## Opto Circuits subsidiary Eurocor's partner Micell Technologies enrolls first patient in randomized trial for MiStent DES, a novel sirolimus-eluting stent system

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Opto Circuits (I) Ltd.'s wholly-owned subsidiary Eurocor GmbH is pleased to announce that their partner Micell Technologies has successfully enrolled the first patient in their randomized trial (DESSOLVE II) for the MiStent™ Drug Eluting Coronary Stent System (MiStent DES), a novel sirolimus-eluting stent system using Eurocor's bare metal platform from Eurocor. The trial will enroll approximately 270 patients and upon successful completion, will be submitted to obtain CE marking

The MiStent DES employs Micell's proprietary and patented supercritical fluid technology which applies a precisely controlled absorbable polymer - active drug (sirolimus) matrix onto Eurocor's leading Genius® Magic Cobalt Chromium Bare Metal (BMS) stent system. The polymer dissolves and releases the drug into the surrounding tissue in a controlled manner, designed to optimize dosing of the drug throughout the effected artery. In GLP preclinical trials, the drug completely elutes and the polymer is eliminated from the stent within 45 to 60 days *in vivo*, resulting in a bare-metal stent.

DESSOLVE II is a prospective, controlled, 2:1 unbalanced randomized, multi-center study of approximately 270 patients. Patients will be enrolled at 26 clinical sites in Europe, New Zealand and Australia. Stefan Verheye, M.D., Ph.D. at Middelheim Hospital, Antwerp, Belgium enrolled the first patient in the study. Candidates for the trial are patients with documented stable or unstable angina pectoris or ischemia. The primary endpoint is superiority of MiStent DES in minimizing in-stent late lumen loss at nine months, compared to Medtronic's Endeavor® DES, as measured with angiography in treated *de novo* lesions ranging in diameter from 2.5 to 3.5 mm and amenable to treatment with a maximum 23 mm long stent.

Along with secondary clinical endpoints such as major adverse cardiac events and revascularization rates, the extent of stent coverage and re-endothelialization, via optical coherence tomography (OCT), and endothelial function (vasomotor response) will be evaluated in a subgroup of patients at nine months. More information on the DESSOLVE II trial can be found at ClinicalTrials.gov.

"Drug-eluting stents have significantly improved and expanded our ability to treat coronary atherosclerotic lesions compared to bare-metal stents," said William Wijns, M.D., Cardiovascular Center, Aalst, Belgium, and principal investigator of the study. "However, cardiologists are still looking for options to improve safety and outcomes. The MiStent DES may address some of these issues directly. Based on recent GLP animal data, the polymer and drug are gone from the stent within 45 to 60 days. This may reduce the risk of late-stent thrombosis related to long-term exposure to DES non-erodible polymers. Given the relatively short residence time of polymer on the stent, MiStent DES may allow for a shorter duration of dual anti-platelet therapy and be a safer choice for non-compliant patients. These performance enhancing properties are what interventional cardiologists are looking for in a new drug-eluting stent."

In 2009, Maxcor Lifesceince, Inc., a subsidiary of Opto Circuits (I) Ltd entered into a strategic cooperation agreement with Micell Technologies for developing and commercializing leading edge Rapamycin (Sirolimus) - based drug-eluting stents (DES) and drug-eluting balloons (DEB).

## **About: Micell Technologies Inc.**

Micell Technologies is a biomedical company that is enhancing the performance of medical devices with innovative drug-delivery systems. By applying its unique surface and polymer modification technologies, Micell can precisely and consistently control drug elution and the duration of polymer exposure creating the potential for a therapeutic solution for 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 <a href="https://www.micell.com">www.micell.com</a>.

The MiStent Drug Eluting Coronary Stent System is an investigational device. It is not yet approved or available for sale in any market.

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