Micell Technologies Announces Positive Data from Clinical Studies of MiStent SES

The Associated Press

Micell Technologies, Inc.

today announced positive data from two clinical studies of its investigational MiStent@ Sirolimus Eluting Absorbable Polymer Coronary Stent System (MiStent SEST), a thin-strut drug-eluting stent distinguished by a rapid-absorbing drug/polymer coating designed to control drug release. Eighteen-month outcomes from the DESSOLVE I trial, and nine-month data supporting all study endpoints in the DESSOLVE II trial, were presented by David Kandzari, M.D., Director of Interventional Cardiology and Chief Scientific Officer for the Piedmont Heart Institute of Atlanta, Ga. These data, presented at the 24th Annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium held in Miami, Fla., will be available on the TCT website, www.tctmd.com, following the conference. Based on the cumulative findings and pending regulatory approval, Micell anticipates that MiStent SES may provide an innovative treatment option with an impressive safety profile for patients suffering from coronary artery disease.

Dr. Kandzari said, "MiStent has demonstrated excellent results as well as treatment advantages we have not seen in other drug-eluting stents.

Achieving minimal progression of late lumen loss from four- through 18-month assessments is unique and a significant positive clinical outcome. Once MiStent is available to physicians, this novel product will also present interventional cardiologists with a meaningful and important alternative in addressing the limitations of permanent polymer DES products. Indeed MiStent's performance characteristics and clinical data can serve as a foundation for the improvement of patient care." Data presentations at TCT included the following: Eighteen Month Clinical and Imaging Results from the DESSOLVE I First-in-Human Trial of the MiStent SES with Absorbable Polymer: MiStent SES mean in-stent late lumen loss (LLL) was essentially unchanged through 18 months post-procedure in patients with discrete de novo lesions in native coronary arteries. Initial angiographic evaluations on 25 subjects had a mean in-stent late lumen loss (LLL) of 0.07 mm. The mean 18-month LLL for the same 25 subjects was essentially unchanged at 0.09 mm. Intravascular ultrasound (IVUS) confirmed minimal change in neointimal hyperplasia in the long-term follow-up with an initial mean (standard deviation) percent obstruction of 7.24.8% and 11.28.1% at 18 months. The major adverse cardiac events (MACE) rate at 18 months was unchanged from 12 months with only one non-target vessel non-Q-wave myocardial infarction (MI).

Nine Month Imaging and Twelve Month Clinical Results from the DESSOLVE II Randomized Trial of the MiStent SES with Absorbable Polymer: MiStent SES demonstrated statistically superior performance as compared to the Endeavor@

Sprint DES (Endeavor) for the primary endpoint of in-stent LLL. At nine months' follow-up, in-stent LLL was 0.27 mm with a target lesion revascularization (TLR) rate of 0.9%. The MACE rates were 4.3% for MiStent SES and 6.7% for Endeavor.

"DESSOLVE II, a randomized controlled study, successfully met all endpoints. Patient evaluations at nine months confirmed that MiStent SES provided a healing profile comparable to that of a bare metal stent, with a median of only 0.3% uncovered stent struts, zero malapposition, and a return of normal endothelial function with 100% of MiStent-treated vessels showing vasodilation. DESSOLVE II builds on the results of the first-in-human DESSOLVE I study, in which there was no increase in late lumen loss through 18 months post-procedure," said Dennis J. Donohoe, M.D., Micell's Chief Medical Advisor. "Each aspect of the MiStent SES was considered when designing a next-generation stent intended to deliver the efficacy of a drug-eluting stent with the safety profile of a bare metal stent.

MiStent SES has the potential to address a pressing need to improve patient safety without sacrificing efficacy." 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 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 superiority of the MiStent SES in minimizing in-stent late lumen loss at nine months, compared to Medtronic's Endeavor@ 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 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 strong signal of safety. Micell has submitted these data 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 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 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 also is developing a 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 results of DESSOLVE I and DESSOLVE II clinical trials, the safety and efficacy of the MiStent SES, and development and commercialization 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- 10/23/2012 /Web Site: http://www.micell.com CO: Micell Technologies, Inc.; 24th Annual Transcatheter Cardiovascular Therapeutics (TCT); TCT 2012 ST: Florida North Carolina Georgia IN: HEA SU: TRI TDS PRN -- CL98347 -- 0000 10/23/2012 18:46:48 EDT http://www.prnewswire.c

Source URL (retrieved on *09/22/2014 - 2:28am*):
http://www.mdtmag.com/news/2012/10/micell-technologies-announces-positive-data-clinical-studies-mistent-ses?qt-recent_content=0