
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 6-K

**Report of Foreign Private Issuer
Pursuant to Rule 13a-16 or 15d-16 under the Securities Exchange Act of 1934**

For the month of January 2017

Commission File Number 001-37626

Mesoblast Limited

(Exact name of Registrant as specified in its charter)

Not Applicable

(Translation of Registrant's name into English)

Australia

(Jurisdiction of incorporation or organization)

Silviu Itescu

Chief Executive Officer and Executive Director

Level 38

55 Collins Street

Melbourne 3000

Australia

(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F:

Form 20-F Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Yes No

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Yes No

On January 13, 2017, Mesoblast Limited filed with the Australian Securities Exchange a new release announcement, which is attached hereto as [Exhibit 99.1](#), and is incorporated herein by reference.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly organized.

MESOBLAST LIMITED

/s/ Charlie Harrison

Charlie Harrison
Company Secretary

Dated: January 17, 2017

Item _____

99.1 Press release of Mesoblast Ltd, dated January 13, 2017.



Cellular Medicines for Intractable Serious and Life-Threatening Diseases

Dr. Silviu Itescu, Chief Executive

January 2017

ASX:MSB/Nasdaq: MESO

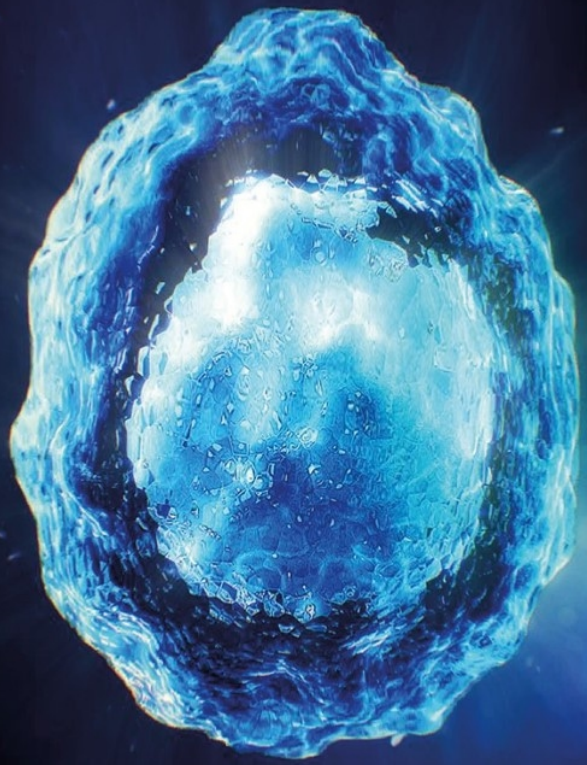


CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This presentation includes forward-looking statements that relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this presentation are forward-looking statements. Words such as, but not limited to, "believe," "expect," "anticipate," "estimate," "intend," "plan," "targets," "likely," "will," "would," "could," and similar expressions or phrases identify forward-looking statements. We have based these forward-looking statements largely on our current expectations and future events, recent changes in regulatory laws, and financial trends that we believe may affect our financial condition, results of operation, business strategy and financial needs. 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 current and potential future business partners 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. Forward-looking statements should not be read as a guarantee of future performance or results, and actual results may differ from the results anticipated in these forward-looking statements, and the differences may be material and adverse. You should read this presentation together with our financial statements and the notes related thereto, as well as the risk factors, in our most recently filed reports with the SEC or on our website. Uncertainties 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. We do not undertake any obligations to publicly update or revise any forward-looking statements, whether as a result of new information, future developments or otherwise.

Our Mission, Vision and Focus:

Mesoblast is committed to bring to market its disruptive cellular medicines to treat serious and life-threatening illnesses where there are currently no alternative treatments



Compelling Investment Proposition: Building a Leading Franchise of Cellular Medicines



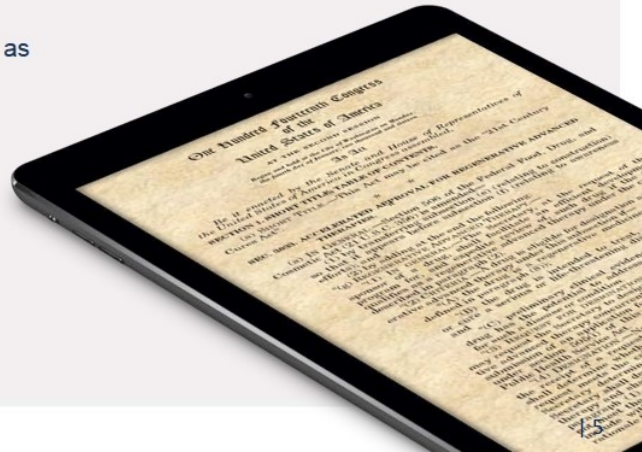
Leader in Disruptive Cellular Technology Platform	Proven Capability for Commercial Translation	Advanced Pipeline of Cellular Medicines
<ul style="list-style-type: none">▪ Extensive patent portfolio▪ Highly potent immunoselected mesenchymal lineage precursors and progeny▪ Deep expertise in cellular pathways and mechanisms	<ul style="list-style-type: none">▪ Scalable industrialized manufacturing▪ "Off the shelf" product capabilities to target large markets▪ Proven understanding of regulatory and reimbursement landscape▪ TEMCELL® HS. Inj. (aGVHD), approved in Japan¹	<ul style="list-style-type: none">▪ Three Tier 1 product candidates in Phase 3, one in Phase 2▪ Focused on serious and life-threatening diseases with commensurate pricing▪ Evidenced-based clinical data in place supporting efficacy across multiple indications▪ Multiple upcoming clinical milestones & corporate development

* Mesenchymal lineage adult stem cells (MLCs) including mesenchymal precursor cells (MPCs) and culture-expanded mesenchymal stem cells (MSCs).
1. Commercialization rights to Japan were out-licensed to JCR Pharmaceuticals.

The 21st Century Cures Act (“Cures Act”): Legislation for An Expedited Approval Path for Cellular Medicines Designated as Regenerative Advanced Therapies



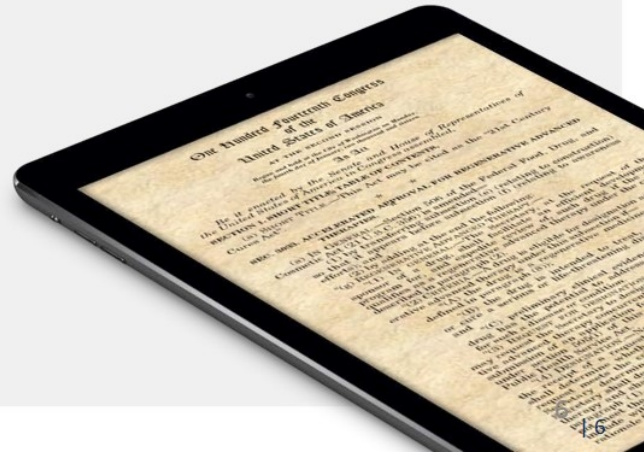
- Cellular medicines may be designated as regenerative advanced therapies, if they are intended to treat, modify, reverse, cure a serious or life-threatening disease or condition, and there is preliminary clinical evidence indicating the potential to address the unmet medical need
- Key benefits of the legislation for cell-based medicines, designated as regenerative advanced therapies, include:
 - Eligibility for priority review and accelerated approval
 - Potential to utilize surrogate endpoints for accelerated approval
 - Potential to utilize a patient registry data and other sources of “real world evidence” for post approval studies, subject to approval by the FDA



Implications of the Cures Act: Mesoblast Products for Serious and Life-Threatening Diseases Well Positioned

The 21st Century Cures Act will:

- Shorten clinical development time
- Shorten timeframes to FDA approval
- Reduce costs of development
- Increase the prospect of near-term revenue
- Position Mesoblast's advanced product candidates for attractive pricing



Recent Corporate Development:

Negotiations for a Development and Commercialization Partnership Underway



- December 22, 2016 - Entered into an equity purchase agreement with Mallinckrodt Pharmaceuticals for ~US\$ 21.7 million¹
- Exclusively negotiate a commercial and development partnership for:
 - MPC-06-ID for moderate/severe chronic low back pain due to disc degeneration
 - MSC-100-IV for acute GVHD
- Exclusive period of up to 9 months for the two product candidates in all territories outside of Japan and China
- **Mallinckrodt Pharmaceuticals**
 - Gains a significant opportunity to opt-in to a pipeline of transformative regenerative therapy assets in late-stage development
 - Track record of success in commercializing medicines for immune-mediated diseases and pain management
- **Mesoblast Limited**
 - Leadership position in cellular-based medicines
 - Best-in-class allogeneic, “off-the-shelf” mesenchymal lineage adult stem cell platform

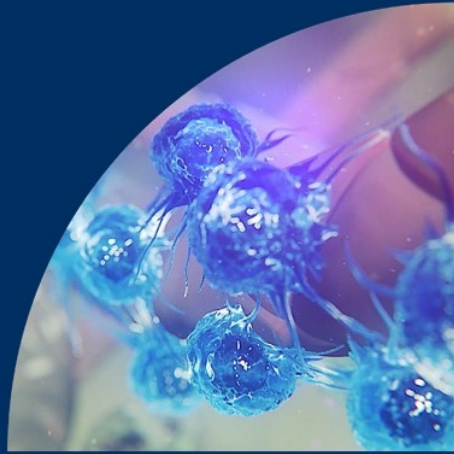
1. Mallinckrodt has bought approximately 20.04 million (4.99%) of Mesoblast's ordinary shares.

Financial Highlights



- At September 30, 2016, the Company had cash reserves of \$US60.4 million
- In order to absorb the incremental costs of the MPC-150-IM program in advanced heart failure in FY17, the Company has executed its planned operational streamlining and re-prioritization of projects
- Cash outflows for Q1 FY17 were reduced by 28% compared with the comparable FY16 quarter
- In January 2017, we received \$A29.6 million/US\$21.7 million pursuant to an equity purchase agreement with Mallinckrodt Pharmaceuticals¹
- As previously announced, a fully discretionary equity facility has been established for up to \$A120 million/\$US90 million over 36 months

1. Mallinckrodt has bought approximately 20.04 million (4.99%) of Mesoblast's ordinary shares.



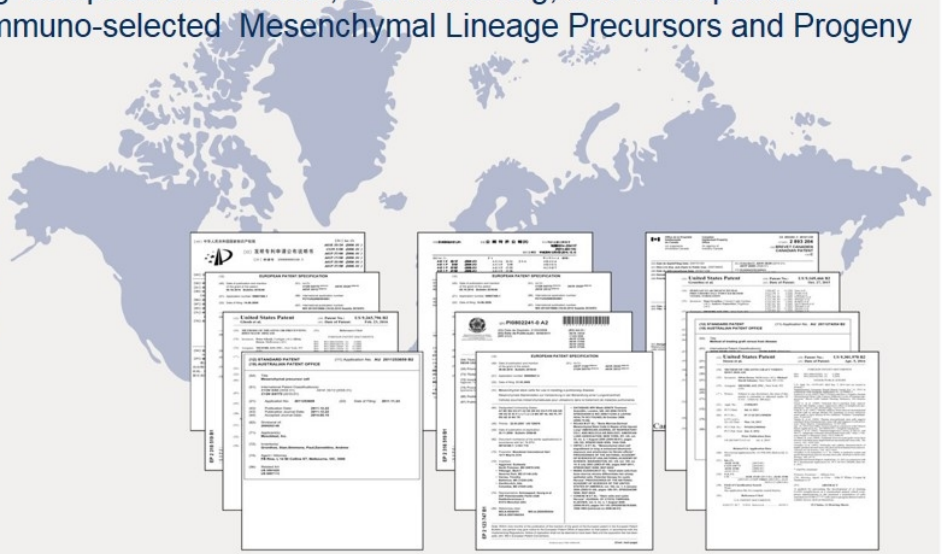
Proprietary Mesenchymal
Lineage Technology Platform



The Mesoblast Difference: Intellectual Property is Core to Our Strategy:

An Extensive Portfolio Covering Composition of Matter, Manufacturing, and Therapeutic Applications of Highly Potent Immuno-selected Mesenchymal Lineage Precursors and Progeny

796 Patents - 72 Patent Families Protection across major markets including US, Europe, Japan and China

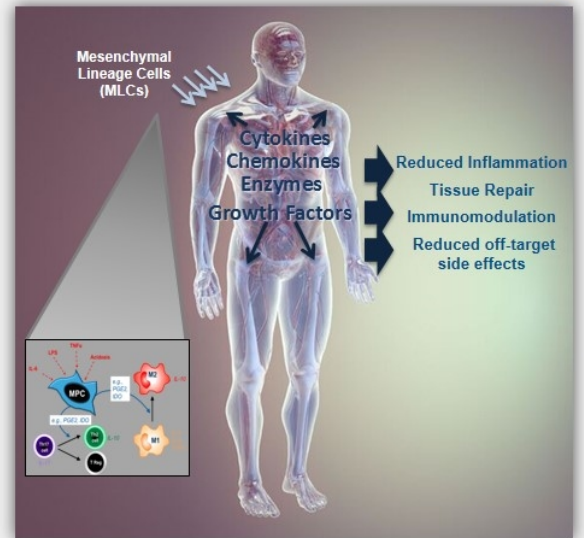


Note: Excludes possible patent term extension; as of January 2017.

The Mesoblast Difference:

Transforming the Science of Cellular Medicine into Commercial Reality

- Mesenchymal lineage immuno-selected precursors and progeny cells (MLCs)
- STRO-1/STRO-3 immuno-selection provides a homogeneous and potent population of MLCs with receptors that respond to inflammatory and damaged tissue signals
- In response to activating signals present in damaged tissues, MLCs secrete a diverse variety of biomolecules responsible for immunomodulation and tissue repair¹
- Specificity of triggering signals potentially reduces likelihood of off-target side effects
- Optimal response likely to occur when signals are greatest in most advanced disease states
- Clinical data across broad range of indications show amplified efficacy in hardest to treat patient populations



1. Singer and Caplan Annu. Rev. Pathol. Mech. Dis. 2011. 6:457-78.

The Mesoblast Difference: Scalable Manufacturing For High Margin Medicines






- Manufacture completed for clinical supply of all current Phase 3 trials
- Regulatory activities ongoing to meet requirements for commercial manufacturing across product pipeline
- Specific formulations defined for product delineation
- In-house proprietary serum media formulations developed to deliver step-change yield improvements and eliminate source capacity constraints
- Continued development using large commercial-grade bioreactors to move towards automation, reduction in labor and COGS improvements





Diverse Pipeline of Cellular Medicines

Portfolio of Advanced Product Candidates: Ideally Positioned for the 21st Century Cures Act Environment

							Commercialization	
	Platform	Product Candidate	Therapeutic Area	Pre-Clinical/ Pre-IND	Phase 2	Phase 3	Approval	Partnering ¹
Tier 1	MPC	MPC-150-IM	Advanced (Class 3) HF End Stage (Class 4) HF	→	→	→		
	MPC	MPC-06-ID	Chronic Low Back Pain	→	→	→		
	MPC	MPC-300-IV	RA DN/Type 2 Diabetes	→	→	→		
	MSC	TEMCELL® HS Inj MSC-100-IV	Acute GVHD Acute GVHD	→	→	→	Japan	 
Tier 2	Includes MSC-100-IV (Crohn's disease – biologic refractory), MPC75-IA (Acute Cardiac Ischemia), MPC-25-Osteo (Spinal Fusion) and MSC-75-IA (Knee Osteoarthritis)							

This chart is figurative and does not purports to show individual trial progress within a clinical program. For product registration purposes, Phase 3 programs may require more than one trial. Tier 1 programs represent our lead programs where we focus the majority of our time and resources. Tier 2 programs are also in development and may advance to Tier 1 depending on the merit of newly generated data, market opportunity or partnering options.

1. On December 22, 2016, Mesoblast Ltd. entered into an equity purchase agreement with Mallinckrodt Pharmaceuticals for ~US\$ 21.7m to exclusively negotiate a development and commercialization partnership for rights to GVHD and Chronic Low Back Pain outside of the Chinese and Japanese markets.



**MPC-150-IM
Chronic Heart Failure (CHF)
Program**

**Multi-billion dollar
blockbuster potential**

MPC-150-IM:

Targets the Most Serious and Life-Threatening Complications of Heart Failure

Significant Burden of Illness and Unmet Need

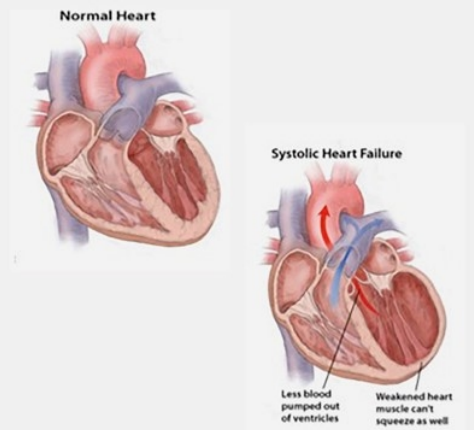
- Globally, 17-45% of heart failure patients die within 1 year of hospital admission
- Majority of these patients die within 5 years of admission¹
- MPC-150-IM to target advanced HFrEF NYHA Class II-III with the objective of reducing major cardiovascular events (e.g. mortality and hospitalizations)

Minimal Treatment Options

- Despite recent advancements in pharmacotherapy, limited treatment options are available for patients with advanced NYHA Class II-IV Heart Failure with Reduced Ejection Fraction (HFrEF)²

Attractive Market Opportunity

- ~1.9m NYHA Class II-IV patients with LVEF<40% in the US alone³
- Over \$60.2bn/yr in U.S. direct costs when this illness is identified as a primary diagnosis⁴
– \$115bn as part of a disease milieu⁴; hospitalizations result in ~69% of expenditures⁵



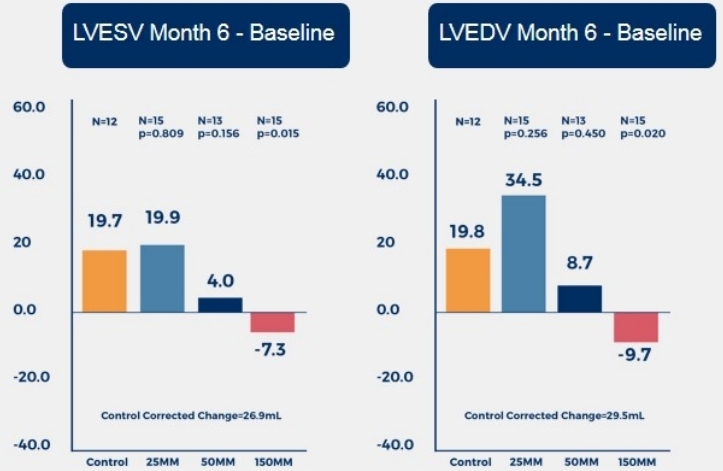
1. Heart Failure: Preventing disease and death worldwide – European Society of Cardiology 2014.
2. ACC/AHA/HFSA Focused Update on New Pharmacological Therapy for Heart Failure: An Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure
3. Gurwitz JH, Magid DJ, Smith DH, et al. Contemporary Prevalence and Correlates of Incident Heart Failure with Preserved Ejection Fraction. The American journal of medicine. 2013;126(5):393-400.
4. Derived by applying a HF-REF prevalence rate of 32.6% to the U.S. rate of 5.7m U.S. patients.
5. A Reevaluation of the Costs of Heart Failure and Its Implications for Allocation of Health Resources in the United States. Voigt J. Clinl Cardiol. 37, 5, 312-321 (2014)
5. The Medical and Socioeconomic Burden of Heart Failure: A Comparative Delineation with Cancer. Dimitrios, F. International Journal of Cardiology (2015). doi: 10.1016/j.ijcard.2015.10.172

Chronic Heart Failure (CHF) Program:

Phase 2 Randomized Placebo Controlled Trial in 60 Patients HF Class II/III and LVEF<40%



- Objectives:
 - Identify a dose response and an optimal therapeutic dose
 - Identify optimal target population for therapeutic effect
- Placebo vs. 25, 75, 150M MPCs injected by endomyocardial catheter
- At 6 months: Dose-dependent effect seen on left ventricular remodeling, with 150M cell dose (MPC-150-IM) showing greatest effect vs. controls

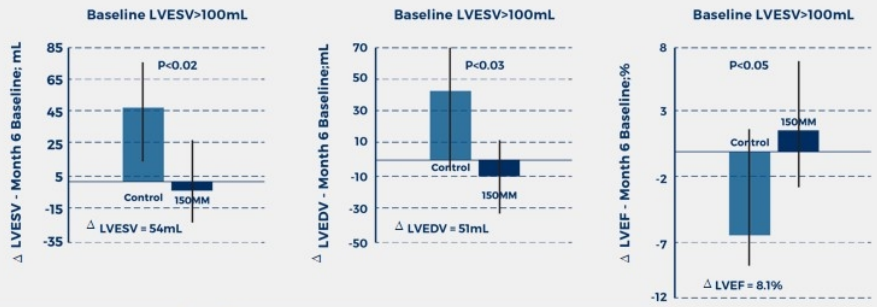


Source: Circ Res. 2015; 117:576-584. Perin E et al. A Phase II Dose-Escalation Study of Allogeneic Mesenchymal Precursor Cells in Patients With Ischemic or Non-Ischemic Heart Failure.

Chronic Heart Failure (CHF) Program:

Phase 2 Therapeutic Benefit on LV Remodeling is Amplified in Subjects with LVESV >100ml

- Placebo corrected benefit of 150M cell dose on cardiac volumes and ejection fraction at 6 months was greatest in patients with more advanced heart failure as defined by baseline LVESV >100ml at baseline



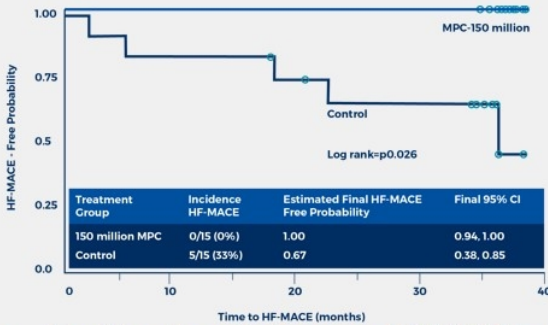
	Change (Entire cohort) Month 6 minus baseline			Change (LVESV>100mL) Month 6 minus baseline			P-values
	PBO (n=15)	150M MPC (n=15)	Δ, PBO corrected	PBO (n=7)	150M MPC (n=11)	Δ, PBO corrected	
LVESV	+20	-7	-27	+46	-8	-54	<0.02
LVEDV	+20	-10	-30	+41	-10	-51	<0.03
LVEF	-2.3	+0.6	+2.9	-6.4	+1.7	+8.1	<0.05

Source : Perin et al., Journal of Cardiac Failure 2015; Vol 21(8): S107; 19th Annual Scientific Meeting of the Heart Failure Society of America, Emerson et al.

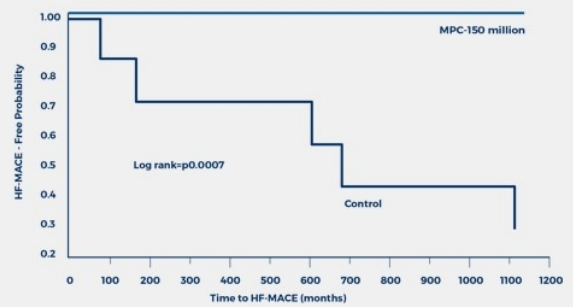
Chronic Heart Failure (CHF) Program:

Phase 2 Clinical Results Show A Single High-dose Injection May be Sufficient For Durable (36 Months) Protection Against HF-MACE¹ in Patients With Advanced Heart Failure

% HF-MACE Kaplan-Meier Curve over 36 months following treatment in all patients¹



HF-MACE Kaplan-Meier Curve over 36 months following treatment in patients with LVESV>100ml²



- Over 36 months, patients receiving 150M MPC had significantly greater probability of remaining free of a first HF-MACE vs. controls (0% vs. 33%, $p = 0.026$ by log-rank)
- All HF-MACE events occurred in controls with baseline Left Ventricular End Systolic Volume (LVESV)>100ml, where the treatment effect size was even greater (0% vs. 71%, $p = 0.0007$ by log rank)
- Controls with baseline LVESV>100ml had 11 total/recurrent HF-MACE events over 36 months vs. 0 in matched patients receiving 150M MPCs ($p=0.0007$)

1. HF-MACE is defined as a composite of cardiac related death or non-fatal heart failure hospitalisations. 2. Circ Res. 2015; 117:576-584. Perin E et al. A Phase II Dose-Escalation Study of Allogeneic Mesenchymal Precursor Cells in Patients With Ischemic or Non-Ischemic Heart Failure 3. Journal of Cardiac Failure 2015; Vol 21(8): S107; 19th Annual Scientific Meeting of the Heart Failure Society of America, Emerson et al.

MPC-150-IM:

Phase 3 Trial Targets Advanced Heart Failure

- Patients with large baseline LVESV and advanced heart failure are at highest risk of HF-MACE
 - *Have increased likelihood of having recurrent HF hospitalizations*
 - *Existing therapies are inadequate and economic burden is greatest*
- To confirm that MPC-150-IM reduces HF-MACE in patients with advanced heart failure, the ongoing Phase 3 trial is designed to enrich for patients with advanced heart failure and high risk of HF-MACE
 - *Enrichment for these patients based on heart failure hospitalization in the past 9 months and/or significantly elevated baseline NT-proBNP*

- The trial's primary endpoint is a comparison of recurrent HF-MACE between cell-treated patients and controls
- Terminal events are also being analyzed as they relate to non-fatal recurrent HF-MACE

MPC-150-IM:

Phase 3 Trial Operational Update

- The trial's primary endpoint is a comparison of recurrent heart failure-related major adverse cardiovascular events (HF-MACE) in advanced CHF patients receiving either MPC-150-IM by catheter injection into the left ventricular heart muscle, or control
- Phase 3 trial for 600 patients is recruiting well across North American sites; currently over 300 patients enrolled
- After reviewing patient data in April and October 2016, the trial's DSMB has maintained its recommendation that the study should continue as planned
- The Company intends to perform in 1Q CY17 an interim analysis to assess the trial's primary endpoint
- Interim analysis will guide the Company's discussions with the FDA in line with the 21st Century Cures Act for a potential pathway to accelerated approval

A 3D anatomical illustration of a human spine, showing the vertebrae and intervertebral discs. A medical gauge with a needle is positioned over one of the discs, and a syringe is shown injecting a substance into the disc. The background is a soft, glowing gradient of blue and purple.

Chronic Low Back Pain (CLBP) Due to Disc Degeneration

Multi-billion dollar
blockbuster potential

MPC-06-ID:

Alternative to Invasive Surgery and Opioid Use for Chronic Low Back Pain Patients

Significant Burden of Illness and Unmet Need

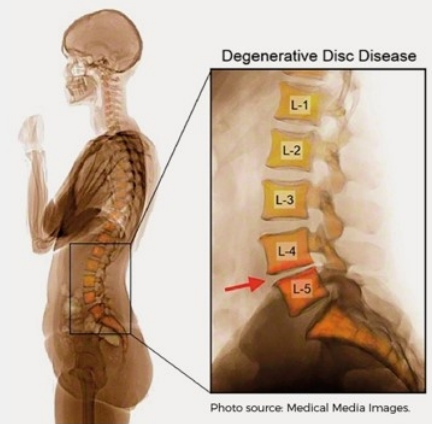
- Back pain causes more disability than any other condition¹
- Inflicts substantial direct and indirect costs on the healthcare system¹, including excessive use of opioids in this patient population

Minimal Treatment Options

- Patients failing opioids and epidural steroids are limited to highly invasive surgical procedures²

Attractive Market Opportunity

- In 2016, over ~7m U.S. patients are estimated to suffer from CLBP due to degenerative disc disease (DDD)^{3,4,5}
- MPC-06-ID development program targets over ~3.2m patients



1. Williams, J., NG, Nawi, Felzter, K. (2015) Risk factors and disability associated with low back pain in older adults in low-and middle-income countries. Results from the WHO Study on global ageing and adult health (SAGE). PloS One. 2015; 10(8): e0127880.
2. Simon, J., McAuliffe, M., Shamim, F. (2015) Discogenic Low Back Pain. Phys Med Rehabil Clin N Am 25 (2014) 305–317.
3. Decision Resources: Chronic Pain December 2015.
4. LEK & NCI opinion leader interviews, and secondary analysis.
5. Navigant: Commercial Assessment for a Proprietary Cell-Based Therapy for DDD in the U.S. and the EU3 – August 2014.

MPC-06-ID:

Phase 2 Trial Results Support Phase 3 Program¹

General Overview

- 100 patients with >6 months of CLBP due to DDD and unresponsive to conservative therapies (incl. opioids and epidural steroids) were evaluated in a randomized, placebo controlled Phase 2 trial
- Safety-cells and treatment procedure were well tolerated
- Event rates cell treated and control subjects were similar

Description of Efficacy Endpoints:

- Visual Analog Scale (VAS) scored from 0-100, evaluated at 1,3,6,12 and 24 months
 - Minimally clinical important difference (MCID) in VAS is defined as >30% improvement²
 - Guidance from key opinion leaders and payers requires > 50% in pain reduction at a distinct time point
- Oswestry Disability Index (ODI) is a standardized measure of function and was evaluated at 1,3,6,12 and 24 months
 - Minimally clinical important difference (MCID) in ODI is defined as >30% or 10 point improvement¹
 - 15 point improvement has been used as the MCID for surgical devices to support FDA and EU marketing authorization³

1. Clinicaltrials.gov identifier: NCT02412735.

2. Ostelo RWJ, Deyo RA, Stratford P, et al. Interpreting change scores for pain and functional status in low back pain. Spine 2008; 33(1):90-94.

3. EMA-SEED 2015.

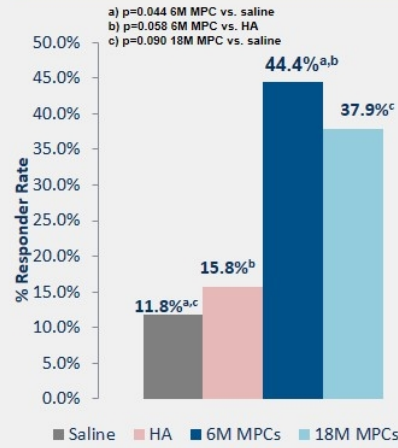
MPC-06-ID:

Phase 2 Data Support Composite Pain and Function Endpoint in Ongoing Phase 3 Study - Consistent with Potential as an Alternative to Surgery and Opioid Use for CLBP Patients

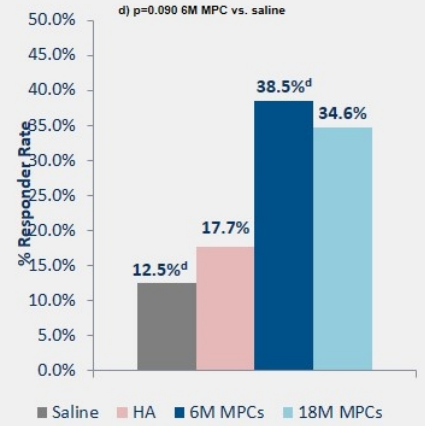
Treatment Success Composite Endpoint 50% VAS back pain reduction AND 15 point ODI improvement AND no intervention at the treated level

The primary endpoint for the ongoing Phase 3 trial is Overall Treatment Success (using a composite of 50% improvement in lower back pain and 15 point improvement in function at both 12 and 24 months)

% Patients with Treatment Success at 6 & 12 Months¹



% Patients with Treatment Success at 12 & 24 Months²



1. Source Mesoblast Ltd.
2. DePalma, et. Al. "Randomized, Controlled Trial Evaluating Safety & Effectiveness of Immunoselected, Allogeneic Mesenchymal Precursor Cells for Low Back Pain" Spine Intervention Society (SIS) Annual Meeting 2016.

MPC-06-ID:

Phase 3 Trial Operational Update

- The 24-month results from the Company's 100-patient Phase 2 trial of MPC-06-ID for treatment of CLBP were presented at the 24th Annual Scientific Meeting of the Spine Intervention Society; received the 2016 Best Basic Science Abstract award
- A 360-patient Phase 3 trial is recruiting well across sites in US and Australia
- On track to complete recruitment in 2017
- FDA has provided written guidance:
 - *Use of a composite primary endpoint is acceptable for approval*
 - *Primary endpoint aims to provide an alternative to surgery*
 - *Agreed thresholds for pain (50% decrease in VAS) and function (15 point improvement in ODI)*
 - *Two time points (12 and 24 months) for meeting pain and functional improvement criteria*
 - *No intervention at the treated level through 24 months*



Acute Graft vs Host Disease (aGVHD)

**Our nearest-term revenue product candidate:
MSC-100-IV for steroid-refractory aGVHD**

MSC-100-IV: Acute Graft vs Host Disease

Serious and Life-Threatening Complication of Bone Marrow Transplants

Significant Burden of Illness and Unmet Need

- aGVHD - a severe immunological reaction occurring in BMT patients
- Steroid-refractory aGVHD (SR-aGVHD) patients have mortality rates as high as 95%¹
- Is a major limitation in successful allogeneic hematopoietic stem cell transplants¹
- Refractory aGVHD is associated with significant extended stay hospital costs²

Minimal Treatment Options

- No regulatory approved treatment for SR-aGVHD outside of Japan
- No broad consensus on off-label second-line agents

Attractive Market Opportunity

- ~30,000 allogeneic BMTs performed globally (~20K US/EU5) annually, ~20% pediatric^{4,5}
- Received approval in Japan (TEMCELL® HS Inj.) for aGVHD in 2015; reimbursed up to ~\$USD195k per full treatment course³



1. West, J., Saliba, RM., Lima, M. (2011) Steroid-refractory acute GVHD: predictors and outcomes. *Advances in Hematology*.
2. Anthem-HealthCore/Mesoblast claims analysis (2016).
3. Based on a ¥/PY = \$USD 0.008375 spot exchange rate on as of the market close on November 11, 2016. Amounts are rounded. Source: Bloomberg
4. Gratwohl A et al Quantitative and qualitative differences in use and trends of hematopoietic stem cell transplantation: a Global Observational Study. *Haematologica*. 2013 Aug;98(8):1282-90.
5. CIBMTR, Decision resources GVHD Epi Nov 2012.

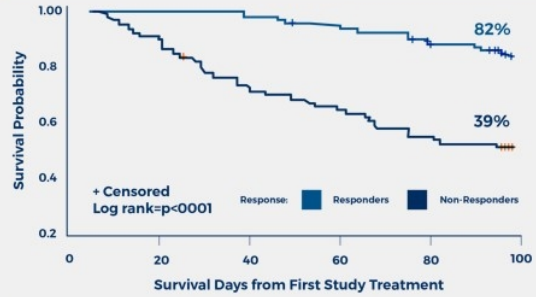
MSC-100-IV:

Prior Clinical Results¹ Support Ongoing Phase 3 Trial in Children with Steroid Refractory Acute GVHD (SR-aGVHD)

MSC-100-IV as first line therapy in children with SR-aGVHD

Response at Day 28	Randomized Placebo Controlled Trial		Expanded Access Program
	Placebo	MSC-100-IV	MSC-100-IV
Responder	3/14 (21.4%)	9/14 (64.3%)	29/36 (81%)
Non-responder	11/14 (78.6%)	5/14 (35.7%)	7/36 (19%)
p-value=0.0014 (combined treated vs control)			

MSC-100-IV in Children with SR-aGVHD who failed multiple other modalities
 - Survival of Pediatric Patients Treated with MSC-100-IV 28-Day Responders vs Non-responders n=241 -



- Demonstrates that MSC-100-IV has an effect when used as first line therapy in children with SR-aGVHD
 - compared with placebo control patients, MSC-100-IV produced superior overall response at day 28, a clinically meaningful endpoint (p=0.0014)*
- FDA agreement on ongoing 60 patient Phase 3 trial and it's eligibility for accelerated approval pathway
- Enrollment criteria: MSC-100-IV offered as first line therapy in children with SR-aGVHD

¹ Protocols 275 (NCT00759018) and 280(NCT00366145).

Acute Graft vs Host Disease: Product Development Strategy

Pediatric GVHD0001/GVHD002: Phase 3 study ongoing, ~40 sites planned¹

- *Multi-center, single-arm, open-label to evaluate efficacy and safety to day 100 (study 001) and from day 100 to day 180 (study 002)*
- *At least 60 pediatric patients (2 months to 17 years inclusive)*
- *aGVHD following allogeneic HSCT failing systemic corticosteroid therapy*



Endpoints¹:

- Primary endpoint: Overall response at Day 28
- Key secondary endpoint: Survival at Day 100 in responders at Day 28
- Subjects evaluated at Days 28, 56 and 100 in study 001, and out to Day 180 in study 002

Adult GVHD

- *Complete targeted Phase 3 study in high-risk subset of adult patients with aGVHD (liver and gut disease)*
- *Market development and access work in parallel*
- *Launch adult product in major markets planned for 2021*

1. Clinicaltrials.gov identifier: NCT02652130.

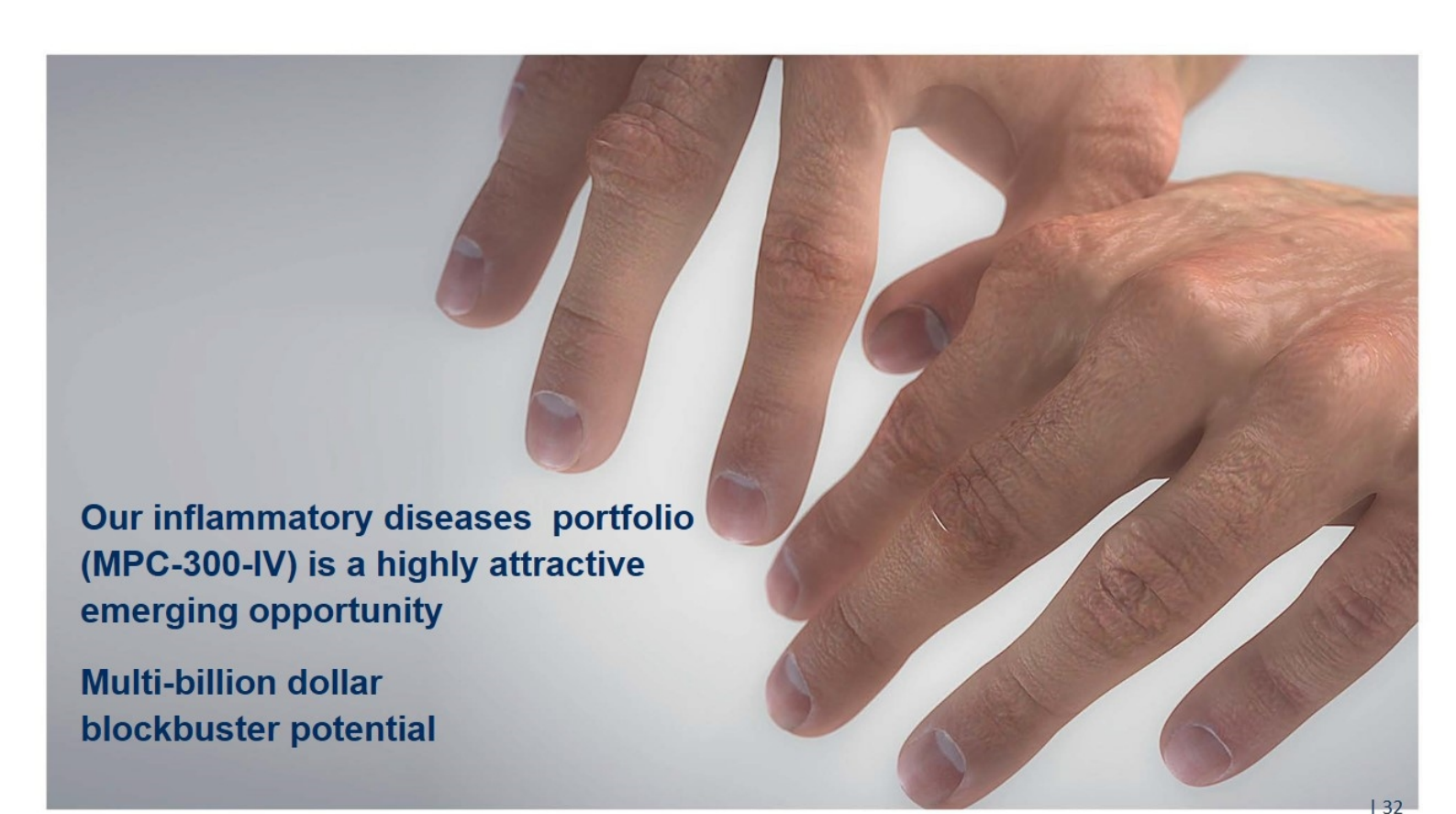
GVHD001:

Successful Interim Futility Analysis in 4Q CY16

- Predefined Bayesian futility rule that determined the predictive probability of success using the primary endpoint of Day 28 overall response
- Method determined the likelihood of obtaining a statistically significant treatment effect at study completion, conditional on the data observed at this interim time point
- DSMB notified Mesoblast that analysis was successful
- Interim analysis outcome is consistent with what has previously been demonstrated for the product used in this indication under both expanded access protocol and earlier placebo-controlled trial



- Enrollment in the study is ongoing across multiple sites in the United States and will continue
 - *Completion is expected in mid-2017*
 - *Commercial launch activities are underway*



Our inflammatory diseases portfolio (MPC-300-IV) is a highly attractive emerging opportunity

Multi-billion dollar blockbuster potential

MPC-300-IV: Biological Refractory Rheumatoid Arthritis (RA)

Significant Burden of Illness and Unmet Need

- RA is associated with multiple co-morbidities and psychosocial impairments¹
- Mesoblast development program targets the **biologic refractory** population²
 - ~1/3 of RA patients treated with TNF- α inhibitors are inadequate responders and percentage fail multiple treatments ; numbers increasing due to use of biosimilars
 - Many patients also experience waning efficacy over time

Minimal Treatment Options

- Providers and Payers desire new therapies with alternative mechanisms of action that:
 - Reduce signs and symptoms
 - Induce remission
 - Offer an improved safety profile in refractory setting^{2,3}

Attractive Market Opportunity

- ~5.3m prevalent cases in the US, Japan, and EU5; 2.4m in the US alone in 2014⁴
- Anti-TNF refractory population in the U.S. is the fastest growing branded market segment, projected to increase by ~8% annually or greater and potentially higher with the expected market entry and greater availability of anti-TNF biosimilars⁴



Photo source: WebMD.

1. Cutolo, M., Kitas, GD., et. al. (2014) Burden of disease in treated rheumatoid arthritis patients: Going beyond the joint Seminars in Arthritis and Rheumatism 43 (2014) 479-488.
2. Decision Resources: Unmet Need Immune and Inflammatory Disorders – Rheumatoid Arthritis April 2016.
3. Decision Resources: Evolution of the RA Treatment Paradigm: US Physician and Payer Perceptions as More Convenient Options Emerge December 2015.
4. Decision Resources: Unmet Need Immune and Inflammatory Disorders – Rheumatoid Arthritis April 2016.
5. Decision Resources Rheumatoid Arthritis – Disease Landscape & Forecast - January 2016; Market Forecast Methodology; Access & Reimbursement – August 2016.

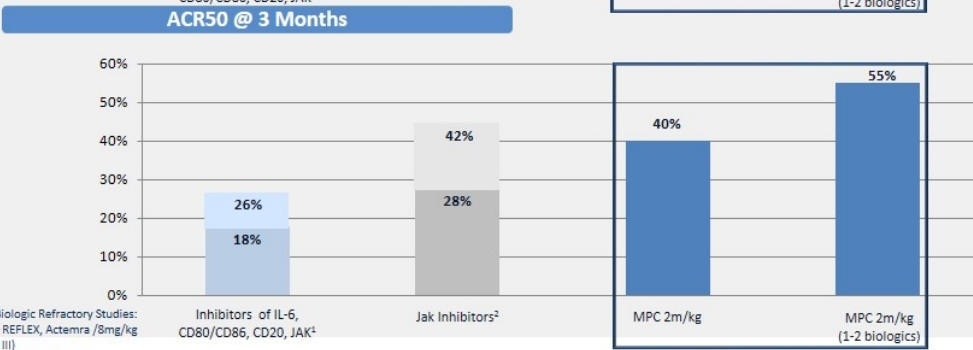
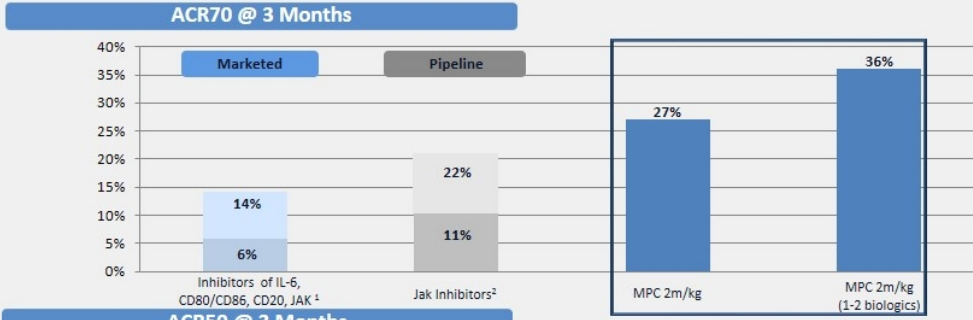
MPC-300-IV: Biological Refractory RA

Phase 2 Efficacy Responses at Week 12

	All Subjects				Subgroup with prior use of 1-2 Biologics			
	Placebo	1M/kg	2M/kg	P=value 2M=kg vs. placebo	Placebo	1M/kg	2M/kg	P=value 2M=kg vs. placebo
	N=16	N=16	N=16		N=9	N=10	N=11	
ACR70	0%	20%	27%	0.04	0%	20%	36%	0.09
ACR50	19%	27%	31%	>0.1	11%	30%	55%	0.07
ACR20	50%	47%	50%	>0.1	33%	60%	55%	>0.1
HAQ-DI<0.22	38%	53%	93%	0.003	33%	60%	91%	0.02
HAQ-DI LS mean change from baseline	-0.2	-0.3	-0.6	0.02	-0.1	-0.4	-0.7	0.03
DAS28-CRP LS mean change from baseline	-1.4	-1.3	-2.0	>0.1	-1.1	-1.8	-2.4	0.06
DAS28-CRP ≤ 3.2	19%	27%	36%	>0.1	22%	30%	40%	>0.1

MPC-300-IV: Biological Refractory RA

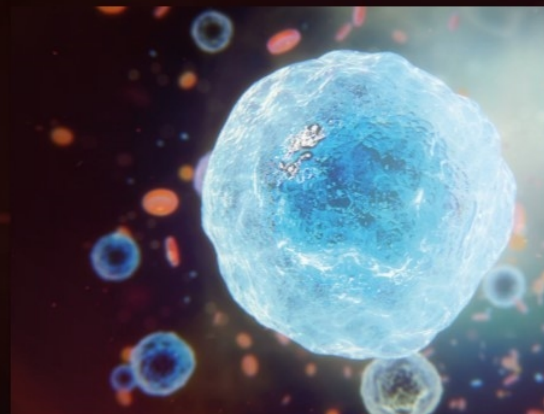
Phase 2 ACR Responses Compared to Published Comparators at Week 12



¹Inhibitors of IL-6 / CD80-CD86/CD-20/ JAK; Biologic Refractory Studies: Orencia (BMS) – ATTAIN, Rituxan (Roche) – REFLEX, Actemra /8mg/kg (Roche) – RADIATE, Xeljanz /5mg bid (Phase III)
² Jak Inhibitors Biologic Refractory Studies: baricitinib/4mg (Eli Lilly/Incyte) – RA – BEACON, ABT-494 /12mg (AbbVie) – Phase IIB

Upcoming Planned Milestones and Catalysts Over the Next 12 Months

- **MPC-150-IM**
 - Phase 3 interim analysis for Class II/III (1Q CY17)
 - Phase 2B complete trial enrollment for Class IV (Mid-17)
 - Phase 2B data read-out Class IV (4Q CY17)
- **MSC-100-IV**
 - Phase 3 complete trial enrollment (1H CY17)
 - Phase 3 data read-out (4Q CY17)
- **MPC-06-ID**
 - Phase 3 complete trial enrollment (2H CY17)
- **MPC-300-IV**
 - 9-Month data readout (1H CY17)
- **Potential corporate partnerships**



A microscopic image showing numerous cells, likely stem cells or cancer cells, with a blue fluorescent glow. The cells are spherical and densely packed, with some showing internal structures. The background is dark, making the blue fluorescence stand out.

Cellular medicines offer
unique solutions to intractable
medical challenges

Thank You



