Acute Myocardial Infarction from the Cardiovascular Cell Therapy Research Intracoronary Stem Cell Delivery Two to Three Weeks Following failure. B167 gene therapy is highly effective as new therapy for non-ischemic heart approach in an established animal model of heart failure, support that VEGF-

These results, obtained with a clinical applicable interventional the known anti-apoptotic capacity in the treatment group. 

Conclusions: These results, obtained with a clinical applicable interventional approach in an established animal model of heart failure, support that VEGF-B167 gene therapy is highly effective as new therapy for non-ischemic heart failure.

TCT-823 Results from LateTIME: A Randomized, Placebo Controlled Trial of Intracoronary Stem Cell Delivery Two to Three Weeks Following Acute Myocardial Infarction from the Cardiovascular Cell Therapy Research Network

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Background: Meta-analysis suggest that intracoronary (IC) administration of autologous bone marrow mononuclear cells (BMCs) delivered early after acute myocardial infarction (MI) may improve left ventricular (LV) function. However, many patients early post MI are unstable or present to sites without cell delivery capabilities, and it is unknown if changes in the myocardium or bone marrow will alter the homing and engraftment of BMCs when delivered several weeks post-MI. LateTIME was a randomized, double-blind, placebo-controlled trial sponsored by the National Heart, Lung and Blood Institute (NHLBI) and CCTRN to investigate the possible effects of VEGF-B gene therapy were tested in 23 chronically instrumented dogs with tachypacing-induced dilated cardiomyopathy. 

The porcine 10% coronary overstretch model was employed for analysis of lateTIME trial. Five (5) domestic swine were enrolled in this study. Through a left thoracotomy, the shaft of the MitraSpacer (Cardiosolutions, Inc.) is a novel approach to address mitral regurgitation by introducing a dynamic spacer with characteristics that constantly adjust to the instantaneous hemodynamics of the mitral apparatus and left atrium (LA). The purpose of this study was to evaluate the safety of the MitraSpacerTM within the mitral valve apparatus in the domestic swine model. 

Methods: Five (5) domestic swine were enrolled in this study. Through a left thoracotomy, the shaft of the MitraSpacerTM was introduced through the left ventricular (LV) apex and advanced in to the left atrium avoiding the chordae tendineae. Once the device was in place, the balloon located in the distal portion of the shaft was partially filled with an imiprodine/saline mix introduced by a subcutaneous access port to the desired volume. After implantation, all animals were survived up to 90 days and heart and device were examined for further histological analysis. 

Results: Following implantation, device performance was assessed by fluoroscopy and echocardiography. The volume within the balloon shifted during the cardiac cycle in all cases following the direction of blood flow and applied pressure. All enrolled animals survived up to 90 days for terminal imaging and tissue harvest. Echo data showed no change in LV ejection fraction from baseline to 90 days, 60±4.7% and 61±7.3% respectively, and slight changes in LA and LV volumes consistent with the rate of growth of the animal over time. In addition, there were no observations of disruption in LV diastolic function, pulmonary vein inflow, or tricuspid regurgitation. The histological analysis demonstrated minimal impact to the mitral apparatus despite constant contact with the device, and no evidence of thromboembolism in the heart and peripheral organs.

Conclusions: In a healthy animal model, the long term placement of the MitraSpacerTM was feasible, maintained cardiac performance and caused no structural changes to the mitral apparatus over 90 days.