

## asx announcement

### **MESOBLAST - CEPHALON ALLIANCE HIGHLIGHTED AT JP MORGAN HEALTHCARE CONFERENCE**

**Melbourne, Australia: 12 January 2011:** The strategic alliance between regenerative medicine company, Mesoblast Limited (ASX: MSB; US OTC: MBLTY), and global biopharmaceutical company, Cephalon Inc. (Nasdaq: CEPH), was highlighted at the 29<sup>th</sup> annual JP Morgan Healthcare Conference in San Francisco yesterday.

Cephalon CEO J. Kevin Buchi focused on the companies' strategy to develop and commercialize Mesoblast's Mesenchymal Precursor Cell (MPC) therapeutics for degenerative conditions of the cardiovascular and central nervous systems as well as for hematopoietic stem cell transplantation in cancer patients.

Mr Buchi told the conference that the alliance with Mesoblast provided Cephalon with "a cutting-edge entry into regenerative medicine."

"It is an opportunity to deliver a profoundly beneficial treatment to patients with high unmet medical needs with a product that we believe has solid intellectual property and a long life cycle."

Following is a copy of the slides focusing on the most recent clinical results from Mesoblast's cardiovascular and bone marrow transplant trials.

#### **About Mesoblast Limited**

Mesoblast Limited (ASX: MSB; OTC ADR: MBLTY) is a world leader in the development, manufacture, and commercialization of biologic products for the broad field of regenerative medicine. Mesoblast has the worldwide exclusive rights to a series of patents and technologies developed over more than 10 years relating to the identification, extraction, culture and uses of adult Mesenchymal Precursor Cells (MPCs). More information - [www.mesoblast.com](http://www.mesoblast.com)

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# 29th Annual J.P. Morgan Healthcare Conference

January 10-12, 2011

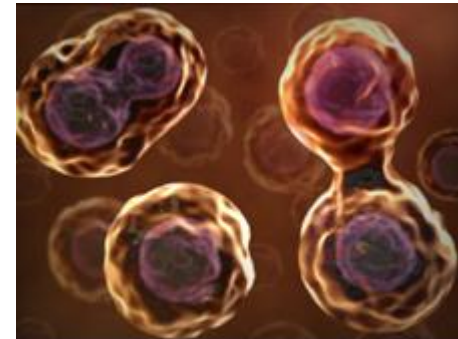
# Safe Harbor Statement

This presentation contains forward-looking statements that involve risks and uncertainties. These statements may concern, among other things, our business strategy and market opportunities, the development of pharmaceutical products, and future financial and operating results.

Additional information that may affect our business and financial prospects, as well as factors that would cause our actual performance to vary from our expectations, may be found in our filings with the Securities and Exchange Commission.

# Mesenchymal Precursor Cell (MPC) License From Mesoblast Limited

**MPCs produce cytokines and/or growth factors that induce endogenous tissue repair or cell proliferation**



**Promising early data with:**

- Congestive Heart Failure – phase 2**
- Myocardial Infarction – pre-clinical**
- Bone marrow transplant (cord blood expansion) – phase 2**

***Single Intra-Myocardial Injection Of Allogeneic MPC For  
Long-Term Treatment of Congestive Heart Failure***

## ***Phase 2a Congestive Heart Failure (CHF) Clinical Trial***

- **60 patient multi-center, randomized, controlled trial**
- **Class II-IV CHF with EF < 40%**
- **Randomized 3:1 controls to MPC at 25 M, 75 M, or 150 M cell doses**
- **Cells injected by JNJ NOGA Myostar™ catheter**
  
- **Primary endpoint of safety already met:**
  - no adverse events associated with MPC at any dose**
  
- **Secondary endpoints evaluate effects of MPC on**
  - (a) cardiac/heart failure hospitalization events over time**
  - (b) cardiac-related mortality over time**
  - (c) cardiac functional parameters after patients complete 12 months**

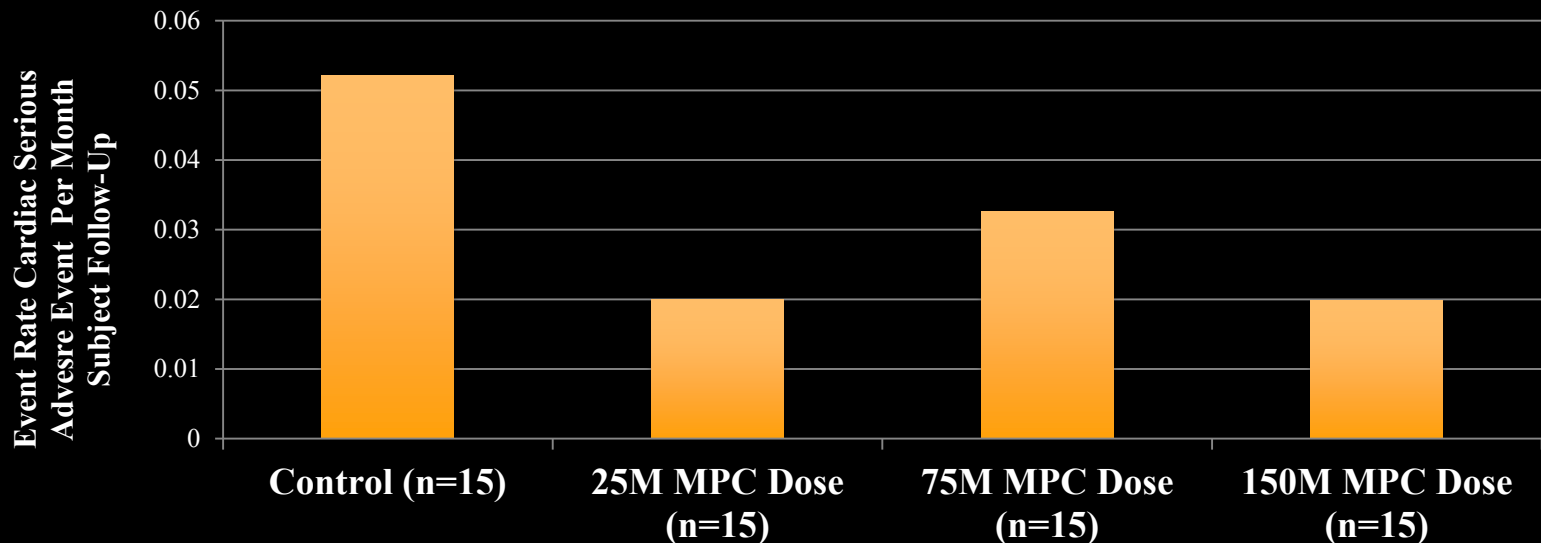
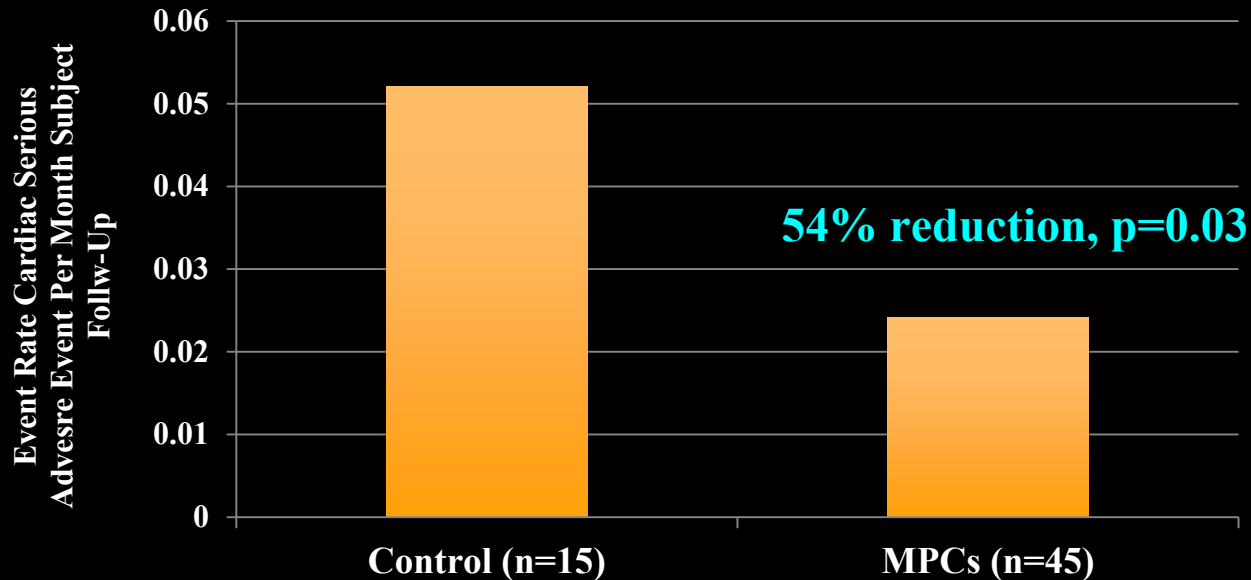
## ***Over 1.5 Years Study Follow-Up, MPC Treated Patients Had Fewer Cardiac-Related Events, Hospitalizations, And Deaths Than Controls***

<b>Event</b>	<b>MPC treatment (N=45) No. patients with event (%)</b>	<b>Controls (N=15) No. patients with event (%)</b>	<b>p value</b>
<b>Any Serious Adverse Cardiac Event (SAE)</b>	<b>20 (44.4%)</b>	<b>14 (93.3%)</b>	<b>0.001</b>
<b>Repeat SAEs</b>	<b>5 (11.1%)</b>	<b>5 (33.3%)</b>	<b>0.102</b>
<b>Any Hospitalization For Heart Failure</b>	<b>5 (11.1%)</b>	<b>3 (20.0%)</b>	<b>0.4</b>
<b>All Cause Deaths</b>	<b>2 (4.4%)</b>	<b>2 (13.3%)</b>	<b>0.26</b>
<b>Cardiac Deaths</b>	<b>0 (0.0%)</b>	<b>2 (13.3%)</b>	<b>0.059</b>
<b>Any Major Adverse Cardiac Event (MACE*)</b>	<b>3 (6.7%)</b>	<b>6 (40%)</b>	<b>0.005</b>
<b>MACE or Any Hospitalization for Heart Failure</b>	<b>6 (13.3%)</b>	<b>6 (40%)</b>	<b>0.056</b>

**Interim data analysis December 2010, after all patients have reached 6 months follow-up**

**\*MACE defined as composite of MI, revascularization, or cardiac death**

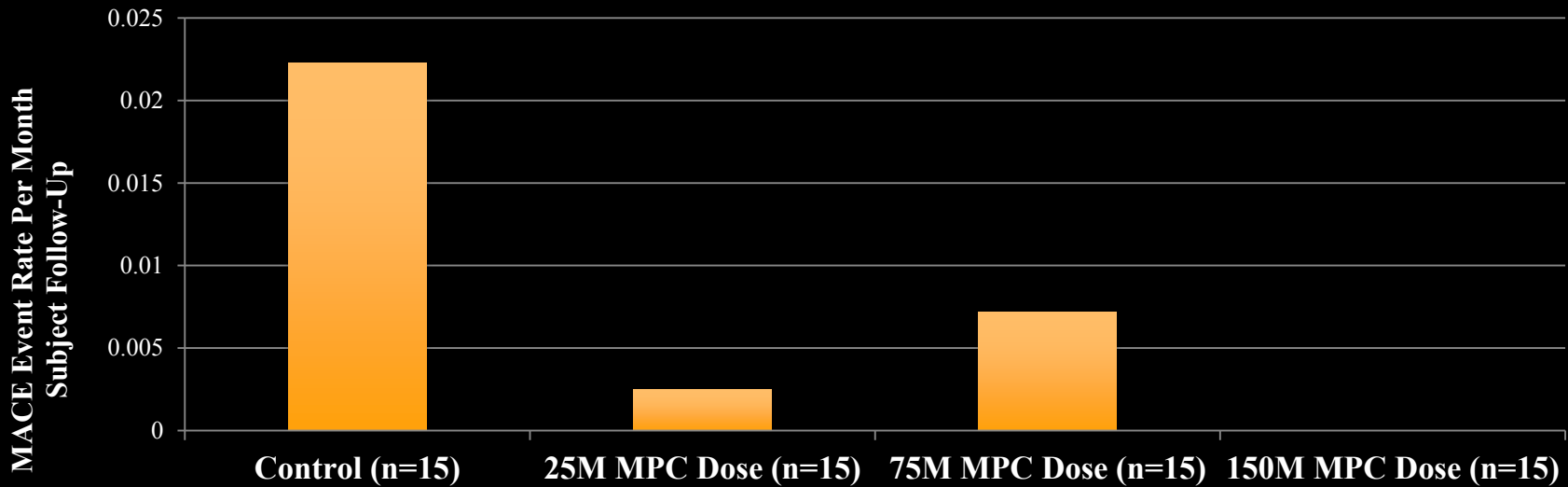
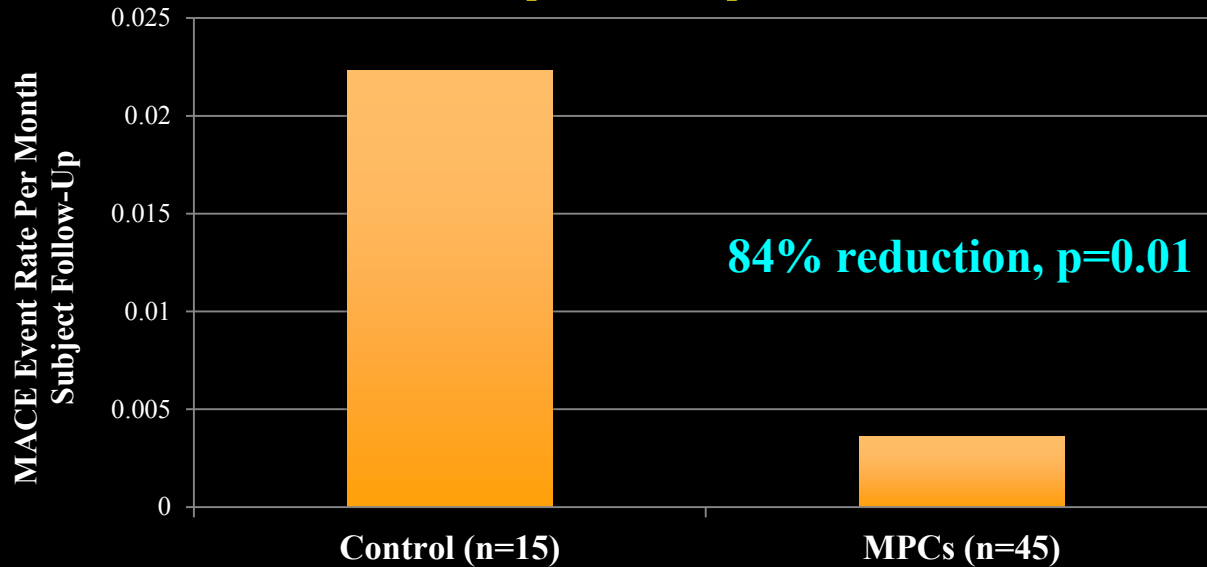
## ***MPC Treatment Lowers Rate Of Serious Adverse Cardiac Events Over Time***



MPC treated (n=45) followed for total 827.6 person-months  
 Controls (n=15) followed for total 268.5 person-months

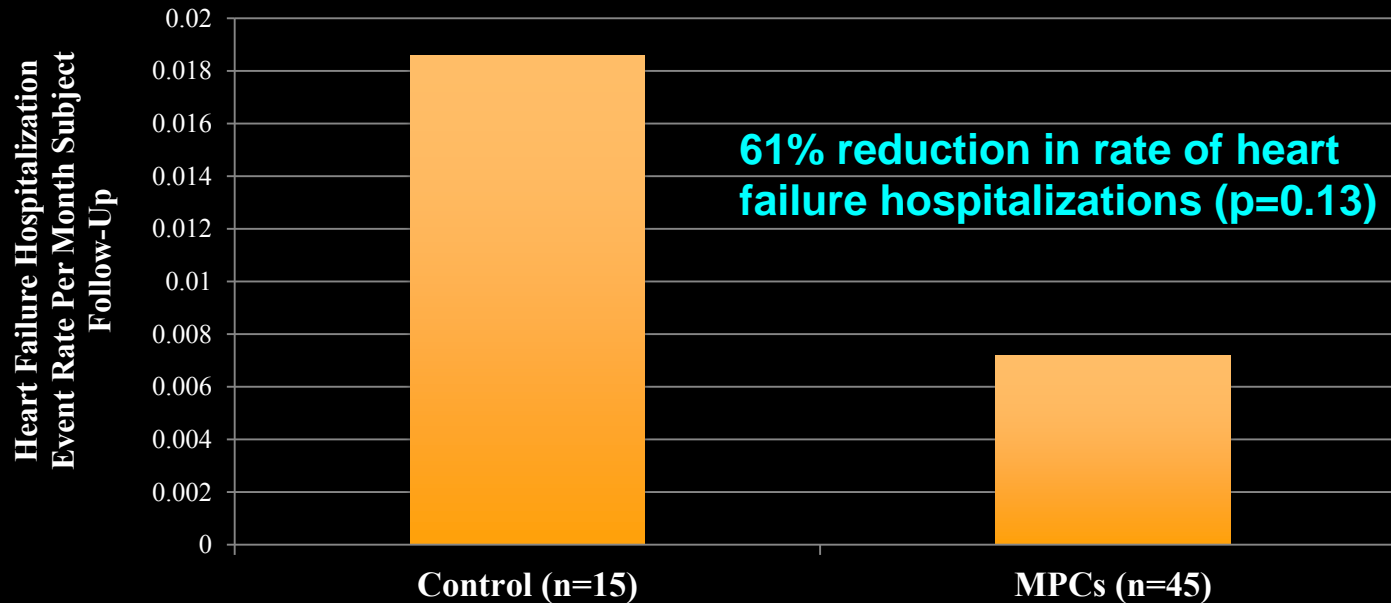
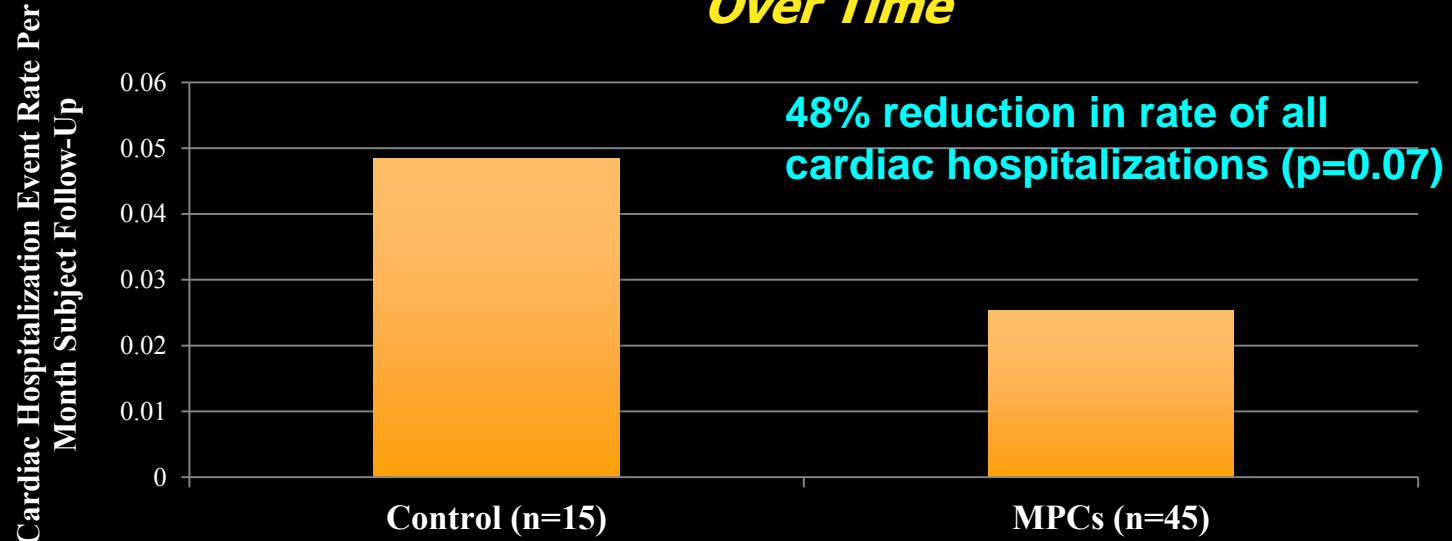


## ***MPC Treatment Lowers Rate Of Major Adverse Cardiac Events (MACE\*) Over Time***



- MACE defined as composite of MI, revascularization, or cardiac death
- MPC treated (n=45) followed for total 827.6 person-months
- Controls (n=15) followed for total 268.5 person-months

## ***MPC Treatment Lowers Rate Of All Cardiac-Related And Heart Failure Hospitalizations Over Time***



MPC treated (n=45) followed for total 827.6 person-months  
Controls (n=15) followed for total 268.5 person-months

## ***Conclusions***

### **Safety and Efficacy:**

- **Intra-myocardial injection of allogeneic MPC is safe in patients with advanced congestive heart failure**
- **No cell-related adverse events seen at any dose tested**
- **Interim analyses indicate that MPC treatment significantly reduces rate of major adverse cardiac events, cardiac-related hospitalization, and mortality over time**
- **Lowest MPC dose is at least as effective as higher doses tested**
- **Hard end-points achieved to date form basis for the key primary end-points for FDA Phase 3 trial in heart failure patients**

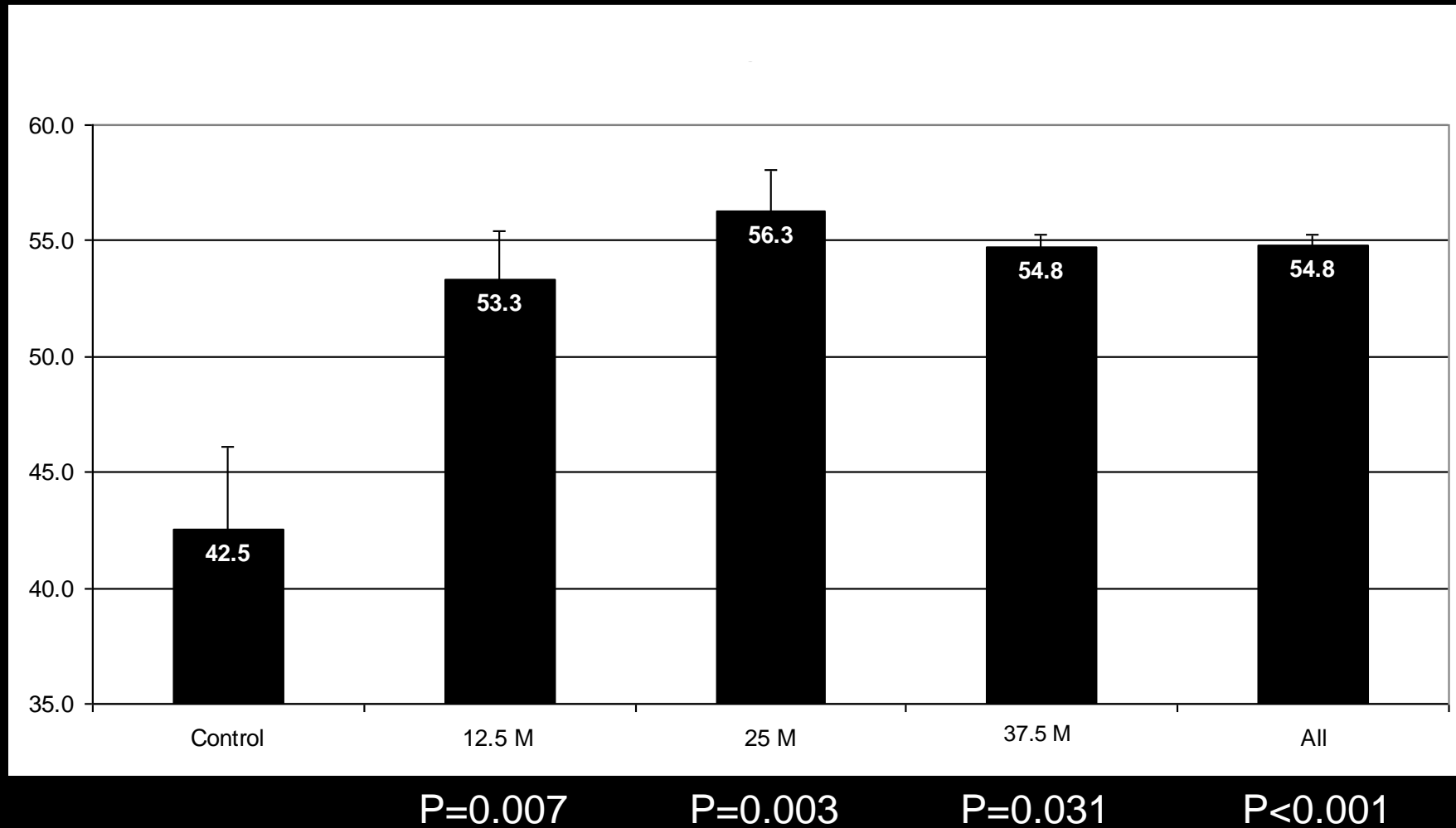
***Intra Coronary Allogeneic Mesenchymal Progenitor Cell  
(MPC) Transplantation In Myocardial Infarction in  
Sheep***

## ***Intra-Coronary Infusion Of Allogeneic Sheep MPC In Acute Myocardial Infarction***

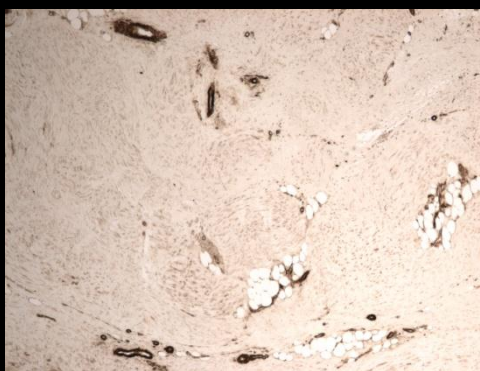
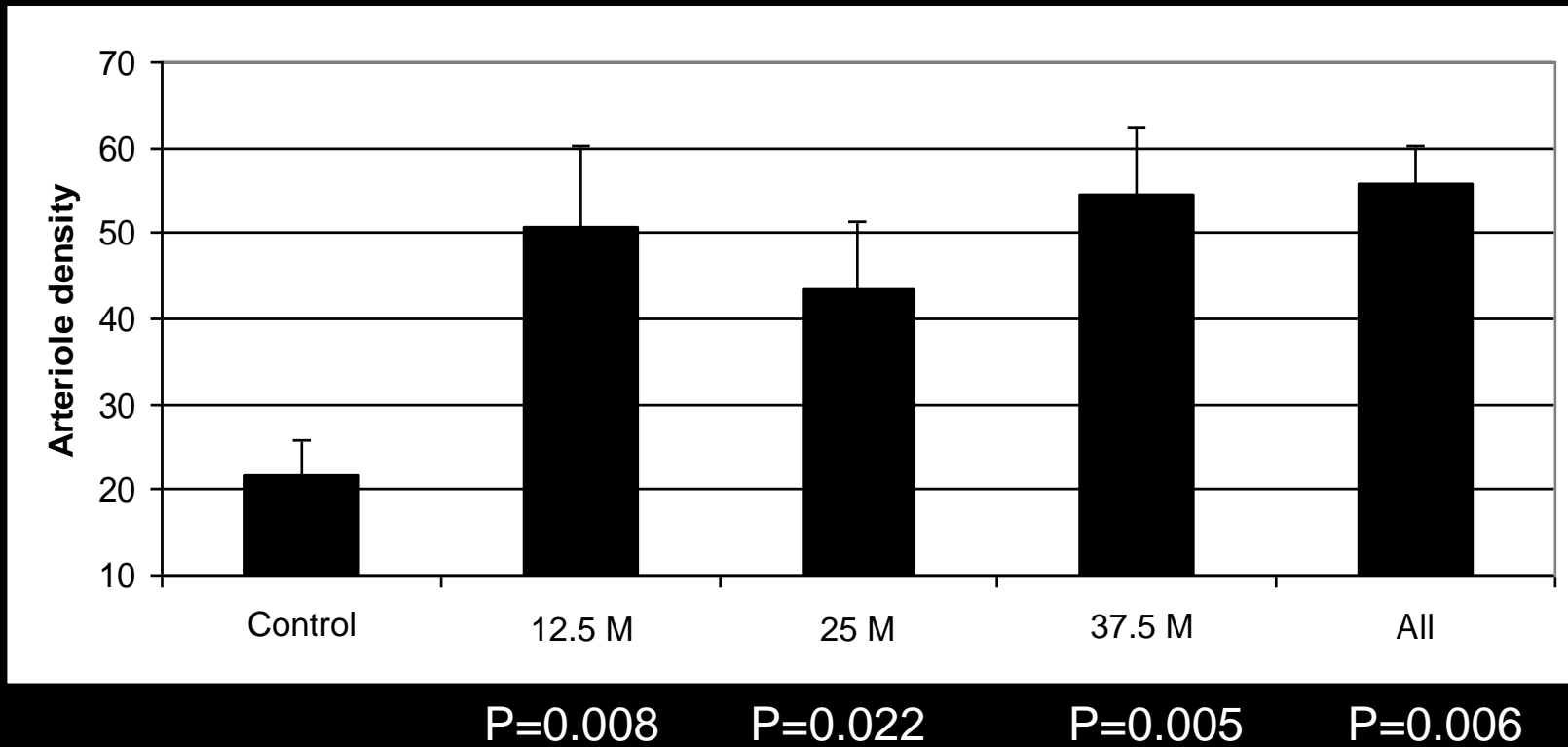
- **A total of 66 sheep**
- **Balloon occlusion 90 minutes / reperfusion  
(analogous to angioplasty + stent)**
- **30 animals survived the heart attack procedure and were included in analysis**
  - **10 control**
  - **7 received 12.5M MPC**
  - **7 received 25M MPC**
  - **6 received 37.5M MPC**
- **Normal TIMI 3 flow in all animals post cells (i.e. no reperfusion problems)**
- **4, 8 week analyses of ejection fraction, left ventricular volumes**
- **At sacrifice, histology for vascular density, collagen content**

# ***Ejection Fraction - Global LV function By PV Loop***

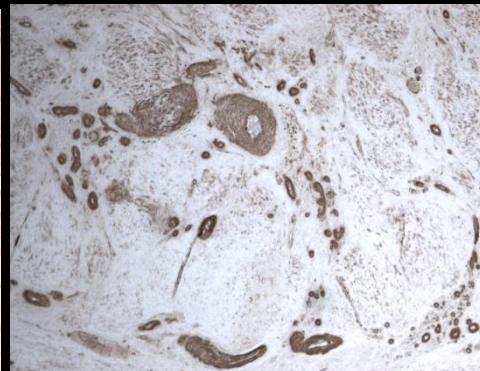
## ***Left Ventricular Ejection Fraction At 8 Week Follow Up***



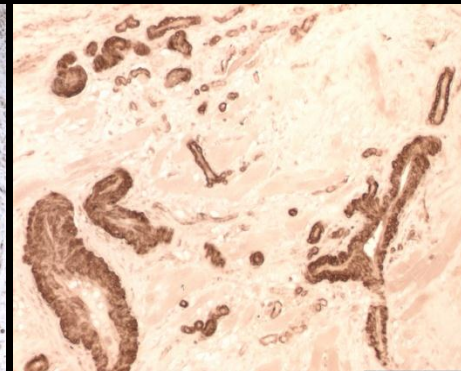
# Arteriolar Density Infarct Zone



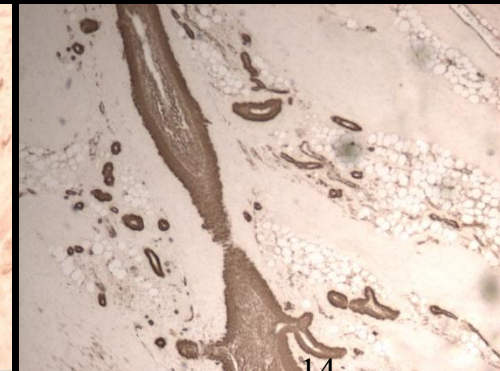
Control



12.5 M



25 M



37.5 M

## ***Conclusions***

### **Safety and Efficacy:**

- **Intra coronary allogeneic MPC infusion is safe and feasible in a large animal model of AMI and reperfusion**
- **No cell-related flow or arrhythmogenic effects seen**
- **MPCs significantly improve EF and ventricular volumes**
- **MPCs induce arteriogenesis**
- **MPCs reduce scarring and collagen replacement of heart muscle**



***Allogeneic MPCs Used As A Feeder Layer To Expand  
Cord Blood Hematopoietic Stem Cells For  
Transplantation***

# ***Results Of Double Cord Transplants Using MPC Expansion***

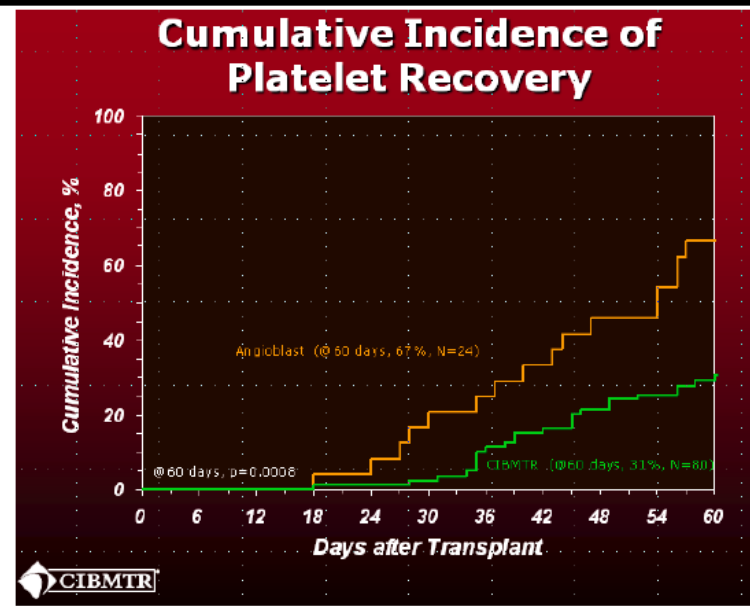
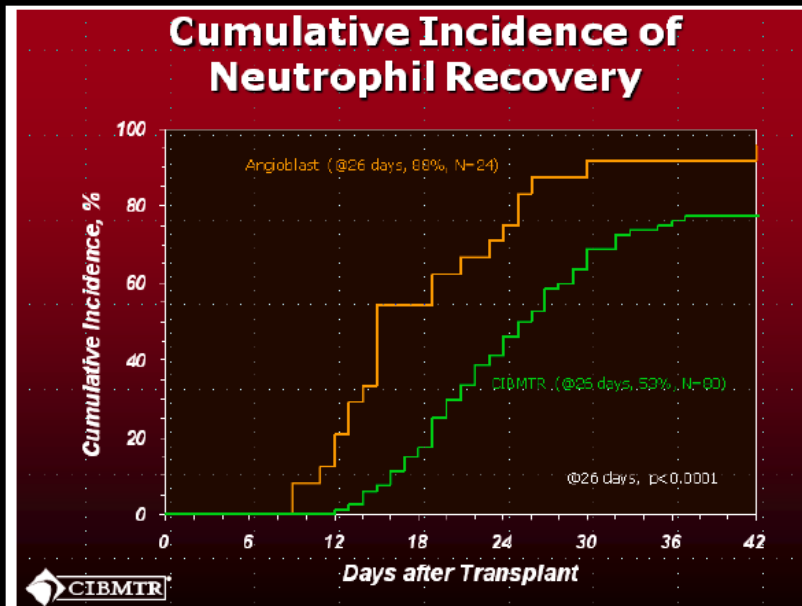
- **25 patients transplanted, under IND protocol**
- **Avg. age 40 yrs, all with myeloablative regimen for disease relapse**
- **Cord CD34+ HSC expanded >44-fold by co-culture with allogeneic MPC**
- **Median time to neutrophil engraftment 15 days**
- **Median time to platelet engraftment 54 days**
- **16% (4/25) patients have Grade III/IV GVHD**
- ***80% (20/25) patients engrafted neutrophils by day 26 and survived at 100 days***

***(compared with 46% non-expanded double cord,  
Brunstein et al Blood 2010)***

# Comparison Of Angioblast Results With CIBMTR Historical Controls 18

In 2008 and 2009 there were 596 non-expanded double cord transplants registered with the CIBMTR across 79 transplant centers.  
(300 with myeloablative conditioning regimens)

	Controls	MPC
Median neutrophil engraftment time	26 days	15 days
Median platelet engraftment time	>120 days	54 days
Neutrophil engraftment <26 days + alive at day 100	46%	84%



**Thank you!**

January 10-12, 2011