mesoblast
the regenerative medicine company

Annual General Meeting

Melbourne
25 November 2014

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 Pharmaceutical Industries Ltd, JCR Pharmaceuticals Co., Ltd, 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.

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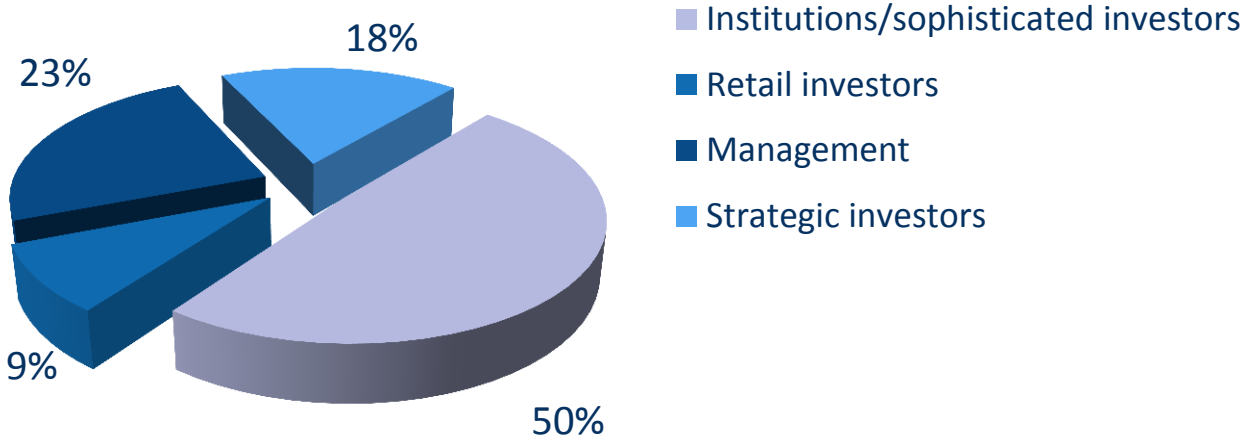
Shareholder value and ownership

Market valuation	
Issued shares (30 September 2014)	~321 million
Current share price (market close, 24 November 2014)	A$4.14
Market capitalization	~A$1.32 billion
Cash reserves (30 September 2014)	A$170.5 million

Shareholder ownership **(30 September 2014)**



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Significant achievements to date

- Successful translation of Mesenchymal Lineage Adult Stem Cell (MLC) based technology platforms for multiple indications
- Portfolio of allogeneic regenerative medicine product candidates, with ***five*** in Phase 3 trials/Phase 3 ready
- Well characterized mechanisms of action support clinical translation
- Established strategic partnerships to support development, manufacturing and commercialization of product candidates
- Large IP portfolio of ***>60 patent families*** which we believe provides long-term commercial protection for MLC based products and other complementary technologies
- Capital market support and strong balance sheet

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2014 FY highlights

- Commencement of Phase 3 trial of Mesenchymal Precursor Cell (MPC) product candidate MPC-150-IM in NYHA class II/III heart failure; actively recruiting across multiple North American sites
- NIH and MSB agree on 120 patient MPC-150-IM trial in advanced / NYHA class IV heart failure
- End of Phase 2 meeting with FDA supports advancing to MPC-06-ID Phase 3 trial in Chronic Discogenic Low Back Pain (CDLBP)
- Significantly expanded intellectual property portfolio of Mesenchymal Lineage Adult Stem Cell (MLC) technology through asset acquisition
- Pathway to accelerated US approval for GVHD has been clarified through discussions with the FDA
- Strategic relationship formed with Singapore Economic Development Board
- Positive Phase 2 CDLBP 12 month results presented at North American Spine Society Annual Meeting
- Positive type 2 diabetes trial results presented at 74th American Diabetes Association Annual Meeting ; results provide support for the ongoing diabetic kidney disease trial

New framework for expedited Japanese approval of regenerative medical products

Legislative framework*

- The Pharmaceuticals, Medical Devices and Other Therapeutic Products Act (PMD Act) takes effect 25 November 2014 in Japan
- Establishes a framework for expedited approval in Japan for regenerative medical products

Key takeaways for Mesoblast

- Conditional product approvals will be based on existing Phase 2 trial results demonstrating probable efficacy and safety with bridging studies in Japanese patients
- Conditional approvals will allow sales of each product candidate for up to 7 years
- Conditionally approved products will be covered by health insurance
- Conditional approvals will cover allogeneic cell therapy product candidates manufactured under GMP outside of Japan; and
- Full approval is expected to require further confirmation of safety and efficacy in a larger population.

With late-stage clinical product candidates in multiple indications, Mesoblast is well positioned to take advantage of this new legislative framework in Japan

*PMDA slide presentation - 5th Asian Cellular Therapy Organization Conference, Osaka; 9 November 2014

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Objectives and Strategy for Japan

Objectives

- To capitalize on clinical data generated to date, our strong intellectual property portfolio, and manufacturing know how for accelerated product regulatory approvals in Japan
- To generate nearer term revenues in the world's second most established healthcare market

Strategy

In order to achieve its corporate objectives in Japan, Mesoblast:

- Has completed prioritization of lead product candidates based on assessment of commercial opportunity and feasibility in Japan
- Will leverage existing Phase 2 clinical trial results for Tier 1 and Tier 2 product candidates
- Has engaged with product development and commercialization experts in Japan
- Has initiated dialog with the Japanese regulatory authority, the PMDA
- Is in active discussions with existing and potential commercialization partners for its product candidates in Japan

The PMD Act will enable Mesoblast to make its cell therapy product candidates available sooner to patients with unmet medical needs, and to achieve nearer term revenues in Japan ahead of other jurisdictions

Our competitive strengths

1. Disruptive technology platform
2. Broad portfolio of distinct late-stage product candidates
3. Scalable manufacturing capabilities
4. Intellectual property leadership
5. Strategic alliances
6. Experienced management team

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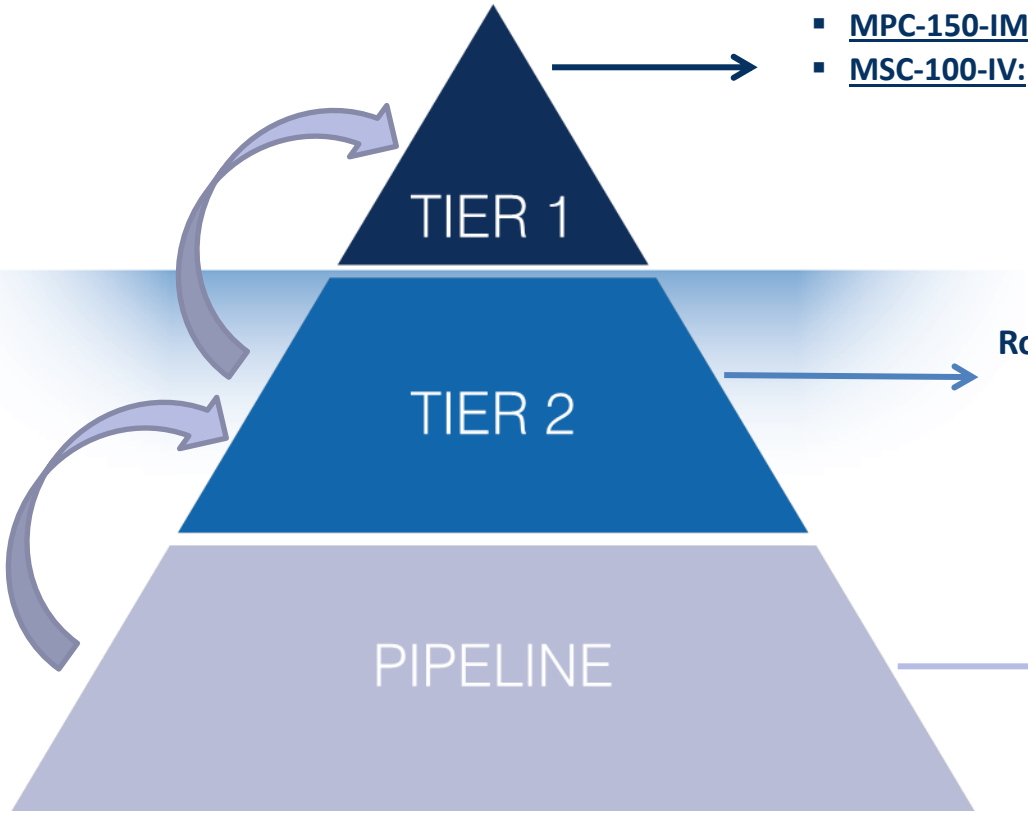
1. Disruptive technology platform

- Mesenchymal Lineage Adult Stem Cell (MLCs) technology platform
  - Highly purified, immunoselected Stro-1/Stro-3 positive Mesenchymal Precursor Cells (MPCs), earliest precursors
  - Culture-expanded Mesenchymal Stem Cells (MSCs), progeny of earliest precursors
  - Diverse source (bone marrow, adipose, dental pulp)
  - Product lifecycle extension developing next generation 'modified' stem cell therapies

- MLCs are present around blood vessels in all tissues, where they can respond to signals associated with tissue damage. This response includes the secretion of a diverse variety of biomolecules that affect various reparative and immunomodulatory mechanisms responsible for maintaining tissue health.

- MLCs have two additional, distinct characteristics that, when combined with our proprietary manufacturing processes, enable allogeneic or "off-the-shelf" use of our product candidates.
  - large-scale culture expansion potential
  - immunomodulation

Focus on bringing late stage products to market



Products with mid term revenue opportunity

- **MPC-06-ID:** Chronic Discogenic Low Back Pain
- **MPC-150-IM:** Heart Failure
- **MSC-100-IV:** GVHD

Robust Development Portfolio

- Progressing to next decision point
- Targeted for partnership
- Capable of acceleration

Emerging Pipeline

- Early stage development and preclinical work

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2. Broad portfolio of distinct late-stage clinical product candidates

Product Candidates	Programs	Preclinical	Phase 2	Phase 3	Filed for approval
Tier I					
MPC-06-ID	■ Chronic Discogenic Low Back Pain (CDLBP)				
MPC-150-IM	■ Class II/III Congestive Heart Failure (CHF)				
	■ Class IV CHF				
MSC-100-IV	■ Acute steroid-refractory GVHD				
JR-031	■ Acute GVHD (Japan)				
Tier II					
MPC-300-IV	■ Diabetic kidney disease				
	■ Rheumatoid arthritis (biologic refractory)				
MPC-25-IC	■ Acute cardiac ischemia				
MPC-25-Osteo	■ Spinal fusion				
MSC-100-IV	■ Crohn's disease (biologic refractory)*				
MPC-CBE	■ Bone marrow transplant				

*An additional Phase 3 program will be necessary prior to BLA filling

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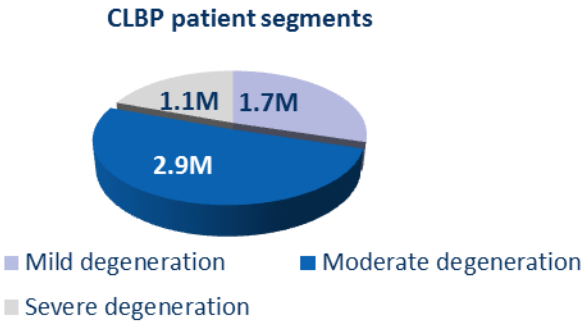
MPC-06-ID: Chronic Discogenic Low Back Pain (CDLBP) – Market opportunity

MPC-06-ID is in development for the treatment of chronic discogenic low back pain (CDLBP) lasting >6 months as a result of moderate degenerative intervertebral disc disease

Market opportunity

- Prevalent CLBP population in the US to grow to 21.9m patients by 2022 [1]
- 55% of CLBP population seek treatment [1]
- ~ 40% of patients with CLBP have a discogenic cause



Gap in treatment options

- For patients who fail conservative treatment (rest, analgesia), and epidural steroids, treatment options are limited to highly invasive therapies such as spinal fusion or artificial disc replacement
- Surgeons report that ~40% of patients ultimately fail back surgery [2]

Targeted physician population

- Specialists: Targeted physician audience & commercial footprint
  - Pain management specialists and anaesthesiologists
  - Orthopedic / spine surgeons

FDA approval for surgical therapies requires concomitant improvement in both pain and function

1.LEK & NCI opinion leader interviews, and secondary analysis
2. Shapiro CM Phys Med Rehabil Clin N Am 2014 Ostelo et al Spine Vol 33,no1.pp90-94

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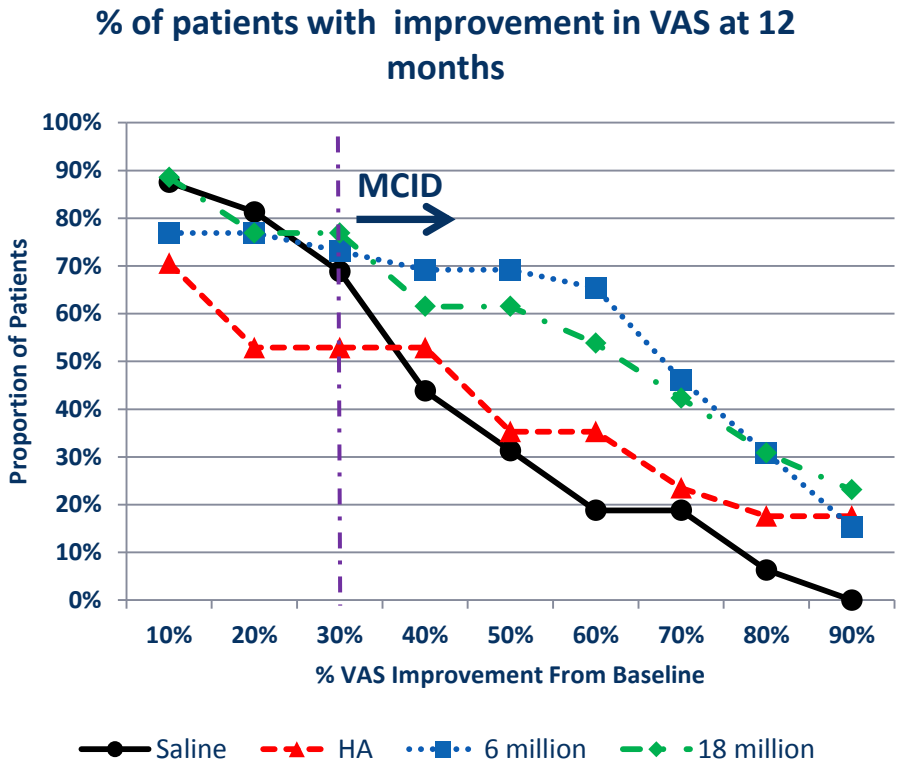
MPC-06-ID: CDLBP 12-month Phase 2 Results - MPCs show greater reduction in pain

Phase 2 trial: 100 patients with >6 months of discogenic low back pain failing other therapies were evaluated in a randomized, placebo controlled trial that compared saline, HA, HA + 6 million MPC, HA + 18 million MPCs injected into culprit painful disc



- Visual Analog Scale (VAS) is a standardized measure of pain scored from 0 -100 and was evaluated at 3 , 6 and 12 months
- Minimally clinical important difference (MCID) in VAS is defined as ≥30% improvement
- At 12 months, both 6 million MPC group and the 18 million MPC group had greater proportions of patients with VAS improvement ≥30% than either control group

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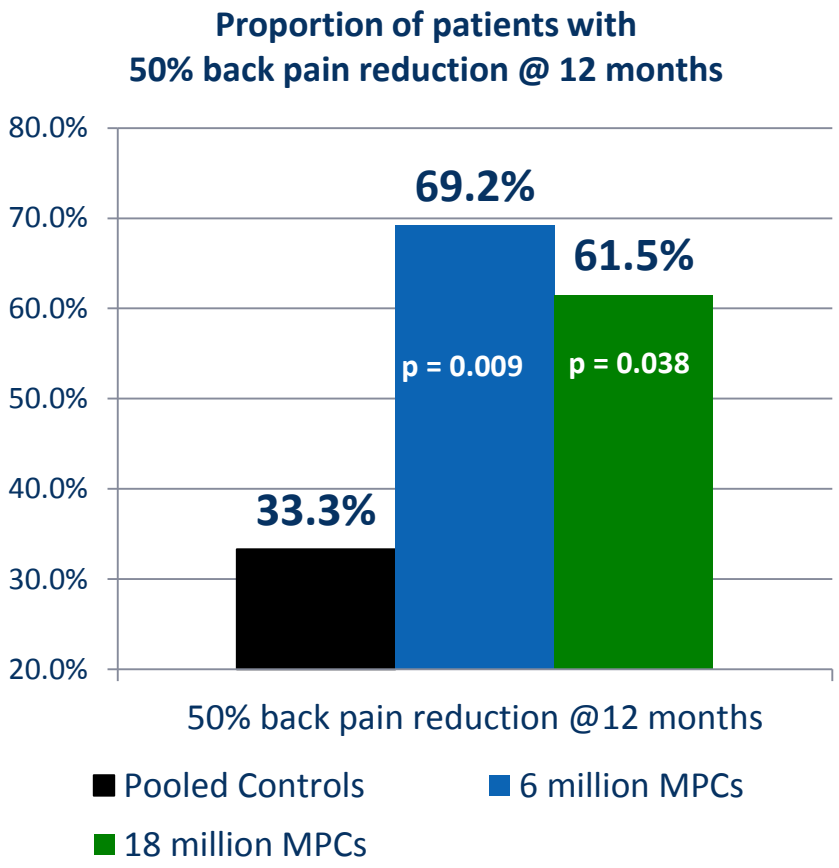
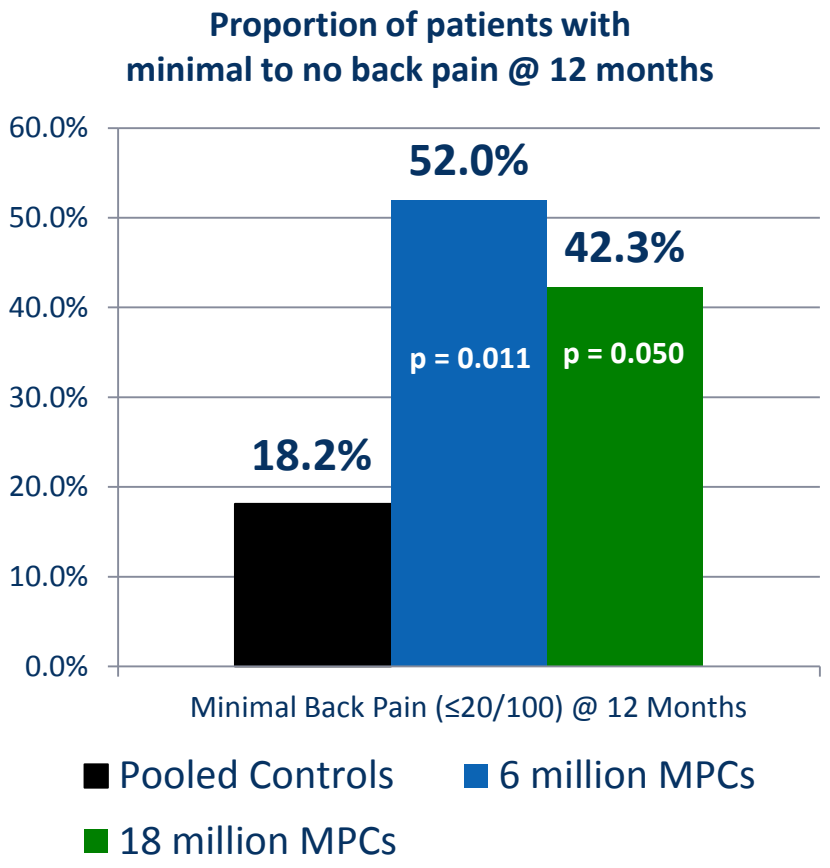
MPC-06-ID: CDLBP 12-month Phase 2 results - MPCs show greater reduction in pain

MPC groups have a greater proportion of patients with at least a 50% improvement in back pain or minimal/no residual back pain (VAS <20) at 12 months relative to controls





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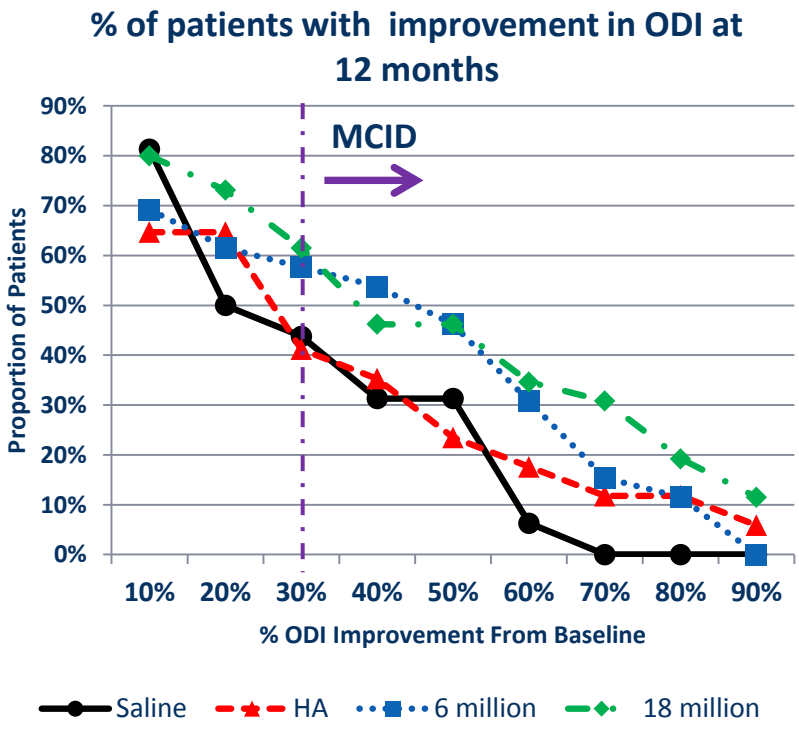
MPC-06-ID: CDLBP 12 month Phase 2 results - MPCs show improvement in function



- Oswestry Disability Index (ODI) is a standardized measure of function and was evaluated at 3, 6 and 12 months
- Minimally clinical important difference (MCID) in ODI is defined as ≥30% or 10 point improvement
- At 12 months, both 6 million MPC group and the 18 million MPC group had greater proportions of patients with ODI improvement ≥30% than either control group

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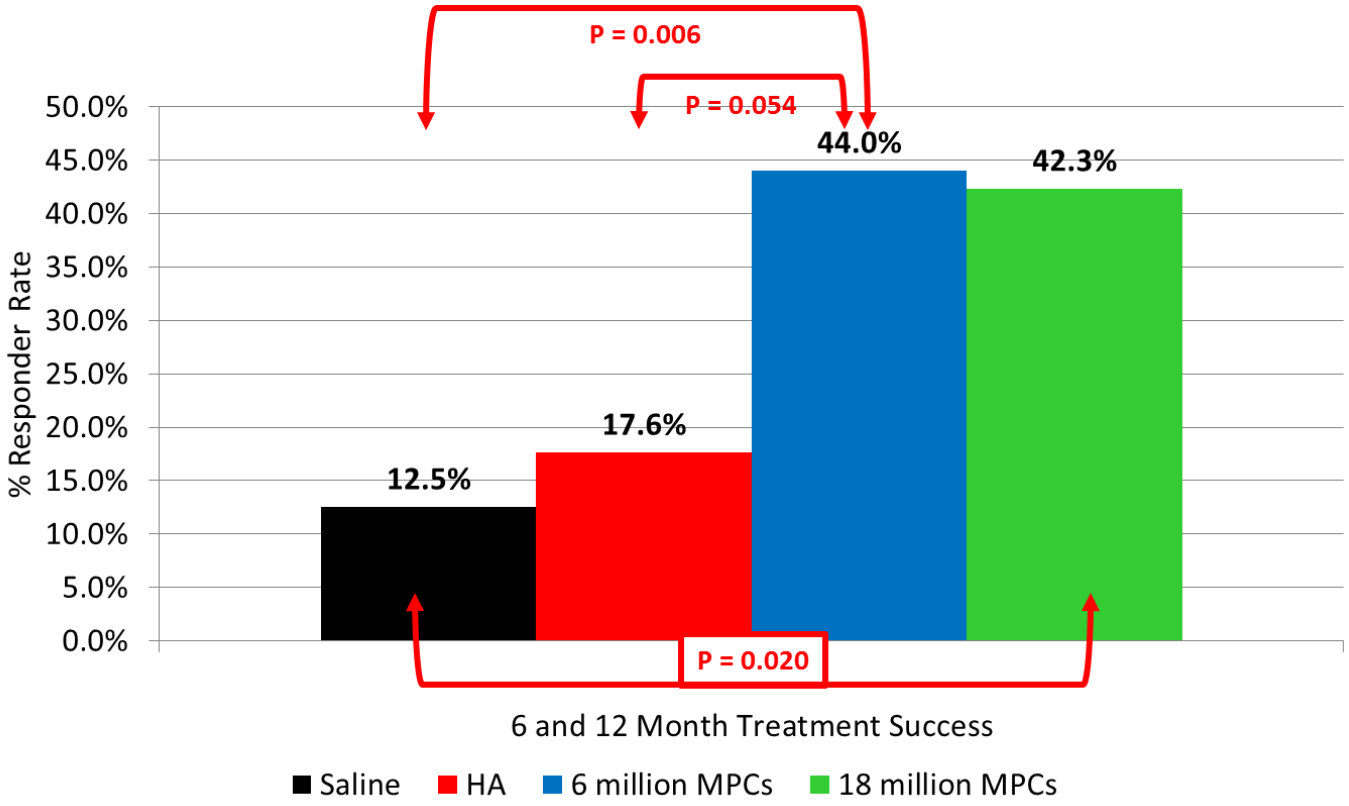
MPC-06-ID: CDLBP – Composite endpoint for Phase 3

Treatment options for CDLBP must address both decreased pain and improved function, defined as MCID in both VAS and ODI [1]. A responder to treatment is defined as meeting both VAS and ODI MCID.



% Responders positive at both 6 and 12 months for Composite of 50% VAS back pain reduction + 15 point ODI improvement + no intervention at the treated level

1. VIII International Forum on Primary Care Research on Low Back Pain (Amsterdam, June 2006)

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MPC-06-ID: CDLBP - Phase 3 clinical program

- Positive End of Phase 2 meeting with FDA supports progression into Phase 3
- Phase 3 study design will measure composite endpoint of decreased pain and improved function over 12 months
- Expected Phase 3 trial initiation end of 2014
- Expected Phase 3 milestones
  - Phase 3 enrollment complete in mid-2016
  - Phase 3 interim analysis mid-2016
  - Phase 3 top line data in mid-2017

MPC-06-ID is positioned to fill the significant treatment gap in patients with moderate to severe CDLBP after conservative treatment options have failed

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MPC-150-IM: Congestive Heart Failure (CHF) – Market opportunity

MPC-150-IM is in development for New York Heart Association (NYHA) class II to IV congestive heart failure

Market opportunity

- 5.1 million people in the US are diagnosed with CHF (2% of the population) [1]
- 825,000 new cases diagnosed each year – growing at 2% per annum [1]
- CHF patients with NYHA Class II/III with low ejection fraction (<35-40%): ~ 40% of all heart failure patients [2]
- CV Hospitalization or all cause mortality among CHF Class III/IV 50% at 16.6 months median follow up duration [3]

Gap in treatment options

- Despite standard of care using pharmacological treatments, Class II/III patients continue to be at high risk of repeated hospitalizations and mortality
- Advanced/NYHA Class III/IV patients only have heart transplant and mechanical support as treatment options

Targeted physician population

- Specialists: Targeted physician audience & commercial footprint
  - Heart failure specialists
  - Interventional cardiologists
  - Cardiac surgeons

MPC-150-IM is positioned to fill the significant treatment gap in patients with advanced NYHA Class II-IV heart failure

1.AHA statistical Update – Heart disease and stroke statistics-2014 update Circulation 2014
2.The National Heart, Lung and Blood Institute; The Organ Procurement and Transplantation Network; The United Network for Organ Sharing; The American Heart Association
3. Metra M et al Eur Heart J 2009 30:3015-3026

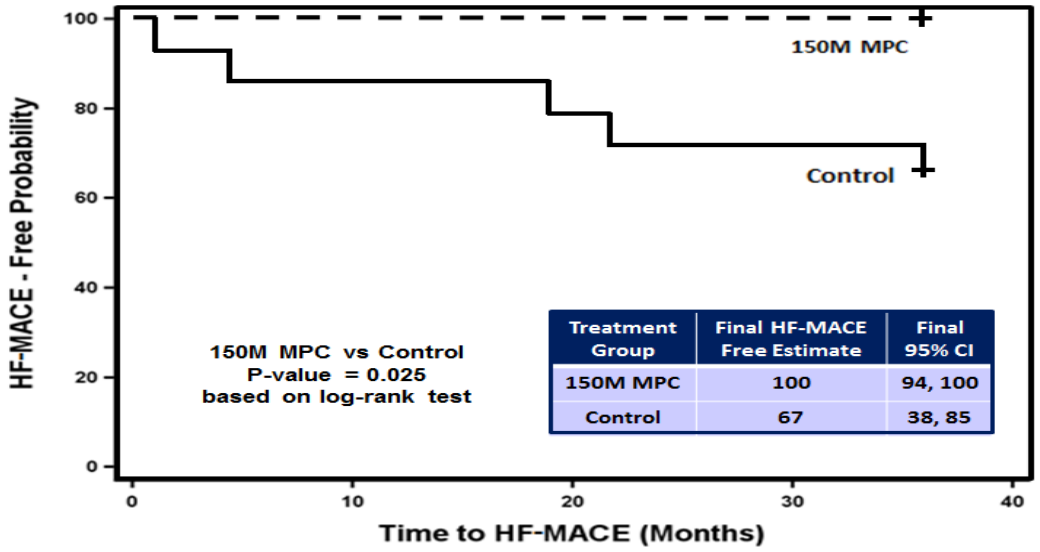
MPC-150-IM Congestive Heart Failure (CHF)- Optimal dose identified in Phase 2

Phase 2 top line results

Overall, results obtained in patients with CHF show positive effects on clinical outcomes, including left ventricular remodeling and functional exercise capacity. The 150 million cell dose showed greatest benefit for reducing HF-MACE long-term.

Specifically:

- Endomyocardial injections of 25, 75 or 150 million MPCs in patients with CHF were feasible and safe.
- At 6 and 12 months, there was a dose-dependent improvement in LVESV and LVEDV, in MPC-treated patients compared with controls;
- The 150 million cell dose showed the greatest effect compared to controls for LV remodeling (LVESV and LVEDV both $p<0.02$)
- Over 36 months of follow up, the 150 million cell dose was associated with a significantly greater probability of remaining free of HF-MACE events compared to the control group (0% versus 33% HF-MACE by Kaplan-Meier, $p=0.025$ by log-rank).



Kaplan-Meier Analysis for Time-to-First HF-MACE 150M vs Control Treatments (36 Months Follow-up)

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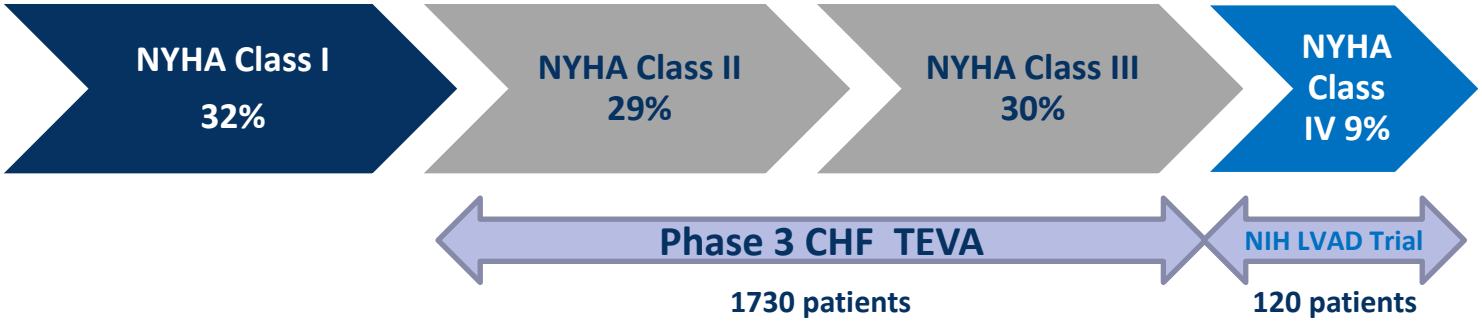
MPC-150-IM: Congestive Heart Failure (CHF) – Phase 3 trial in NYHA II/III HF

- Phase 3 trial is being conducted by our partner Teva and is actively enrolling
- Phase 3 double-blinded, 1:1 randomized, sham-procedure-controlled study evaluating a single dose of 150 million MPCs, delivered via endomyocardial injection catheter to the left ventricle, in NYHA class II/III heart failure patients
- Enrollment criteria will enrich for more advanced heart failure patients (EF≤40%, high BNP levels, heart failure hospitalization <9 months)
- The trial plans to enroll approximately 1,730 patients and will include two interim analyses of efficacy and/or safety
- Database lock in preparation for the first interim analysis is expected Q4 2015
- A second interim analysis is planned for potential resizing, or for early termination

MPC-150-IM: Congestive Heart Failure (CHF) – Trials underway

New York Heart Association (NYHA) classification of heart failure



- NYHA Class II/III Phase 3 Program up and running with targeted completion in 2018. Options for acceleration being discussed with Teva and regulatory authorities
- The National Institutes of Health (NIH) is conducting a 120-patient study in advanced/NYHA Class IV patients

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MSC-100-IV: Graft vs Host Disease – Market opportunity

MSC-100-IV is in development for pediatric and adult patients with acute Graft Versus Host Disease (GVHD) following allogeneic hematopoietic stem cell transplant (HSCT) who have failed to respond to steroid treatment

Market opportunity

- ~30,000 allogeneic HSCTs performed globally each year, 25% pediatric [1,2]
- ~ 50% of all patients develop GVHD (Grades II-IV) [3]
- ~50% acute GVHD steroid-refractory [4]
- Total one year cost of multi risk factor transplant complications USD$845,000 - $1,000,000[5]

No approved treatment options

- Mortality can reach 85% in patients with liver & gut complications
- No currently approved therapies for steroid refractory patients
- Off-label options have mixed efficacy with high toxicity
- Significant need for a new treatment with a favorable risk/benefit profile

Targeted physician population

- Highly targeted physician audience & commercial footprint for lead launch in pediatrics
- ~ 68 centers in the US conduct pediatric allogeneic HSCTs
- ~ 50% of all pediatric transplants concentrated in 12 centers & key metropolitan areas

1.Gratwohl T el al, Quantitative and qualitative differences in use and trends of hematopoetic stem cell transplantation : a Global Observation study. Haematollogica 213;98(8)
2.CIBMTR, Decision resources GVHD Epi Nov 2012.
3.Decision resources Niche Markets and Rare diseases: GVHD Nov 2012
4. Cahn et al prospective evaluation of 2 aGVHD grading systems Blood Aug 2005
5.Svahn BM et al, Increased costs after allogeneic haematopoetic SCT are associated with major complications and re-transplantation BMT 2012; 47:706-715

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MSC-100-IV: Graft vs Host Disease – Evidence of efficacy

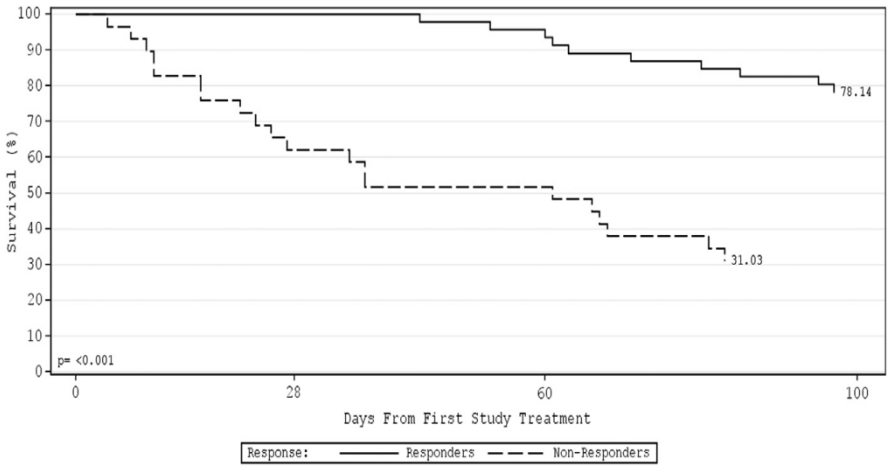
Pediatric Patients [1]

- Expanded Access Program in US has treated in excess of 200 patients
- In first 75 patients, response at day 28 to MSC-100-IV therapy was a significant predictor of improved day 100 survival ($p<0.001$)
- Day 100 survival was 76% in MSC-100-IV responders, compared to 28% in non-responders (p value <0.001, log rank test)

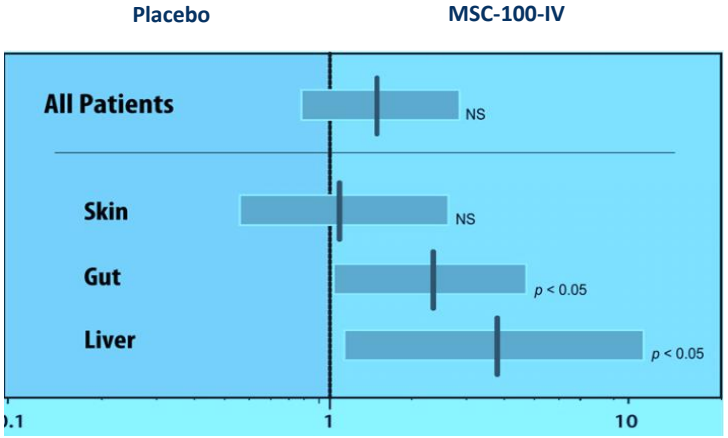
Adult Patients [2]

- In a randomized, placebo-controlled Phase 3 trial, MSC-100-IV significantly improved overall responses in the adult subset with gut or liver GVHD, and resulted in improved survival in this important subset.

Pediatric Day 100 survival [1]



Adult response day 100 by organ (Odds Ratio) [2]



1.Kurtzberg J. et al Allogeneic hMSC therapy as a rescue agent for severe refractory aGVHD in pediatric patients BBMT Nov 2013
2.Martin PJ et al Abstract #41 BBMT Supplement 16 s169-170: Data on file

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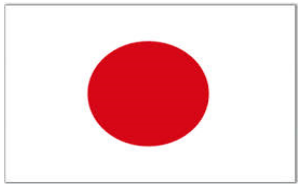
MSC-100-IV/JR-031 : Graft vs Host Disease – Product launch plans

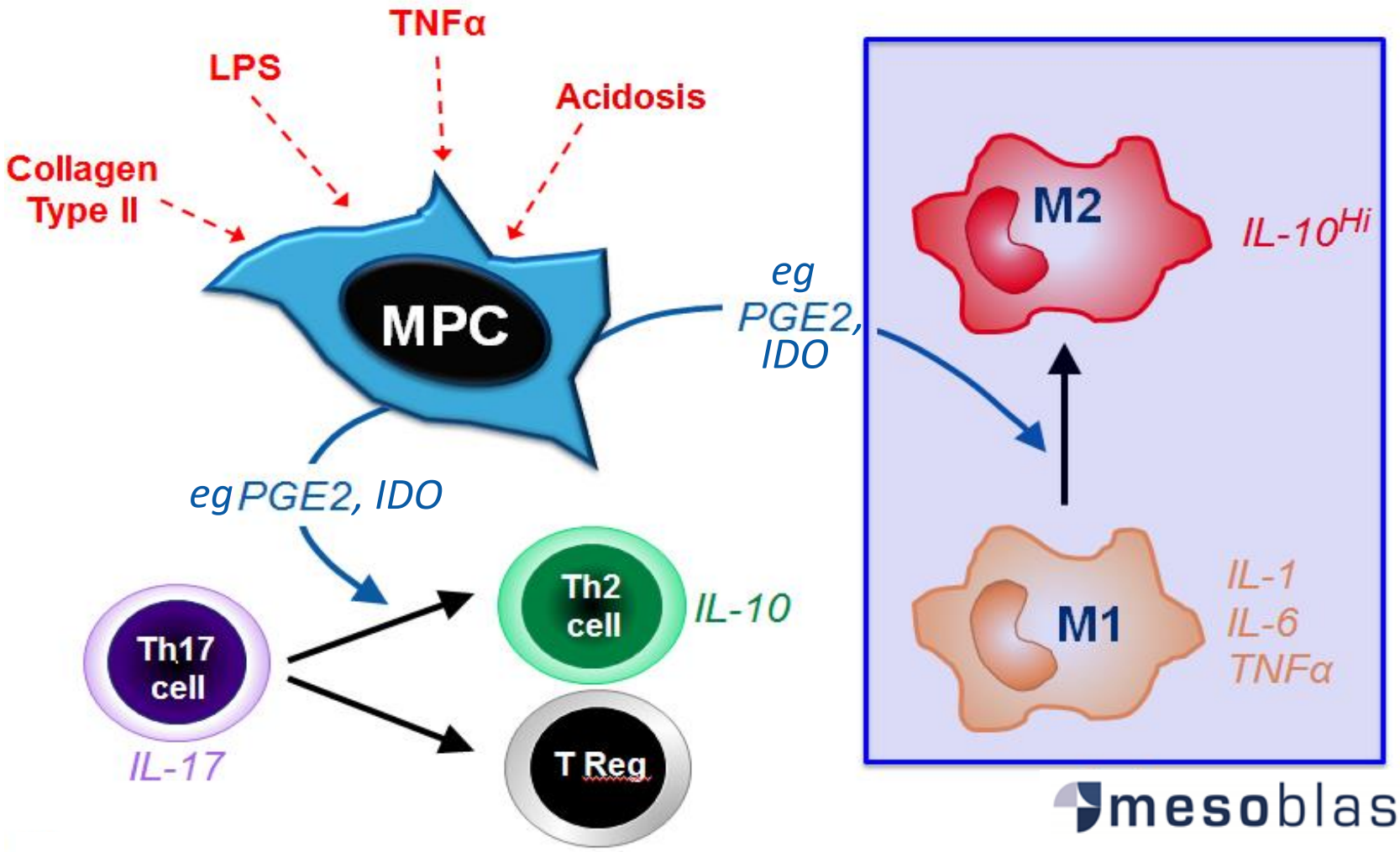


- JCR Pharmaceuticals Co Ltd., our GVHD partner in Japan, filed for regulatory approval for JR-031 in Japan in September 2014 and was granted orphan drug priority review
- North America
  - Canada
    - Manufacturing -Commercial readiness
    - Canadian launch for pediatrics -2016
  - United States
    - Positive FDA meeting July 2014 - pathway for accelerated approval clarified
      - 60 patient open-label phase 3 pediatric trial
      - Confirmatory phase 3 adult trial design in liver/gut subset
    - Manufacturing -Commercial readiness
    - BLA filing for pediatric registration 2016

MSC-100-IV has potential to be first allogeneic stem cell product approved in United States – “halo” effect for Mesoblast’s commercial go to market capability

MPC-300-IV for treatment of Chronic Inflammatory Diseases

Inflammation-dependent induction in MPC and role in regulating the function of both Th17 cells and macrophages



MPC-300-IV for treatment of Chronic Inflammatory Diseases

Phase 2 clinical program in 138 patients across three chronic inflammatory conditions to evaluate safety, efficacy and durability of effect following IV administration of a single MPC-300-IV dose

- 60 patients, type 2 diabetes with inadequately controlled glucose:
  randomized, placebo controlled dose-ranging study completed
- Positive dose-dependent effects seen on reduction in HbA1c at 3 months, with highest dose (2 million MPC/kg) having greatest benefit ($p<0.05$)
- 30 patients, type 2 diabetes and chronic kidney disease:
  randomized, placebo controlled dose-ranging study fully enrolled
  6 month topline data expected Q1 2015
- 48 patients biologic-refractory rheumatoid arthritis:
  randomized, placebo controlled dose-ranging study fully enrolled,
  6 month topline data expected H2 2015

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MPC-300-10-IV for Diabetic Kidney Disease – Market opportunity

Market opportunity

- 40-50% of all diabetes patients (19 million in 2013 in US) develop renal complications. Diabetes accounts for 43% of all kidney failure (ESRD) in the US, making it the primary cause of the condition
- Stage 3b-4 (GFR 20-45 ml/min/1.73 m2) estimated ~200,000 incident cases annually. Total prevalent cases 1.8M[1]
- The estimated annual cost of diabetic nephropathy in the US is $24 billion[2]

Gap in treatment options

- Standard of care (SOC) Renin Angiotensin System (RAS) inhibition modestly slows the progression of diabetic nephropathy (16-25%)
- RAS inhibition reduces the progression to renal replacement or death by 25%, leaving a large residual risk of 75%. Current SOC only slows the rate of deterioration in renal function
- The only treatment option for ESRD is renal replacement (dialysis or transplant); 40% of patients are dead within 2 years of initiating dialysis[3]
- Cost of renal replacement therapy is $100,000/year (dialysis) - $250,000 (transplant)[2]

Targeted physician population

- Patients with Stages 3B-4 are generally managed by the nephrologists. There are ~ 7000 in in the US in practice[3]
- Endocrinologists/ diabetologists also critical. There are ~ 4500 in the US in practice[4]

There is a significant and urgent need for true disease modifying therapies, with the goal of halting or reversing renal damage in patients with chronic kidney disease

1. Levey A and Coresh J.
2. U.S. Renal Data System Annual Data Report 2012
3. Robinson B. et al. *Kidney Int*. 2014 January ; 85(1): . doi:10.1038/ki.2013.252 [In press]
4. 2012 AAMC Physician Specialty Data Book

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MPC-300-IV: Biologic Refractory Rheumatoid Arthritis– Market opportunity

Market Opportunity

- 1.3M Americans afflicted with RA[1]
- Incidence increases with age 8.7/100,000 for ages 18-34 vs 89/100,000 for ages 65-74[1]
- Responsible for 250,000 hospitalizations and 9M physician visits/year in the USA
- Diagnosis of RA is associated with a 2.5x greater risk of CV death
- Targeting moderate to severe RA patients who have failed a previous biologic

Gap in Treatment Options

- Despite standard of care using pharmacological treatments such as NSAIDs, steroids, DMARDs and more recently biological agents such as Anti-TNF and Anti-IL-6 receptor antibody, patients continued to have suboptimal improvement in the majority of their joints
- Sustained remission only occurs in 8-10% of patients on biologics

Targeted Physician Population

- Rheumatologists
  - General internists

Ongoing randomized, controlled Phase 2 Trial in 48 patients with biologic refractory rheumatoid arthritis, comparing two doses of MPC-300-IV against placebo

[1]GlobalData© Rheumatoid Arthritis Therapeutics – Pipeline. Oct 2011

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3. Scalable manufacturing capabilities to enable commercial scale production

Key stages in manufacturing and distribution process

1. Procure bone marrow from healthy, young adult donors
2. Create master cell banks
3. Expand to therapeutic quantities
4. Formulate, package and cryopreserve
5. Distribute

Objectives for achieving commercial scale manufacturing

- Distinct manufacturing processes for each product
- Commercial scale processes with batch-to batch consistency and reproducible release criteria
- Ensure commercial product supply is aligned with projected market needs
  - – Production in Singapore
  - – Scale up in 3D Bioreactors
  - – Optimized cost of goods

Strategic alliance with Lonza, a leader in biopharma manufacturing, including exclusive access to their Singapore stem cell facility for allogeneic product manufacturing

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4. Extensive intellectual property portfolio covering over 60 patent families

Composition of matter and manufacturing process

139 patents or patent applications
Valid through 2019-26

- MPCs – *63 patents or patent applications (valid through 2026)*
- MSCs – *7 patents or patent applications (valid through 2019)*
- DPSCs – *31 patents or patent applications (valid through 2024)*
- Cell manufacturing and production – *38 patents or patent applications*

Specific therapeutic applications

337 patents or patent applications
Valid through 2035

- Immunologic / inflammatory disorders – *74 patents or patent applications*
- Cardiovascular disorders – *65 patents or patent applications*
- Orthopedic disorders – *59 patents or patent applications*
- Oncology / hematology – *85 patents or patent applications*
- Other therapeutic applications – *54 patents or patent applications*

Complementary technologies and additional candidates

134 patents or patent applications
Valid through 2023-32

- Cell-based complementary technologies – *62 patents or patent applications (valid through 2030)*
- SDF-1 – *25 patents or patent applications (valid through 2032)*
- Factors and agents for cardiovascular and other fibrotic indications – *47 patents or patent applications (valid through 2023)*

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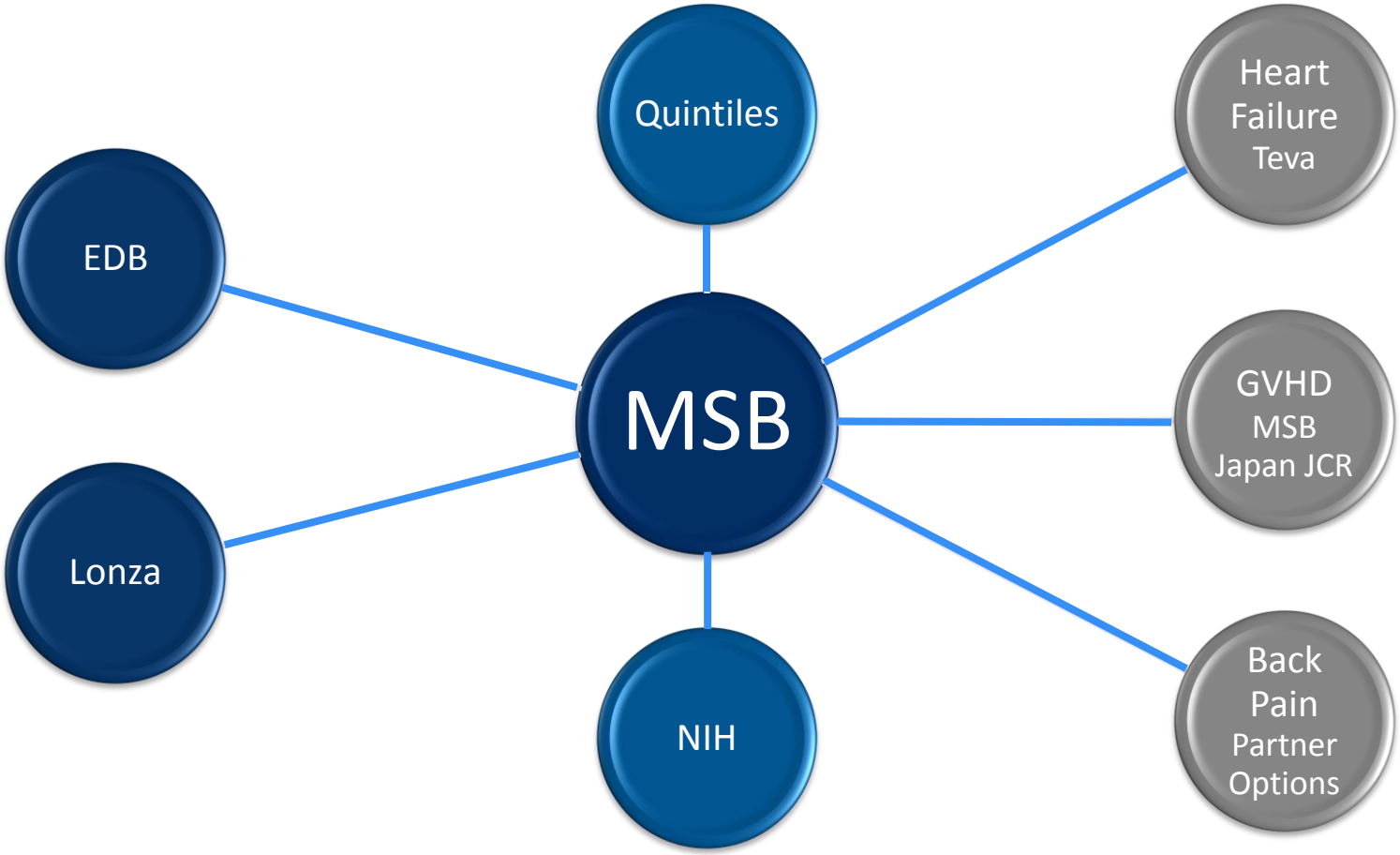
5. Build strategic partnerships

Manufacturing | **Development** | **Commercialization**



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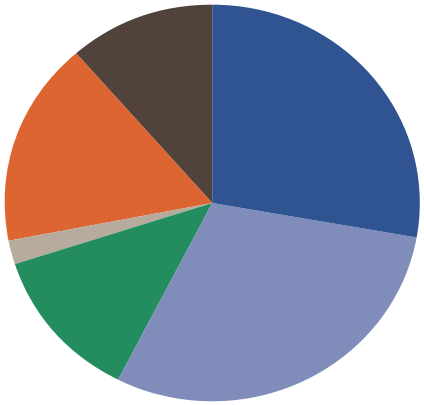
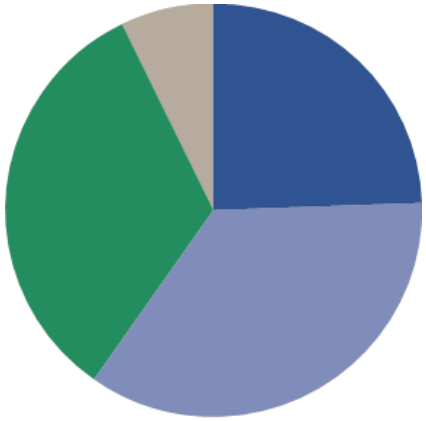
6. Experienced management team

Industry background



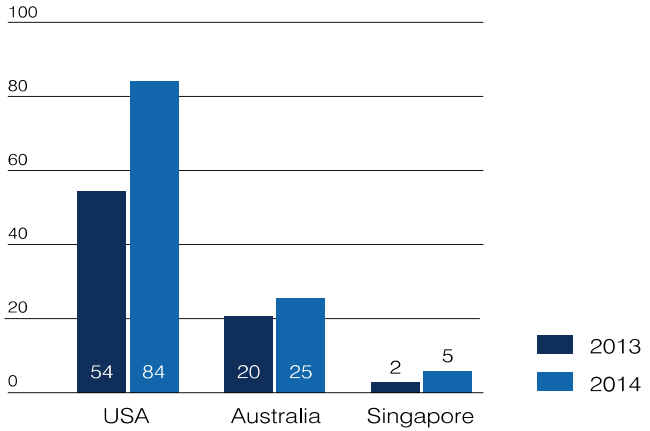
- Pharma – 27.8%
- Specialty Biotech – 29.9%
- Academia – 12.4%
- Regulatory Agencies – 2.1%
- Corporate/Professional – 16.5%
- Other – 11.3%

Qualification level

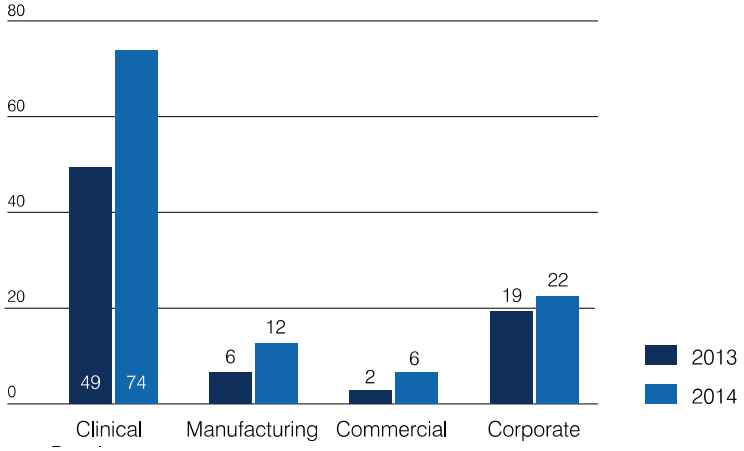


- PhD/MD – 24.7%
- Masters degree – 35.1%
- Bachelor degree– 33.0%
- Other – 7.2%

Location



Function



Building an experienced team for late-phase clinical execution and market launch

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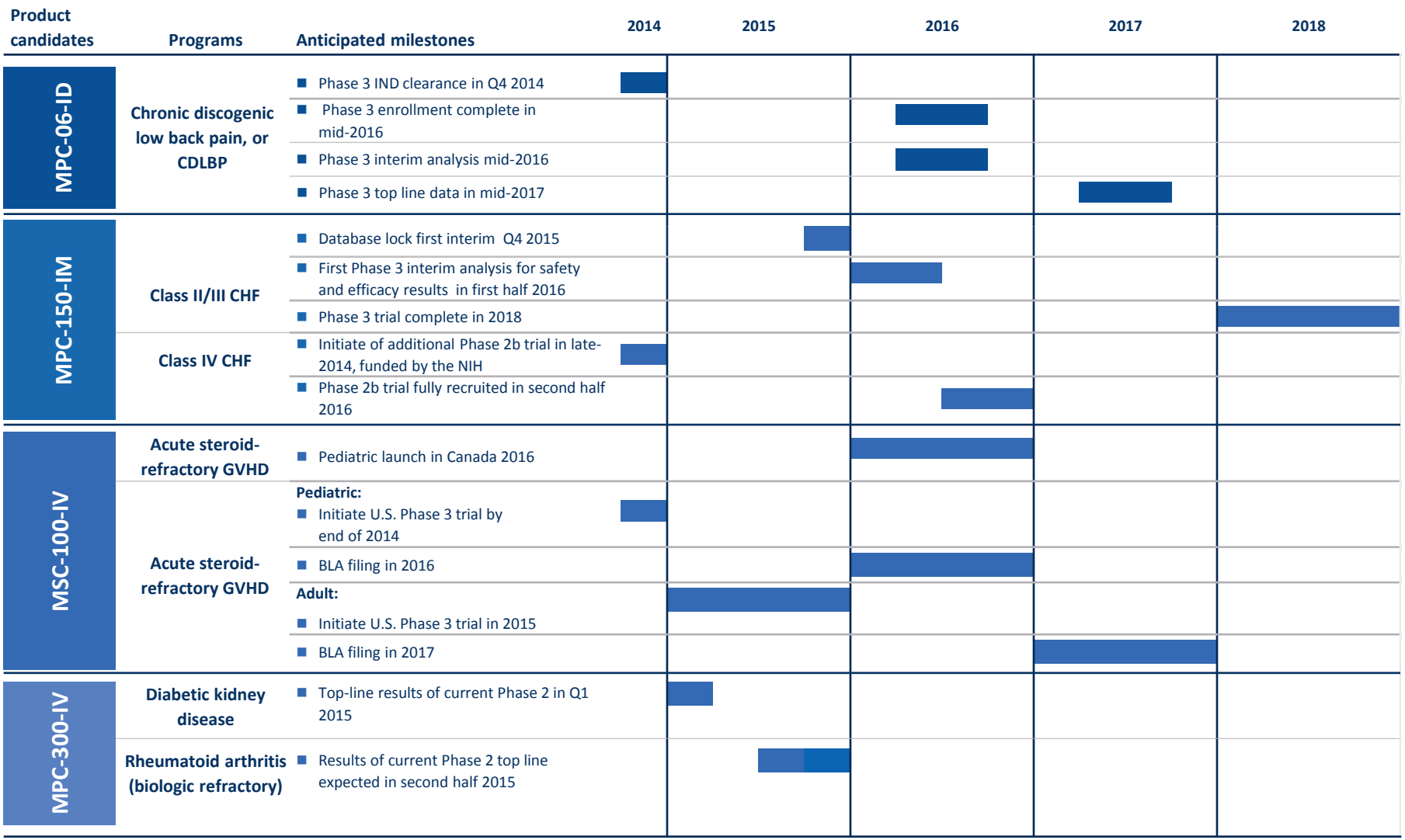
Upcoming milestones



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Questions / Thank you

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