

## **FDA Approves Phase 1 Stem Cell Research Therapy For Congestive Heart Failure**

*By Cardiostem*

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*Myoblast cell therapy for congestive heart failure presented at american college of cardiology late breaking clinical trial session*

SAN DIEGO, CA (March 25, 2007) – Today, Nabil Dib, M.D., M.Sc., FACC, Director, Clinical Cardiovascular Cell Therapy, University of California, San Diego, Director of Cardiovascular Research of Catholic Health Care West's Chandler Regional and Mercy Gilbert Hospitals, Phoenix, AZ summarized a catheter delivery, safety study with myoblasts that is the culmination of several years of previous study assessing the safety of using muscle precursor cells (myoblasts) to treat severe congestive heart failure, a condition in which areas of the heart are failing because of the presence of scarred, inelastic tissue. The cells were taken from the legs of patients with congestive heart failure, cultured using a proprietary technique, and then transplanted into the scar tissue.

Dr. Dib's presentation, "First United States Randomized Controlled Trial Utilizing 3-Dimensional Guided, Catheter-based Delivery of Autologous Skeletal Myoblasts for Ischemic Cardiomyopathy: Feasibility, Safety, and Improvement in Cardiac Performance" took place at 11:15AM CST in the Ernest N. Morial Convention Center, New Orleans, LA as part of the American College of Cardiology's Innovation in Intervention: i2Summit "Innovation in Intervention": i2 Summit is an annual meeting for practicing cardiovascular interventionalists sponsored by the American College of Cardiology in partnership with the Society for Cardiovascular Angiography and Interventions. He reported that the administration of myoblasts by a minimally invasive, 3-D guided, injection catheter is safe and feasible, that the viability of the tissue resulting from these cellular transplants can be detected by NOGA electromechanical recording, that patients receiving cells experienced improvements in heart failure symptoms, and showed beneficial ventricular remodeling. The work advances the growing body of clinical data documenting the benefits of myoblast transplantation in heart failure patients and in removing concerns raised by early studies that myoblasts could increase potential for heart arrhythmias. Dr. Dib's presentation clearly showed that the patient's receiving myoblasts were at no greater risk for arrhythmia than were the corresponding control patients that did not receive cells.

The work presented represents the culmination of many years of pre-clinical research to perfect the delivery technique such that repeatable survival of cells in scar tissue within the heart can be obtained. Previous work from Dr. Dib and others had shown that injection of myoblasts into the heart muscle during open heart surgery was safe, feasible, and produced benefit in patients: this was measured not only by improvement in symptoms, but also by MRI measurements of heart dimensions, by PET scan measurement of new living tissue, and by measures of wall motion showing renewed contraction. However, these previous studies all had the limitation that the myoblasts had to be delivered during open heart surgery. Now, for the first time, 3-D guided catheter delivery of myoblasts has shown similar results. This now opens up a whole new realm of possibilities for the treatment of heart disease with myoblasts. It may be in the not too distant future that patients suffering from fatigue and shortness of breath due to heart failure will be able to undergo a myoblast injection one day, go home the next, and in the ensuing months begin to resume a more normal life, freer from previous limitations.

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