

Micell Technologies Announces Clinical Data Presentations at TCT 2012

The Associated Press

Micell Technologies, Inc.

today announced that data from clinical studies of its investigational MiStent@ Sirolimus Eluting Absorbable Polymer Coronary Stent System (MiStent SEST) will be presented at the 24th Annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium to be held in Miami, Fla. on October 22 - 26, 2012. David Kandzari, M.D., Director of Interventional Cardiology and Chief Scientific Officer for the Piedmont Heart Institute of Atlanta, Ga. will be presenting the MiStent SES program update, including the clinical outcomes from the DESSOLVE I trial 18 month follow-up, and the DESSOLVE II trial 9 month follow-up. The MiStent SES is a thin-strut drug-eluting stent distinguished by a rapidly absorbable coating designed to control drug release.

Data presentations include: -- DESSOLVE II: A Prospective, Randomized Trial of a Biodegradable Polymer-based Sirolimus-Eluting Stent versus a Zotarolimus-Eluting Stent. Tuesday, October 23, 2:00-3:00 p.m. EDT -- Eighteen-Month Clinical and Imaging Results from the DESSOLVE I First-in-Human Trial of the MiStent SES with Absorbable Polymer.

Tuesday, October 23, 8:00-10:00 a.m. EDT -- Nine Month Imaging and Twelve Month Clinical Results from the DESSOLVE II Randomized Trial of the MiStent SES with Absorbable Polymer. Tuesday, October 23, 8:00-10:00 a.m. EDT -- Stents with Absorbable Tissue-Deployable Coatings Can Distribute Drug More Uniformly Between Struts. Tuesday, October 23, 8:00-10:00 a.m. EDT About DESSOLVE I and DESSOLVE II Studies The DESSOLVE I trial, the first clinical assessment of safety and efficacy of the investigational MiStent SES, 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., Ph.D., Cardiovascular Center, Aalst, Belgium and John Ormiston, M.B.Ch.B. Mercy Angiography Unit, Auckland, New Zealand are co-principal investigators for this trial.

The DESSOLVE II CE (Conformite Europeenne) Mark trial is a randomized, multi-center study of patients with documented stable or unstable angina pectoris. The

primary endpoint is in-stent late lumen loss at nine months 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 184 patients in July 2011. Data analysis confirms that DESSOLVE II met all study objectives, demonstrated a competitive in-stent late lumen loss, and achieved a strong signal of safety. Micell has submitted these data to European regulatory authorities as part of its application for a CE Mark.

About the MiStent SES 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 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.

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. These properties are intended to enhance safety as compared to conventional permanent polymer DES.

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 in 90 days to promote long-term 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 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.

The MiStent Sirolimus Eluting Absorbable Polymer 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 is also developing a

Micell Technologies Announces Clinical Data Presentations at TCT 2012

Published on Medical Design Technology (<http://www.mdtmag.com>)

drug-coated balloon for vascular interventions. Visit us at www.micell.com.

Caution Regarding Forward Looking Statements This press release contains forward looking statements that can be identified by the fact that they do not relate strictly to historical or current facts. Forward looking statements include words such as "anticipates," "estimates," "expects," "projects," "intends," "plans," "believes" and words and terms of similar substance in connection with the clinical outcomes of the DESSOLVE I and DESSOLVE II studies and the safety and efficacy of the MiStent SES. We caution readers that the forward looking statements contained in this press release are predictions based on our current analysis of and expectations about future events and speak only as of the date of this press release.

These forward looking statements are not guarantees of future performance and are subject to risks and uncertainties, including, but not limited to the following: the results of our clinical trials; our ability to obtain regulatory approval of the MiStent SES; the successful development and commercialization of the MiStent SES; the ability of the MiStent SES to effectively and successfully compete with current commercially available drug eluting stent technologies; and our ability to maintain and protect our proprietary stent coating technology. Actual results, performance or achievements could differ materially and adversely from those expressed or implied by any forward looking statement contained in this press release.

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

Contact: Micell Technologies Arthur J. Benvenuto, Chairman & CEO (919) 313-2104
SOURCE Micell Technologies, Inc.

-0- 10/16/2012 /Web Site: <http://www.micell.com> CO: Micell Technologies, Inc.;
Transcatheter Cardiovascular Therapeutics Scientific Symposium ST: North Carolina
IN: HEA BIO MTC SU: SVY TDS PRN -- CL93497 -- 0000 10/16/2012 12:00:00 EDT
<http://www.prnewswire.c>

Source URL (retrieved on 01/29/2015 - 7:33pm):

http://www.mdtmag.com/news/2012/10/micell-technologies-announces-clinical-data-presentations-tct-2012?qt-most_popular=0&qt-video_of_the_day=0