

X-Cell Medical Completes Enrollment for Clinical Trial of ETHOS I Estradiol Eluting Stent

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PRINCETON, N.J.--(BUSINESS WIRE)--Nov. 21, 2005--X-Cell Medical, Inc. announced today that the Company has completed enrollment in its multinational clinical trial to study the safety and effectiveness of the ETHOS I Coronary Stent System.

ETHOS I stents are coated with slow-release and moderate-release formulations of 17 beta-estradiol, an approved and safe drug used in hormone replacement therapy and other indications. An overview of the potential cardioprotective and safety benefits of using estradiol to reduce restenosis in human coronary arteries and the ETHOS I study design was presented at the 2005 Transcatheter Cardiovascular Therapeutic symposium (TCT) by Alexandre Abizaid, MD, PhD of the Cardiovascular Research Foundation and Martin Leon, MD of Columbia University Medical Center.

"We are pleased with the rapid completion of enrollment in this study and the enthusiastic response of our multinational investigators who have worked so hard to recruit patients. Ninety patients have been enrolled in the blinded phase of the study and we greatly appreciate the efforts of all those involved," said Steve Peltier, X-Cell's Executive Director of Regulatory Affairs. "We have seen a high level of interest in the emerging clinical evidence demonstrating that there have been no safety concerns with ETHOS I at this early stage. We are on track to present the full results from this study in mid-2006."

"A take-home lesson from TCT 2005 was that the increase in reported cases of stent thrombosis needs to be addressed and overall safety of existing drug-eluting stent (DES) products remains a concern," said X-Cell Medical President and CEO, Dr. Oded Ben-Joseph. "In this regard, estradiol's pro-healing properties are likely to provide the patient with a safer alternative to current treatments and also allow X-Cell to enter into the DES space with a truly novel product."

About the ETHOS I study

ETHOS I is a three-center, randomized, double-blind, prospective study that will be followed by an open label phase during which patients will receive the optimal elution profile. The study will eventually include 150 patients once the optimal release formulation has been chosen. The study is comparing the ETHOS I drug-eluting stent (DES) with a leading bare-metal stent for the elimination of restenosis in patients eligible for balloon angioplasty with symptomatic ischemic heart disease due to discrete de novo and/or restenotic coronary artery lesions. The study is being conducted at the Heart Center Siegburg, Siegburg, Germany under the direction of Prof. Eberhard Grube; at Krankenhaus de Barmh. Bruder, Trier, Germany under the direction of Dr. Karl-Eugen Hauptmann; and at the Institute Dante Pazzanese of Cardiology, Brazil under the direction of Dr. Alexandre Abizaid. Data analysis and management will be conducted by the Cardiovascular Research Foundation, based in New York City, NY.

About Estradiol

Suppression of neointimal hyperplasia, the underlying cause of in-stent restenosis, by 17 beta-estradiol released from the stent surface, represents a novel approach for drug eluting stents and is the basis for the ETHOS I clinical study. Estrogens are known to inhibit smooth muscle cell proliferation and to accelerate endothelial regeneration, suggesting that estrogen coated stents may reduce restenosis in human coronary arteries. This was previously demonstrated in the 30 patient EASTER registry trial, using a non-optimized drug delivery system.

About X-Cell Medical

X-Cell Medical is discovering and developing next generation drugs for the medical device industry. X-Cell is applying its multi-disciplinary expertise in drug discovery, formulation, delivery and clinical development to bring advances in biotechnology to the interventional cardiology marketplace. The Company is currently focusing on the local and targeted delivery of drugs with superior safety and efficacy profiles for cardiovascular indications including restenosis, myocardial infarction and vulnerable plaque.

Located in Princeton, New Jersey, X-Cell Medical is backed by leading venture capitalists and the most influential cardiology device users in the industry. X-Cell's lead compound, 17 beta-estradiol, is presently being tested in the ETHOS I clinical trial. More information is available on the Net: <http://www.x-cellmedical.com>.

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