Micell Technologies Announces Development and Distribution Agreement to Bring MiStent SES to China

The Associated Press

Micell Technologies, Inc. has entered into an agreement with Hefei Life Science Technology Park Investment and Development Co., Ltd. (Hefei Life Science), for the clinical development, marketing and distribution of the MiStent Sirolimus Eluting Absorbable Polymer Coronary Stent System (MiStent SES@)in the People's Republic of China ("PRC"), including Hong Kong and Macau. Hefei Life Science, based in Anhui Province in Eastern China, will fund and manage clinical development programs necessary to obtain regulatory approval for MiStent SES in the Chinese markets.

Under the agreement, Micell will manufacture and supply MiStent SES for clinical and commercial use. Sinopharm, based in Shanghai and the first Chinese pharmaceutical company included in the Fortune Global 500 list, will provide distribution and logistical support while SinoMedCare, of Shanghai, will contribute marketing and sales support.

The agreement includes annual purchase commitments commencing upon regulatory approval of MiStent SES for commercial sale in China.

"This agreement creates a strong opportunity for MiStent SES to enter the Chinese market and build upon our recent CE Mark approval in Europe," commented Arthur J. Benvenuto, Micell's Chairman and Chief Executive Officer. "Sinopharm and SinoMedCare bring strengths to this partnership with Hefei Life Science that we expect will make this important medical innovation in the coronary stent market readily accessible to patients in Greater China." 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 (Conformite Europeenne) Mark approval for MiStent SES for the European Economic Union in June 2013, but is not approved in the United States or any other countries. A two year follow-up of DESSOLVE I and II clinical studies subjects was completed in 2013, and they currently are undergoing long-term follow-up.

Source URL (retrieved on *07/29/2014 - 6:08am*):
http://www.mdtmag.com/news/2013/10/micell-technologies-announces-development-and-distribution-agreement-bring-mistent-ses-china