

## **Micell Technologies Announces Positive Preliminary Data from DESSOLVE I Study of MiStent<sup>®</sup> Sirolimus Drug Eluting Coronary Stent System**

DURHAM, N.C., November 8, 2011 -- Micell Technologies, Inc. today announced the release of preliminary data from the first-in-human clinical study of the MiStent<sup>®</sup> Sirolimus Drug Eluting Coronary Stent System (MiStent DES), a thin-strut drug-eluting stent distinguished by a rapid-absorbing drug/polymer coating designed for controlled drug release. Four, six and eight month data from the DESSOLVE I trial were presented at the Transcatheter Cardiovascular Therapeutics Conference (TCT 2011) by John Ormiston, M.D., Mercy Angiography Unit, Auckland, New Zealand, a principal investigator in the study. TCT will make the presentation available on its website at [www.tctmd.com](http://www.tctmd.com) following the conference.

“These preliminary study results demonstrated excellent performance by the MiStent DES at up to eight months post-procedure -- when patients typically experience the greatest increase in neointimal hyperplasia,” said Dr. Ormiston. “MiStent DES is intended to provide enhanced patient safety and outcome by eliminating long-term exposure to DES non-erodible polymers. In addition to delivering clinical performance, MiStent DES may also enable physicians to pursue shorter duration dual anti-platelet therapy, and offer a safer choice to their non-compliant patients or patients who may be undergoing additional surgical procedures.”

Thirty patients were treated with the MiStent DES with independent subgroups of 10 patients assigned to a four month, six month or eight month follow-up. The primary efficacy endpoint was in-stent late lumen loss (LLL). Safety was assessed by incidence of major adverse cardiac events (MACE) and presence of tissue coverage within the treated artery at each time point. Angiography, intravascular ultrasound (IVUS) and optical coherence tomography (OCT) imaging results were measured by independent core laboratories. Preliminary analysis of the data demonstrated a very low median in-stent late lumen loss of 0.03 mm at four months, 0.10 mm at six months and 0.08 mm at eight months follow-up with no binary restenosis or revascularizations. The mean in-stent late lumen loss values at four, six and eight months were 0.01, 0.21 and 0.09 mm, respectively. The mean and median values were comparable except at the six month time point, in which one patient experienced a high late loss value due to treatment of a highly calcified lesion and under-expansion of the stent. When data from this patient is excluded, the six month mean LLL is 0.10 mm. The median percent of stent struts covered by tissue was 96% at eight months, 97% at six months and 90% at four months per OCT analysis. IVUS confirmed good inhibition of neointimal hyperplasia. A MACE rate of 6.7%, including two non-Q wave myocardial infarctions (MI), one peri-procedural and one non-target vessel MI, was reported through eight months follow-up.

“The MiStent DES was designed to address a need for improved patient safety while providing equivalent or better efficacy as compared to currently available drug eluting stents,” observed Dennis Donohoe, M.D., Chief Medical Advisor to Micell. “The excellent clinical outcomes of the DESSOLVE I trial demonstrate the value of the MiStent design in enabling elimination of drug and polymer from the stent in 45 to 60 days and providing patients the best of DES and BMS in one solution.”

## **About DESSOLVE I and DESSOLVE II Studies**

The DESSOLVE I trial, the first clinical assessment of safety and efficacy of the MiStent DES, treated thirty patients with *de novo* lesions in coronary arteries ranging in diameter from 2.5 to 3.5 mm and amenable to treatment with a maximum 23 mm length stent. Subjects were enrolled across five study centers in New Zealand, Australia and Belgium. Three independent subgroups of 10 patients each were evaluated using angiography, IVUS and OCT at three time points: four, six and eight months. The primary efficacy endpoint was in-stent late lumen loss. Safety was assessed by incidence of major adverse cardiac events (MACE) and presence of strut coverage with tissue within the treated artery at each time point. William Wijns, M.D., Cardiovascular Center, Aalst, Belgium and John Ormiston, M.D., Mercy Angiography Unit, Auckland, NZ are co-principal investigators for this trial.

The DESSOLVE II CE Mark trial is a multi-center study of patients with documented stable or unstable angina pectoris. The primary endpoint is superiority of the MiStent DES in minimizing in-stent late lumen loss at nine months, compared to Medtronic's Endeavor<sup>®</sup> Sprint DES, as measured by the angiography core laboratory in *de novo* coronary lesions in vessels ranging in diameter from 2.5 to 3.5 mm and amenable to treatment with a maximum 30 mm length stent. The DESSOLVE II study completed enrollment of 183 patients in July 2011.

## **About the MiStent DES**

The MiStent Sirolimus-Eluting Coronary Stent System is designed to optimize healing in patients with coronary artery disease. Micell's rapid-absorbing drug/polymer coating is intended to precisely and consistently control drug elution and polymer exposure duration to reduce the safety risks associated with current commercially available drug-eluting stent technologies.

The MiStent DES innovative stent system includes a proprietary stent coating that contains crystalline drug (sirolimus) and an absorbable polymer. As the polymer softens and disperses from the stent into the adjacent tissue, the coating provides controlled and sustained release of therapeutic levels of drug within the surrounding tissue. Results of animal studies have determined that the drug/polymer 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 in 90 days to promote long-term patency and compatibility with the artery.

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 DES leverages the benefits of Eurocor's (CE Marked) Genius<sup>®</sup> MAGIC Cobalt Chromium Coronary Stent System, a state-of-the-art bare-metal stent, which has demonstrated excellent deliverability, conformability and flexibility.

The MiStent Sirolimus-Eluting Coronary Stent System is an investigational device currently being evaluated in international clinical studies and is not yet approved or available for sale in any market.

### **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 also is developing a drug-coated balloon for vascular interventions. Visit us at [www.micell.com](http://www.micell.com).

Micell, Micell Technologies, the Micell Logo, and MiStent are among the registered trademarks of Micell Technologies, Inc.

### **Contact: Micell Technologies**

Arthur J. Benvenuto, Chairman & CEO  
(919) 313-2104