no progression of LLL (0.10 / 0.09 mm and 0.09 mm respectively).

The company is preparing for a post-marketing clinical program of 2,000 patients comparing the MiStent SES® to the Xience® Everolimus Eluting Coronary Stent System in a randomized design to show non-inferiority of target lesion failure at 12 months and superior performance by the MiStent SES® at 24 months with significantly less progression of LLL.

With this CE Mark approval, Micell is preparing to make the MiStent SES® commercially available in Europe and other markets where CE Mark approval can expedite the registration process. The MiStent Sirolimus Eluting Absorbable Polymer Coronary Stent System is not currently available for sale in any market.

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About the MiStent SES

The MiStent Sirolimus Eluting Absorbable Polymer Coronary Stent System (MiStent SES) is designed to optimize healing in patients with coronary artery disease. MiStent's rapidly absorbable coating is intended to precisely and consistently control drug elution and limit polymer exposure duration to reduce the safety risks associated with current commercially available drug-eluting stent technologies.

The innovative MiStent SES system includes a proprietary stent coating that contains crystalline drug (sirolimus) and an absorbable polymer. The coating provides controlled and sustained release of therapeutic levels of drug as the polymer softens and disperses from the stent into the adjacent tissue. These properties are intended to enhance safety as compared to conventional permanent polymer DES.

Using an approved drug (sirolimus) and polymer (PLGA), Micell's patented supercritical fluid technology allows a rigorously controlled drug/polymer coating to be applied to a bare-metal stent. The MiStent SES leverages the benefits of Eurocor's (CE Marked) Genius® MAGIC Cobalt Chromium Coronary Stent System, a state-of-the-art bare-metal stent, which has demonstrated excellent deliverability, conformability and flexibility.

Results of animal studies have determined that the coating is cleared from the stent in 45 to 60 days leaving a bare metal stent and the polymer is completely absorbed into the surrounding tissue within 90 days to promote long-term patency and compatibility with the artery.

Micell was granted CE (Conformité Européenne) Mark approval for MiStent SES in June 2013.

About Micell Technologies Inc.

Micell Technologies is a biomedical company that is enhancing the performance of medical devices with innovative drug-delivery systems. Its unique surface and polymer modification technologies enable Micell to precisely and consistently control drug elution and polymer exposure duration, creating the potential for a therapeutic solution to coronary artery disease without the long-term safety concerns of currently available drug-eluting stents. Micell is also developing a drug-coated balloon for vascular interventions. Visit us at www.micell.com.

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.



SENSING TECHNOLOGY



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 www.eurocor.de.

About Opto Circuits (India) Limited

Opto Circuits (India) Ltd. (OCI) is a vertically integrated multinational medical technology Group that specializes in primary, acute and critical care products for the global markets. Group companies such as [Cardiac Science](#), [Criticare](#), [Eurocor](#), [Mediaid](#), [AMDL](#) and [Unetixs Vascular](#) are leaders in vital signs monitors, emergency cardiac care equipment, vascular treatments and sensing technologies. Our USFDA listed and CE marked products are marketed in more than 150 countries and sold through direct and indirect sales channels across many emerging and developed economies. We've been ranked in Forbes' Asia's 200 Best under a Billion lists in 2008, 2009 and 2011. For more information, please visit www.optoindia.com.