
mesoblast
the regenerative medicine company



2012 Half Year Results

27 February 2012

Forward looking statements

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This presentation, including any comments made during or following the presentation, may contain forward-looking statements that are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. These statements may relate to, but are not limited to: expectations regarding the safety or efficacy of, or potential applications for, Mesoblast's adult stem cell technologies; expectations regarding the strength of Mesoblast's intellectual property, the timeline for Mesoblast's regulatory approval process, and the scalability and efficiency of manufacturing processes; expectations about Mesoblast's ability to grow its business and statements regarding its relationships with Teva and Lonza and future benefits of those relationships; statements concerning Mesoblast's share price or potential market capitalization; and statements concerning Mesoblast's capital requirements and ability to raise future capital, among others. Actual results may differ from the results anticipated in these forward-looking statements, and the differences may be material and adverse. Factors and risks that may cause Mesoblast's actual results, performance or achievements to be materially different from those which may be expressed or implied by such statements, include, without limitation: risks inherent in the development and commercialization of potential products; uncertainty of clinical trial results or regulatory approvals or clearances; government regulation; the need for future capital; dependence upon collaborators; and protection of our intellectual property rights, among others. Accordingly, you should not place undue reliance on these forward-looking statements.

Financial review

Brian Jamieson, Non-Executive Chairman



6 month financials – key points

- **Cash:**
 - strong cash position (\$241m) to support future product development

- **Revenue:**
 - includes ongoing allocation of upfront payment received from Teva
 - prior period includes “one off” accounting gain on acquisition of Angioblast Systems

- **Expenses:**
 - includes full 6 months of US operations (prior period only 1 month)
 - significant investment in organizational structure for expanded global operations
 - strengthened expertise in clinical, regulatory, manufacturing and quality assurance
 - increased clinical trial costs associated with expanded programs
 - expanded preclinical programs to accelerate and broaden product offerings
 - increased investment in manufacturing to support Phase 3 trials and commercial rollout, new clinical applications, and to deliver reduced COGs

6 month financials (A\$m)

	Half-year 2011	Half-year 2010
Revenue from continuing operations	18.7	2.3
Other income	0.3	101.6
	19.0	103.9
Research & development expense	22.8	3.6
Management & administration expense	13.8	5.7
Share of losses of equity accounted associate	-	1.5
	36.6	10.8
Profit/(loss) before income tax	(17.6)	93.1
Income tax expense	(26.5)	-
Profit/(loss) for period	(44.1)	93.1

Business overview

Silviu Itescu, Chief Executive



Building a successful biologics life sciences company by understanding and managing corporate risk

- Proprietary platform technology delivers multi-product pipeline
 - multiple shots on goal
 - not dependent on success of any one product
 - enables sequenced development to adjust for greater risk/reward
- corporate partnerships manage execution risk
 - Teva provides global distribution capability, regulatory and clinical trial experience
 - Teva Phase 3 funding alleviates internal cash burn
 - Lonza provides best-in-breed process development & manufacturing capability, alleviates need for internal spend on manufacturing facility
- strong cash position (\$241m) enables simultaneous development of multiple products
 - Mesoblast has sufficient cash to advance new programs in parallel
 - investment in people with expertise in clinical/regulatory development

Our unique adult stem cells

- immunoselected, purified adult mesenchymal precursor cells
 - no ethical or safety issues associated with embryonic stem cells
 - robust global patent portfolio
 - Stro-1 expression defines earliest, most potent precursor of mesenchymal lineage
- easy to expand in large numbers
 - low cost of goods, no supply constraints
 - high margin business model
- non-immunogenic, can be used from one donor for many recipients
 - “off the shelf”, classic pharmaceutical drug model
 - batch to batch consistency
 - clear, rapid regulatory pathway
 - excellent safety profile across all indications

Teva strategic alliance

- Teva has exclusive worldwide commercialization rights to selected cardiovascular and neurologic indications, holds 19.9% stake in Mesoblast
- Teva responsible for funding Phase 2b and Phase 3 clinical development
- Mesoblast retains all manufacturing rights, sells finished product to Teva on transfer price basis
- Mesoblast eligible to receive up to US\$1.7 billion in milestone payments
- Mesoblast cash balance of \$241 million to fund other major indications including
 - type 2 diabetes
 - inflammatory diseases of various tissues (eg lungs)
 - immunologic conditions (eg rheumatoid arthritis)
 - ophthalmic indications
 - orthopedic cartilage and bone conditions

Lonza manufacturing alliance is central to profitability

State-of-the-art manufacturing plant via strategic alliance with Lonza

- Lonza will supply clinical and long-term commercial MPC product needs globally
- Lonza to construct a purpose-built manufacturing facility exclusively for Mesoblast
- Mesoblast can buy out this facility at a pre-agreed purchase price
- Mesoblast will have exclusive access to Lonza's cell therapy facilities in Singapore

Mesoblast retains control of manufacture for all products

- product delineation for distribution partners
- maintain optimal product pricing differences

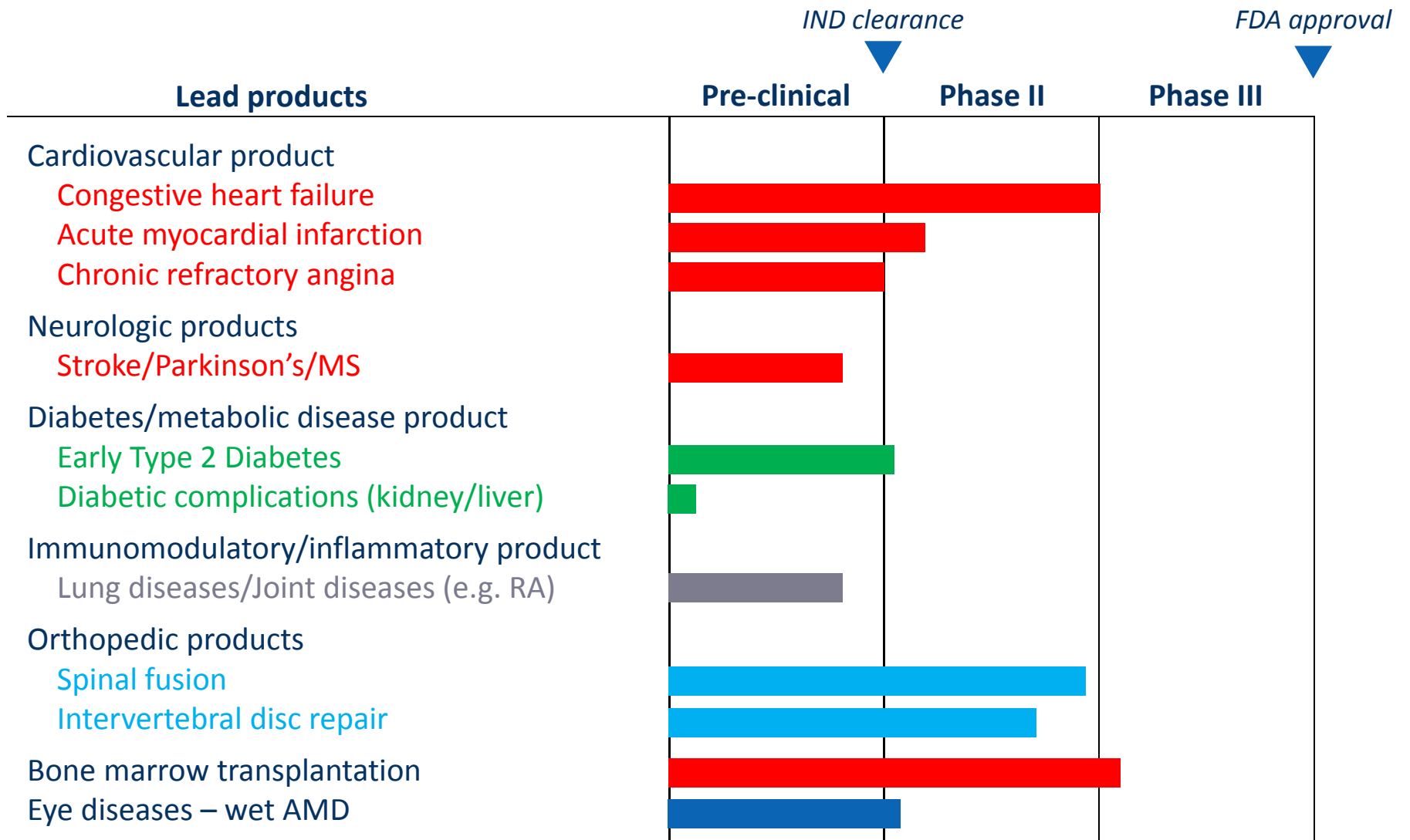
Commercial benefits

- reduced COGS, increased margins on sales price
- state-of-the-art, industrialized manufacturing process
 - R&D support for enhanced second generation products
 - leverage new technologies

Program Update



“Off-the-shelf” product franchises driving value creation



Congestive heart failure – positive results presented at American Heart Association 2011 Annual Meeting

“In general, Phase 3 studies should use endpoints such as mortality and cardiovascular or heart failure hospitalizations, whereas endpoints, such as ejection fraction, that have not been validated as surrogates for clinical outcome are not considered to be acceptable as primary efficacy endpoints for pivotal trials.”

*US FDA, Guidance for Industry, Cellular Therapy for Cardiac Disease
October 2010*

- Major Adverse Cardiac Events (MACE) significantly reduced in MPC-treated patients over mean 22 month follow-up ($p=0.036$). MACE is composite of mortality/heart attacks/revascularization
- MACE risk over time reduced by 78% in MPC-treated patients vs controls ($p=0.011$), with 60-90% risk reduction at every MPC dose
- cardiac mortality significantly reduced in MPC-treated patients compared with controls over mean 22 month follow-up (2% vs 20%, $p=0.02$)
- highest dose of Revascor™ completely prevented any deaths or episodes of heart failure hospitalization over 18 months of follow-up
- highest dose showed evidence of remodeling (reduction in heart volumes) and improvement in functional capacity (increased walking distance), which are key parameters in congestive heart failure

Based on these results, Teva and Mesoblast are moving forward with Phase 3 trial of high dose Revascor™ in heart failure patients.

Intravenous product franchise

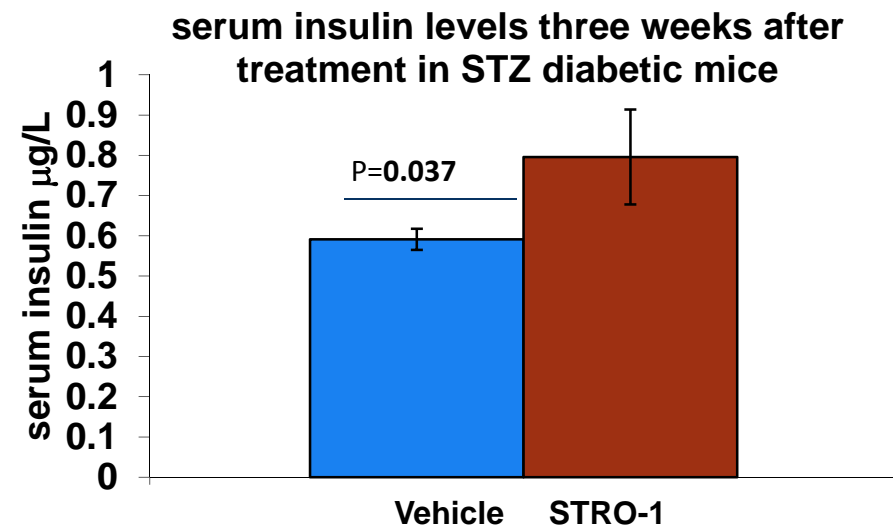
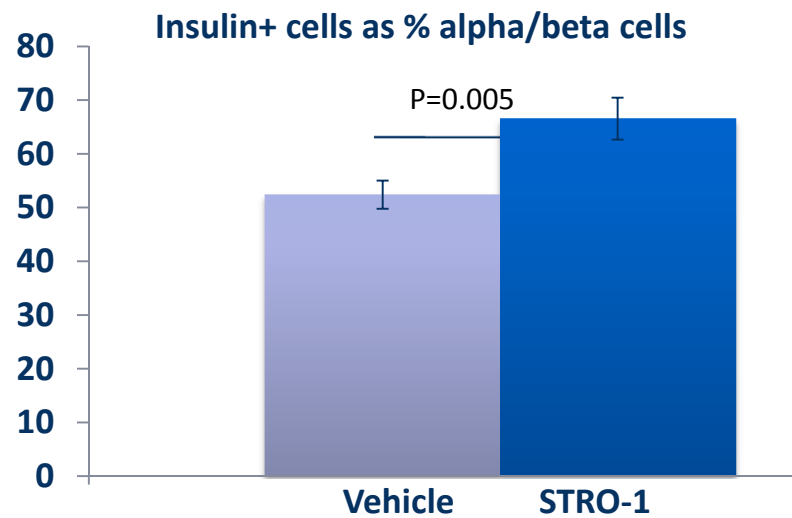
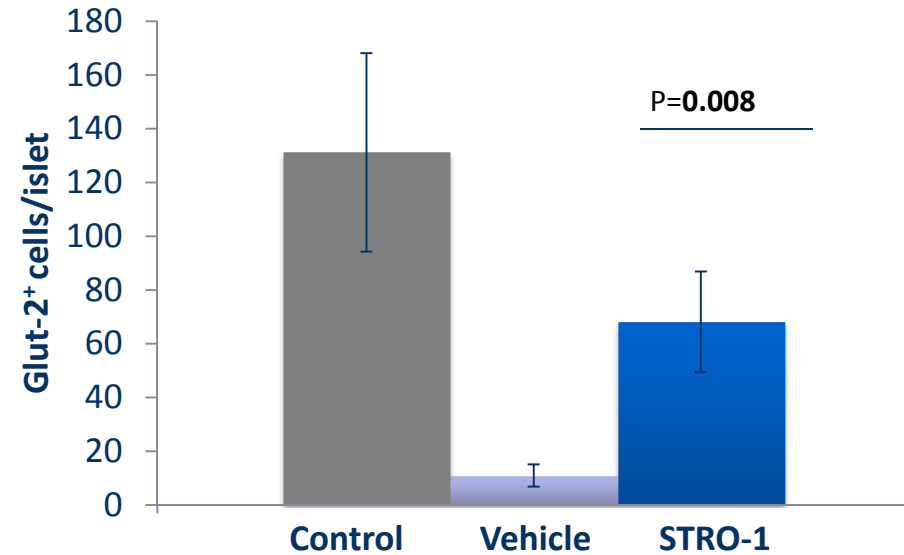
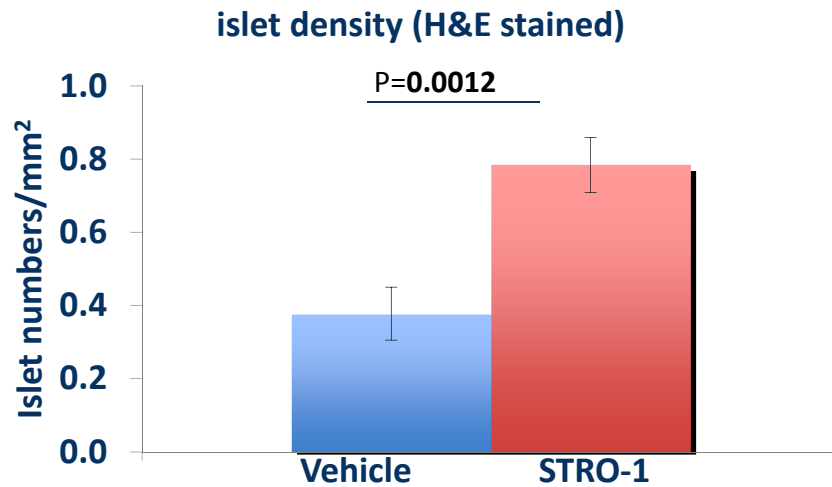
- High value products using systemic administration
- Multiple applications:
 - Type 2 diabetes, and its complications (renal, liver, cardiac)
 - Lung diseases (e.g. inflammatory conditions, asthma)
 - Inflammatory joint diseases e.g. (rheumatoid arthritis)
 - Neurological diseases (e.g. stroke, multiple sclerosis)
- Compelling, highly predictive preclinical data being generated in each area to support early commencement of Phase 2 human trials
- Safety data from first Phase 2 human trials using IV delivery (e.g. diabetes) will be leveraged across other applications

Allogeneic MPCs For Treatment Of Type 2 Diabetes

■ Postulated Mechanisms of Action

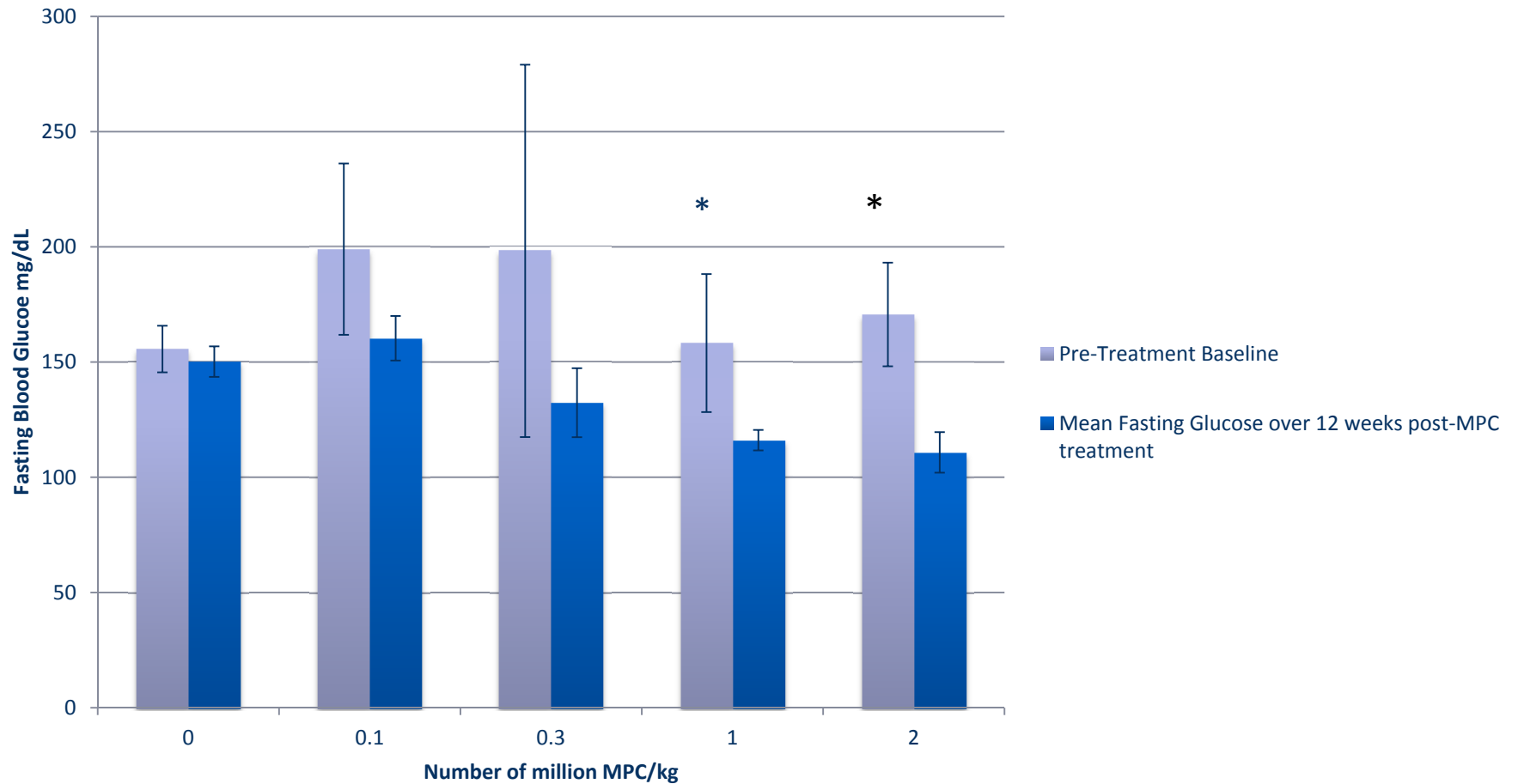
- anti-inflammatory effects systemically (reduce CRP, IL-1)
- pancreas as target (directly via homing or indirectly via secretion of factors)
- peripheral endocrine organs as targets (e.g. bones, adipose tissues)
- restoration of normal pancreatic sensing of high glucose levels
- restoration of normal pancreatic insulin secretion

Human Stro-1+ MPC Increase Islet Numbers, Increase Glucose Sensing Beta Cells, and Restore insulin Production In Mouse islets Damaged by STZ



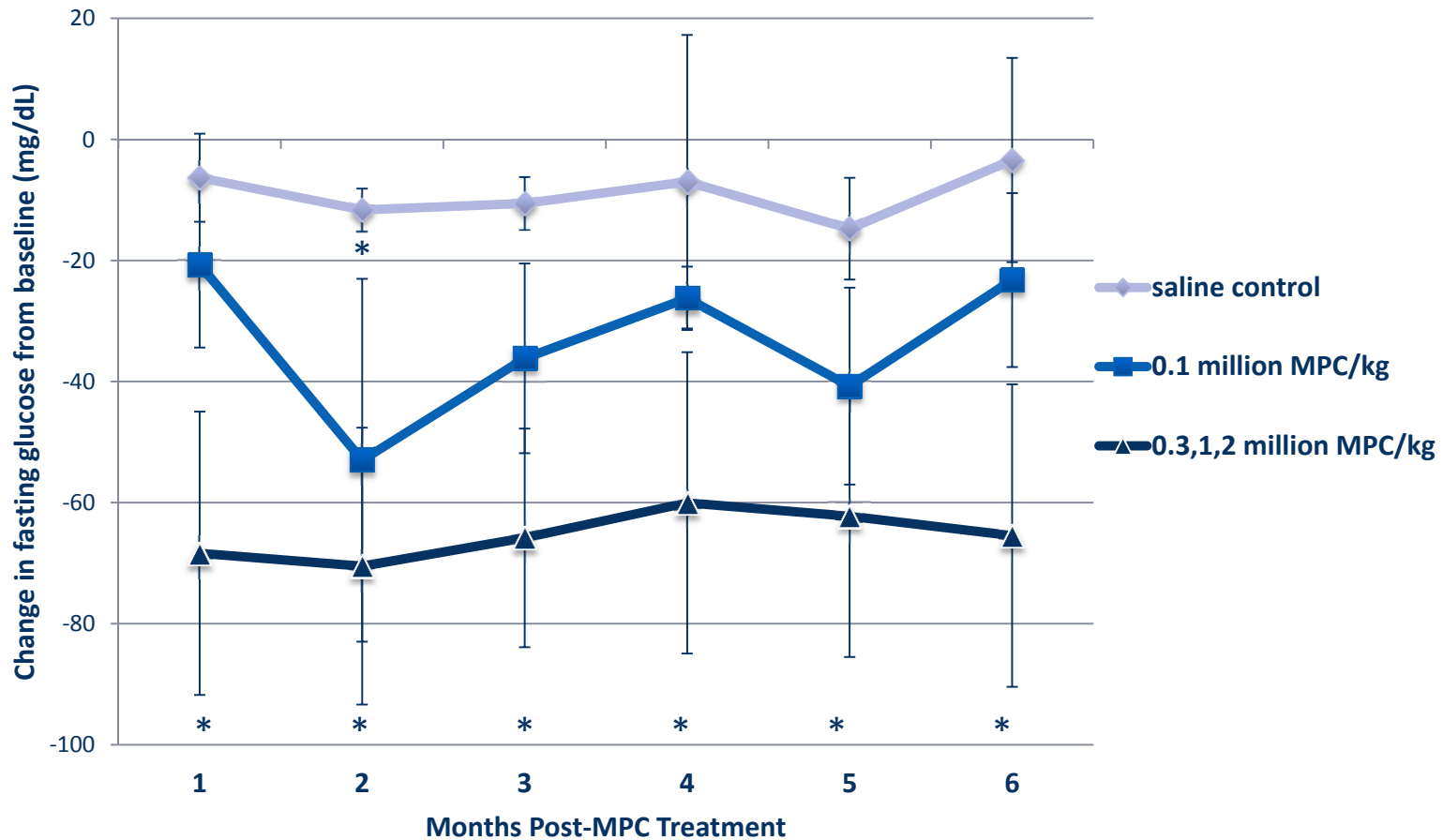
Allogeneic MPC In Obese Non-Human Primates With Type 2 Diabetes

Single Intravenous MPC Injection Causes Dose-Dependent Glucose Reduction Over 3 Months



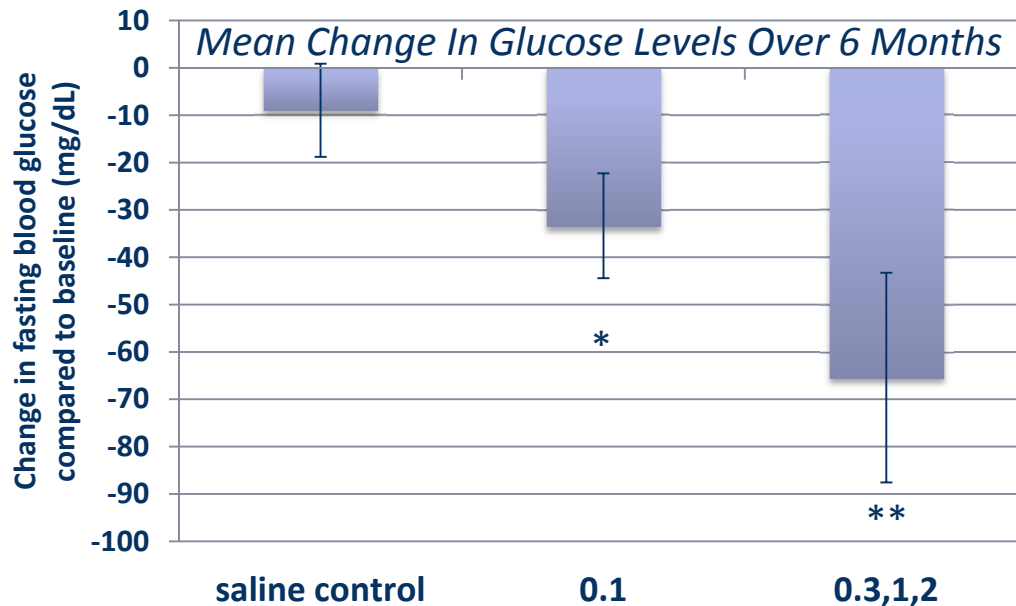
* Significant at $P < 0.05$ compared to respective baseline

A Single IV Dose of 0.3, 1, or 2 Million MPC/Kg Maintains Reduced Glucose Levels For 6 Months In Obese Cynomolgous Monkeys With Type 2 Diabetes



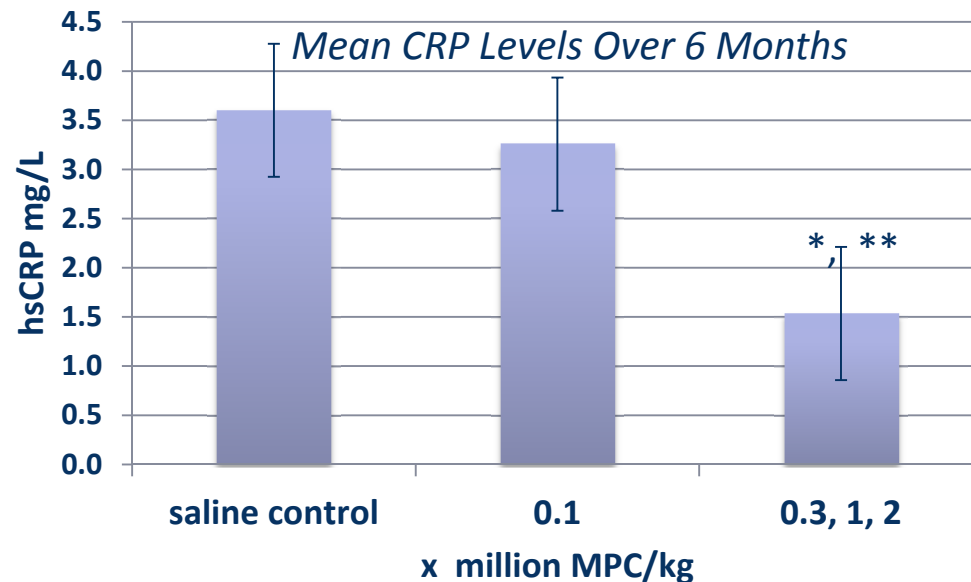
* $p < 0.05$ compared to saline control at each month

Single IV Dose [0.3, 1 or 2 million] MPC/kg Reduces Glucose, CRP Levels For 6 Months



* 0.1 million MPC/kg vs saline controls: $p=0.05$

** [0.3,1, or 2 million] MPC/kg vs saline controls: $p=0.05$



NB: CRP > 3mg/L is a major risk factor for heart attack and death in Type 2 diabetics

* [0.3,1, or 2 million] MPC/kg vs saline controls: $p=0.002$

** [0.3,1, or 2 million] MPC/kg vs 0.1 million MPC/kg: $p=0.016$

Clinical Program In Type 2 Diabetes

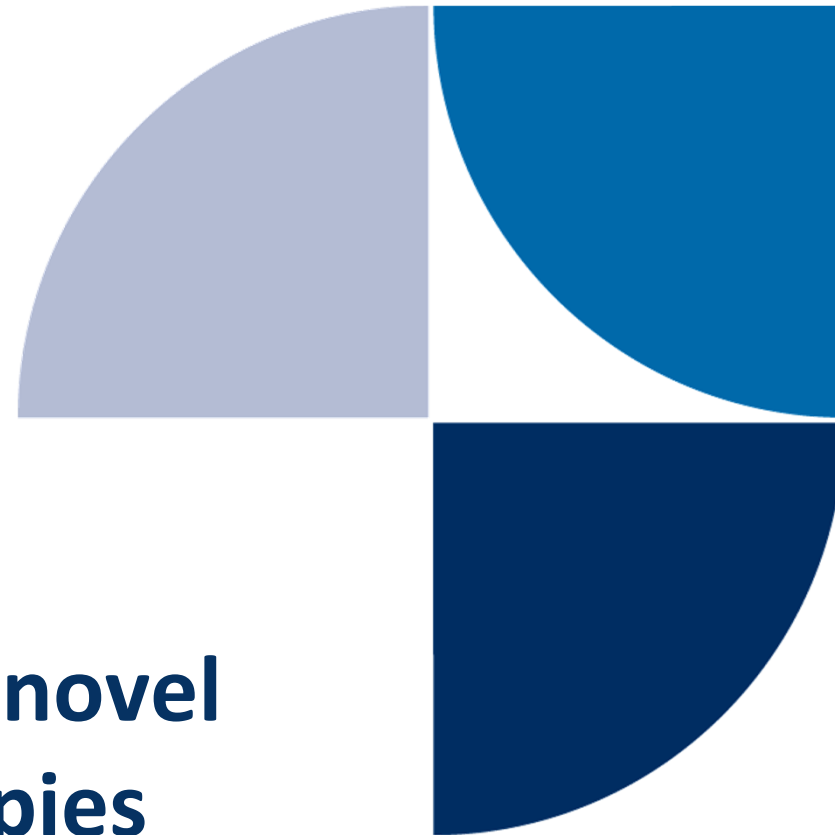
- Non-human primate data show sustained 6-month durability of glucose lowering effect by single intravenous injection of allogeneic MPC at 0.3, 1 or 2 million MPC/kg;
- Accompanying sustained reductions in CRP levels suggest a potential cardioprotective effect of the MPC
- Based on pre-clinical studies, Mesoblast received FDA clearance to begin randomized, placebo controlled Phase 2 clinical trial in 60 patients with Type 2 Diabetes
- Primary endpoint safety and tolerability, secondary endpoints to confirm glucose lowering effects of a single intravenous injection of 0.3, 1 or 2 million MPC/kg over 12 week study period
- Plan to progress to clinical trials in patients with Type 2 Diabetes with renal complications and high risk of death from cardiovascular causes

Value inflexion points – near term

- Teva + Mesoblast to commence Phase 3 trial for congestive heart failure
- completion of Phase 2 spinal fusion trials
- completion of Phase 2 disc repair trial
- interim Phase 2 diabetes data
- expanding the intravenous product franchise, e.g. lung diseases, RA
- further partnering opportunities, strategic initiatives – optimal timing

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**Leading the world in novel
adult stem cell therapies**
