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**Contact:** Amy Murphy  
(202) 375-6476  
amurphy@acc.org

Andrew Crosby  
(901) 575-0010  
acrosby@cvic.com

ACC.09 News Room  
(407) 685-5405

## **STEM CELL CARDIAC PHASE 2 STUDY FOR TREATMENT OF REFRACTORY ANGINA FIRST OF ITS SIZE**

*Largest of any Cell-Based Therapy for Myocardial Disease Completed in the  
United States*

**Orlando, FL** – A successful randomized, double-blinded, placebo-controlled phase 2 clinical trial using an intramyocardial injection of a patient's own CD34 stem cells as treatment for refractory angina was performed at 22 centers across the United States, according to research presented today during the i2 Summit at the American College of Cardiology's 58<sup>th</sup> annual scientific session.

Initially, pre-clinical studies provided evidence that a patient's own CD34+ stem cells (CD34), could stimulate new vessel formation in those patients suffering from ischemic myocardium. Consequently, a phase 1, first-in-human trial was completed providing even further evidence of feasibility, safety and increased bioactivity in those patients with CCS class 3 and 4 angina. The phase 2 study, designed to test the ability of a patient's own stem cells (CD34 cells) to improve blood flow to the heart, could show the ability to improve heart function and reduce the possibility of events such as hospitalizations and heart failure in patients with refractory angina. A total of 167 patients were randomized and completed the injection procedure, and 162 patients completed the six-month evaluation.

“The results from this study provide the first significant evidence that a patient's own stem cells can actually be used as a treatment for their heart disease,” said Dr. Douglas Losordo, lead author from Northwestern University, Chicago, Ill. “This study provides some hope for those patients with currently untreatable angina to be more active with less pain.”

As a phase 2 study this program indicates how this strategy can be executed on a large scale at sites across the country. A program of this size has never been done in any stem cell cardiac study and is critically important if such a therapy is going to be effectively delivered. It also provides information about

appropriate endpoints regarding suitability and sample size of this therapy for a phase 3 efficacy study, the final study that will ultimately determine if the treatment works.

*Dr. Losordo will present the study “Randomized, Double-blind Placebo Controlled Phase 2 Study of Intramyocardial Injection of Autologous CD34+ Cells for Treatment of Refractory Angina” on Saturday, March 28 at 12:00 p.m. in the Chapin Theater Room W320.*

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The American of Cardiology’s Innovation in Intervention: i2 Summit 2009 features the latest in interventional science and is the leading forum and exposition for interventional cardiology. A platform for the world’s leading interventional cardiologists to share knowledge, discuss new ideas and discover new innovations, the i2 Summit 2009, in partnership with the Cardiovascular Research Foundation, is being held in conjunction with ACC.09, the American College of Cardiology’s 58<sup>th</sup> annual scientific meeting. The American College of Cardiology ([www.acc.org](http://www.acc.org)) works to influence health care policy and represents the majority of board certified cardiovascular care specialists through education, research, promotion, and the development and application of standards and guidelines.