

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 February 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

INFORMATION CONTAINED ON THIS REPORT ON FORM 6-K

On February 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.

On February 16, 2017, Mesoblast Limited filed with the Australian Securities Exchange a new release announcement, which is attached hereto as [Exhibit 99.2](#), and is incorporated herein by reference.

On February 16, 2017, Mesoblast Limited filed with the Australian Securities Exchange an investor presentation, which is attached hereto as [Exhibit 99.3](#), 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: February 17, 2017

INDEX TO EXHIBITS

Item

- 99.1 Press release of Mesoblast Ltd, dated February 13, 2017.
- 99.2 Press release of Mesoblast Ltd, dated February 16, 2017.
- 99.3 Investor presentation of Mesoblast Ltd, dated February 16, 2017.

PUBLISHED STUDY RESULTS SHOW THAT MESOBLAST CELLS ADMINISTERED INTRAVENOUSLY SIGNIFICANTLY AMELIORATE JOINT DISEASE IN MODEL OF EARLY RHEUMATOID ARTHRITIS

Study provides translational and mechanistic support for Phase 2 trial results of Mesoblast's cell therapy in patients with biologic refractory rheumatoid arthritis

Melbourne, Australia and New York, USA; February 13, 2017: Mesoblast Limited (ASX: MSB; Nasdaq: MESO) today announced results of a new study published in the current issue of the peer-reviewed journal *Stem Cell Research & Therapy*, showing that a single intravenous infusion of 150 million of the Company's proprietary allogeneic "off-the-shelf" STRO-3 immunoselected Mesenchymal Precursor Cells (MPCs) significantly improved clinical disease severity, reduced joint cartilage erosions, and improved synovial inflammation and histopathology in a large animal model of early rheumatoid arthritis (RA).¹

This is the first study to show that intravenously administered STRO-1/STRO-3 immunoselected MPCs can ameliorate clinical and histopathologic disease severity in a large animal model of collagen-induced arthritis, a highly relevant and predictive model of human RA. The study's lead investigators, from the Faculty of Veterinary and Agricultural Sciences, University of Melbourne, compared treatment with a single intravenous infusion of either 150 million allogeneic, STRO-3 immunoselected and culture-expanded sheep MPCs or saline in 16 sheep with early collagen-induced arthritis. This well-established large animal model of human RA is driven by multiple pro-inflammatory cytokines produced by synovial fibroblasts, T cells and monocytes, and progresses from monoarthritis early in the disease to inflammation of multiple joints (polyarthritis), cartilage erosions, and joint destruction.²

Mesenchymal lineage precursors and stem cells have been shown to be capable of targeting mechanistic pathways that are central to the process of progressive RA in humans, including by inhibiting the joint synovial fibroblast pro-inflammatory factor NF-kappaB that is implicated in synovial proliferation, inflammation, and joint destruction, and by polarizing pro-inflammatory monocytes and T cells to anti-inflammatory states. Notably, STRO-1 positive MPCs have been shown to be at least 10-fold more potent inhibitors of T-cell activation and proliferation than conventional plastic-adherent Mesenchymal Stem Cells (MSCs).³

Key clinical, immunologic, and histopathologic outcomes of the study were:

- Within two days, the MPC-treated group showed significantly faster decline of elevated neutrophil numbers in the blood than saline-treated controls, a white blood cell type that plays a critical role in the clinical manifestations of RA, gout and other inflammatory joint diseases in humans
- Within four days, and over the two-week study period, the MPC-treated group had a significantly lower composite clinical score of lameness, joint swelling and pain compared with saline-treated controls, with significant improvements seen in each of these clinical parameters
- Markers of inflammation in the blood (interleukin 17 and Activin A) were significantly reduced in the MPC-treated group compared with saline-treated controls over the two-week study period
- At the end of the study, the MPC-treated group showed significantly less joint destruction and joint inflammation compared with saline-treated controls, as evidenced by:
 - o significantly reduced joint cartilage erosions
 - o significantly reduced levels of activated synovial fibroblasts and fibrosis
 - o significantly reduced infiltration of synovial tissues with monocytes and CD4 T cells, and;
 - o significantly reduced blood vessel formation within the synovial tissues

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• All of these histopathologic components ameliorated by MPC treatment are key features associated with progressive joint disease and destruction in patients with active RA.

This study shows that Mesoblast's MPCs administered intravenously can significantly ameliorate inflammatory arthritis, and provides important mechanistic and translational support for the improved clinical outcomes previously reported in the ongoing Phase 2 trial with Mesoblast's product candidate MPC-300-IV in patients with RA who are refractory to TNF-alpha inhibitors and other biologic agents.⁴

¹ Abdalmula et al. Stem Cell Research & Therapy (2017) 8:22. Available at: <https://stemcellres.biomedcentral.com/articles/10.1186/s13287-016-0460-7>.

² Abdalmula et al. Vet Immunol Immunopathol. (2014); 159:83.

³ Nasef et al. Int. Jnl. Lab. Hem. (2009) 31, 9.

⁴ Trial NCT01851070. Additional information available at: <https://clinicaltrials.gov/show/NCT01851070>

About Mesoblast

Mesoblast Limited (ASX:MSB; Nasdaq:MESO) is a global leader in developing innovative cell-based medicines. The Company has leveraged its proprietary technology platform, which is based on specialized cells known as mesenchymal lineage adult stem cells, to establish a broad portfolio of late-stage product candidates. Mesoblast's allogeneic, 'off-the-shelf' cell product candidates target advanced stages of diseases with high, unmet medical needs including cardiovascular diseases, immune-mediated and inflammatory disorders, orthopedic disorders, and oncologic/hematologic conditions.

Forward-Looking Statements

This press release 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. 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 press release together with our 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, and 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.

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DURABLE RESPONSES AND SUSTAINED LOW DISEASE ACTIVITY OVER NINE MONTHS AFTER A SINGLE DOSE OF MESOBLAST CELL THERAPY IN RHEUMATOID ARTHRITIS PATIENTS RESISTANT TO ANTI-TNF AGENTS
Key points:

- A single intravenous infusion of Mesoblast's allogeneic "off-the-shelf" Mesenchymal Precursor Cells (MPCs) resulted in durable responses through nine months (39 weeks) in a 48-patient placebo-controlled, randomized Phase 2 trial in rheumatoid arthritis (RA) patients resistant to anti-Tumor Necrosis Factor (TNF) agents
- The safety profile over 39 weeks was comparable among the placebo and both MPC treatment groups, with no cell-related serious adverse events
- Both MPC doses outperformed placebo at week 39 in each of ACR20/50/70 responses, as well as by median ACR-N analysis
- Continuous variables ACR-N, HAQ-DI and DAS-28 were used in line with the FDA Guidance For Industry Rheumatoid Arthritis: Developing Drug Products For Treatment, May 2013, and identified the 2 million MPC/kg dose as the most effective over 39 weeks
- The 2 million MPC/kg dose showed the earliest and most sustained treatment benefit
- The RA population resistant to anti-TNF agents constitutes about one-third of patients treated with these agents, is the fastest growing branded market segment within the \$19 billion global RA biologics market, and is set to grow further as multiple anti-TNF biosimilars become available; the goal of therapy in these patients is to achieve early and sustained low disease activity which correlates with prevention of structural joint damage in RA
- Given the serious nature of anti-TNF resistant RA, MPC-300-IV is well-positioned to be developed as a regenerative advanced therapy to target this major unmet medical need

New York; USA; and Melbourne, Australia; February 16, 2017: Mesoblast Limited (ASX:MSB; Nasdaq:MESO) today announced 39-week data from its Phase 2 trial in patients with rheumatoid arthritis (RA) resistant to anti-Tumor Necrosis Factor (TNF) agents. The results showed that a single intravenous infusion of the Company's proprietary allogeneic cell therapy product candidate, MPC-300-IV, was well tolerated and demonstrated a durable improvement in clinical symptoms, physical function, and disease activity relative to placebo over this period of follow-up.

Mesoblast Chief Executive Silviu Itescu commented: "The nine-month outcomes generated from this study are highly encouraging. The early and durable effects seen from a single infusion of 2 million MPC/kg support the potential of our allogeneic cell therapy to be positioned as an early treatment option for patients resistant to anti-TNF agents."

Major advances in the treatment of RA using biologic agents have resulted in a \$19 billion global market in 2016, the majority of which is due to use of anti-TNF agents. The RA population resistant to anti-TNF agents, which constitutes about one-third of patients treated with anti-TNF agents, is the fastest growing branded market segment within the global RA biologics market, and is set to grow further as multiple anti-TNF biosimilars become available.

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Mesoblast's Phase 2 trial recruited a total of 48 patients with active RA who were on a stable regimen of methotrexate and had an inadequate prior clinical response to at least one anti-TNF agent. Of the 48 patients, 30 (63%) had previously received 1-2 biologic agents. Patients were randomized to a single intravenous infusion of 1 million MPCs/kg (1M/kg, n=16), 2 million MPCs/kg (2M/kg, n=16) or placebo (n=16). The study was comprised of a 12 week primary study period, and a total study duration of 52 weeks.

The primary objective of the study was to evaluate safety and tolerability of a single intravenous MPC infusion in these biologic refractory RA patients through a 12 week primary endpoint. Additional objectives were to evaluate clinical efficacy at the 12 week endpoint and to assess the durability of effects and safety profile through the full 52 week study.

Pre-specified efficacy endpoints included the following: American College of Rheumatology (ACR) composite clinical response, which is an endpoint used in RA clinical trials to measure improvement in signs and symptoms of the disease in terms of 20%, 50% or 70% improvement from baseline; ACR-N which measures the mean or median magnitude of benefit using an ACR composite for a typical patient; the health assessment questionnaire-disability index (HAQ-DI), a standardized measure of functional status; and the DAS28 composite measurement of disease activity; no adjustment for multiplicity was performed as these efficacy endpoints were exploratory and the trial was not powered for efficacy.

Additionally, continuous variables ACR-N, HAQ-DI and DAS-28 were evaluated in a pre-specified manner since the use of endpoints sensitive to change provide better discriminatory power for dose-response assessment, in line with the FDA Guidance For Industry Rheumatoid Arthritis: Developing Drug Products For Treatment, May 2013.

Analyses were performed for the whole study population and for the pre-specified exploratory subgroups based on whether the subjects had previously received 1-2 biologic agents or more than 2 biologic agents.

Key results over nine months are shown in detail in the tables below, and were:

- A single intravenous MPC infusion of either 1 million or 2 million MPC/kg resulted in durable responses through nine months (39 weeks) in the 48-patient placebo-controlled, randomized Phase 2 trial in patients who have failed one or more TNF inhibitors
- The safety profile over 39 weeks was comparable among the placebo and both MPC treatment groups, with no cell-related serious adverse events
- Both MPC doses outperformed placebo at week 39 in each of ACR20/50/70 responses
- Both MPC doses outperformed placebo at week 39 in the proportion of patients who achieved the target of low disease activity (DAS-28_{≤3.2}); disease remission (DAS 28 <2.6) was seen at similar levels across all groups
- Use of continuous variables ACR-N, HAQ-DI and DAS-28, in line with FDA guidance for dose-finding Phase 2 trials of new RA therapies, identified the 2 million MPC/kg dose as the most effective over 39 weeks
- While both MPC doses achieved higher median ACR-N scores compared with placebo at 39 weeks, the 2 million MPC/kg dose achieved the maximal ACR-N score earlier, at 12 weeks
- Over the entire 39 weeks, the 2 million MPC/kg MPC group had a significantly greater ACR-N Area Under the Curve (AUC) than placebo, indicating a more robust durable effect with the higher treatment dose

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- At 39 weeks, there was a dose-dependent treatment effect on mean change from baseline in function (HAQ-DI) and disease activity score (DAS-28), with the 2 million MPC/kg dose showing the greatest effect
- MPC treatment effects for all parameters were greatest in patients who had failed 1-2 biologic agents

Summary of Key Efficacy Responses at Three and Nine Months for All Subjects:

	Week 12			Week 39		
	Placebo	1M/kg	2M/kg	Placebo	1M/kg	2M/kg
	N=16	N=16	N=16	N=16	N=16	N=16
ACR20	50%	47%	53%#	36%	69%	57%
ACR50	19%	27%	40%#	14%	31%	21%
ACR70	0%	20%	27%*	0%	23%	21%
ACR-N median	20%	11%	28%	9%	27%	27%
ACR-N mean Area Under Curve (AUC)	204.7	602.6	1476.3*	1952.4	3033.4	8326.4*
HAQ-DI <-0.22	38%	53%	93%*	46%	75%	64%
HAQ-DI (LS mean change from baseline)	-0.2	-0.3	-0.5*#	-0.1	-0.5	-0.5*
DAS28-CRP (LS mean change from baseline)	-1.4	-1.3	-2.0	-1.8	-1.9	-2.4
DAS28-CRP ≤3.2	19%	27%	36%	29%	54%	50%

* p<0.05 with p-values vs. placebo from Fisher's exact test for frequencies, from ANCOVA model using treatment as factor and baseline value as covariate for mean change, from one-way ANOVA on ranks for median ACR-N, and from t-test on log-transformed geometric mean for ACR-N AUC.

week 12 results have been updated following access to additional patient visit data.

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Summary of Key Efficacy Responses at Three and Nine Months for Subgroup with Prior Use of 1-2 Biologics:

	Week 12			Week 39		
	Placebo	1M/kg	2M/kg	Placebo	1M/kg	2M/kg
	N=9	N=10	N=11	N=9	N=10	N=11
ACR20	33%	60%	55%	22%	67%	60%
ACR50	11%	30%	55%	0%	33%	30%
ACR70	0%	20%	36%	0%	22%	30%
ACR-N median	13%	28%	50%	6%	43%	48%*
ACR-N mean Area Under Curve (AUC)	-393.0	1629.8	1713.8	-1567.0	7786.6*	10102.9*
HAQ-DI <-0.22	33%	60%	91%*	44%	67%	70%
HAQ-DI (LS mean change from baseline)	-0.1	-0.4	-0.6#	-0.1	-0.4	-0.6*
DAS28-CRP (LS mean change from baseline)	-1.1	-1.8	-2.4	-1.8	-2.0	-2.8
DAS28-CRP ≤3.2	22%	30%	40%	33%	56%	67%

*p<0.05 with p-values vs. placebo from Fisher's exact test for frequencies, from ANCOVA model using treatment as factor and baseline value as covariate for mean change, from one-way ANOVA on ranks for median ACR-N, and from t-test on log-transformed geometric mean for ACR-N AUC.

#week 12 results have been updated following access to additional patient visit data.

About Rheumatoid Arthritis

RA is a chronic autoimmune disease of unknown etiology, affecting approximately one percent of the global population. The disease is attributed to chronic inflammation affecting the synovial membrane of multiple joints, which eventually leads to cartilage and bone destruction. The health-related quality of life in patients with RA is significantly impaired by pain, fatigue, and decline in musculoskeletal function. RA is associated with an increased risk of cardiovascular disease and mortality.

Standard criteria established by the American College of Rheumatology (ACR) and the European League Against Rheumatism (EULAR) are used to assess the effectiveness of RA treatments. The ACR20/50/70 response is a composite measure based on achieving 20%/50%/70% improvement in tender joint counts (TJC) or swollen joint counts (SJC) plus improvement in three of the following:

- Patient global assessment
- Physician global assessment
- Patient pain assessment
- Physical function/disability questionnaire (HAQ-DI)
- Acute phase reactant (sedimentation rate or high-sensitivity C-reactive protein)

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The patient and physician global assessments and pain assessment are measured using a visual analogue scale on a scale of 0-100. The ACR-N provides a single number that characterizes the percentage of improvement or deterioration from baseline that a patient has experienced in analogy to ACR20, ACR50, and ACR70 responses. The ACR-N is defined operationally as the lowest of 3 values (the percent change in the SJC, the percent change in the TJC, and the median of the other 5 measures in the ACR core data set). The ACR-N can be used to measure improvement at specific time points in a landmark analysis and expressed as the mean or median ACR-N achieved, or to compare the area under the curve (AUC) by patient over time. This approach may substantially increase the power to detect small differences between treatment arms.

The HAQ-DI assesses physical function in performing a variety of activities of daily living and yields a score ranging from 0-3 (lower is better). A reduction in the HAQ-DI score of -0.22 is the minimal clinically important difference. The DAS28 is another validated RA disease activity index based on a 28 joint count. The derived DAS28 scores are comprised of tender joint count; swollen joint count; acute phase reactant (hsCRP or ESR) and the subject's global assessment of disease but do not include measures of pain or physical function. High disease activity is defined as DAS28 score >5.1; moderate disease activity is defined as DAS28 scores between 5.1-3.2; low disease activity and remission are defined as DAS28 scores of \leq 3.2 and <2.6, respectively.

In line with the FDA Guidance For Industry Rheumatoid Arthritis: Developing Drug Products For Treatment, May 2013, for dose-ranging studies the use of endpoints sensitive to change provide better discriminatory power for dose-response assessment. A clinical endpoint such as the ACR20 response criteria may not be optimal for this purpose, because it is a dichotomous endpoint, and using the proportion of responders in a small group of patients could be unreliable. Continuous variables such as DAS28, HAQ-DI, and ACR-N may be more sensitive to change and provide a more suitable alternative to ACR responder index. For continuous variables where changes from baseline are reported, the Least Squares of the Mean (ANCOVA) is utilized in order to adjust for baseline differences between groups.

About Mesoblast's Product Candidate MPC-300-IV and Potential Mechanisms of Action

Mesoblast's Tier 1 product candidate, MPC-300-IV, comprises 1-2 million immunoselected and culture-expanded STRO-1 positive cells/kilogram which are intravenously delivered. These cells express receptors for various pro-inflammatory cytokines, including TNF-alpha, interleukin-6, or interleukin-17, and are triggered by these cytokines to release potent immunomodulatory factors.

Mesenchymal lineage precursors and stem cells have been shown to be capable of targeting mechanistic pathways that are central to the process of progressive RA in humans, including by inhibiting the joint synovial fibroblast pro-inflammatory factor NF-kappaB that is implicated in synovial proliferation, inflammation, and joint destruction, and by polarizing pro-inflammatory monocytes and T cells to anti-inflammatory states. Notably, STRO-1 positive MPCs have been shown to be at least 10-fold more potent inhibitors of T-cell activation and proliferation than conventional plastic-adherent mesenchymal lineage cells.¹

As reported on February 13, 2016, in the current version of *Stem Cell Research & Therapy*, published results in a sheep model of early RA showed that Mesoblast's MPCs administered intravenously significantly ameliorated inflammatory arthritis, providing important mechanistic and translational support for the improved clinical outcomes seen in this ongoing Phase 2 trial in patients resistant to anti-TNF agents.²

About Mesoblast

Mesoblast Limited (ASX:MSB; Nasdaq:MESO) is a global leader in developing innovative cell-based medicines. The Company has leveraged its proprietary technology platform, which is based on specialized cells known as mesenchymal lineage adult stem cells, to establish a broad portfolio of late-stage product candidates. Mesoblast's allogeneic, 'off-the-shelf' cell product candidates target advanced stages of diseases with high, unmet medical needs including cardiovascular diseases, immune-mediated and inflammatory disorders, orthopedic disorders, and oncologic/hematologic conditions.

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Conference Call and Webcast Details

Mesoblast will hold a conference call beginning at 9:00 am Australian Eastern Summer Time on Thursday February 16, 2017 / 5:00 pm Eastern Standard Time on Wednesday February 15, 2017.

The live webcast can be accessed via: <http://webcasting.boardroom.media/broadcast/589d209414b644e6232ccb86>

To access the call, please dial:

Australia Toll Free	1 800 558 698
Australia Alternate	1 800 809 971
United States	1 855 881 1339
United Kingdom	0800 051 8245
Japan	0053 116 1281
Singapore	800 101 2785
Hong Kong	800 966 806
International	+61 2 9007 3187

The conference identification code is 957783.

Forward-Looking Statements

This press release 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. 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 press release together with our 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, and 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.

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MPC-300-IV: Week 39 Results in Biological Refractory Rheumatoid Arthritis

February 2017



CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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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 immuno-selected 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.

MPC-300-IV:

Biologic Refractory Rheumatoid Arthritis (RA) – Market Landscape

Market Size

- There are 6.0 million prevalent cases in the US, Japan, and EU5, of which there were 2.9 million in the US alone in 2016¹
- Incidence increases with age – 8.7 per 100,000 for ages 18-34 vs. 89 per 100,000 for ages 65-74²
- In 2016, RA treatment was greater than \$19 billion global market and is projected to grow to over \$22.5 billion 2025 primarily due to sales of oral JAK inhibitors.³
- ~30% of patients do not respond or cannot tolerate anti-TNF or other biologic therapies
- In the US, the anti-TNF refractory population is the fastest growing branded market segment, projected to increase by ~8% annually and potentially higher with the expected market entry and greater availability of anti-TNF biosimilars³

1. GlobalData®, Rheumatoid Arthritis Global Forecast 2015-2025 0- January 2017
2. Decision Resources Rheumatoid Arthritis Dec 2015
3. Decision Resources Rheumatoid Arthritis April 2016

MPC-300-IV:

Biologic Refractory Rheumatoid Arthritis (RA) – Market Landscape

Significant Unmet Need

- One third of RA patients do not respond or cannot tolerate current biologic therapies
 - *Sustained low disease activity or remission is seen in low numbers of patients who are refractory to anti-TNF agents and are treated with alternative biologic agents²*
 - *Biologics are associated with increased incidence of opportunistic infections and malignancies*
- Biologics only target single cytokine pathways even though RA involves multiple signals / pathways
- Need for disease-modifying therapies that are well tolerated and induce low disease activity or remission in a greater percentage of patients as early as possible in the disease management

Significant Economic Burden

- In the US alone, total annual societal costs of RA are estimated at \$39.2bn.⁴

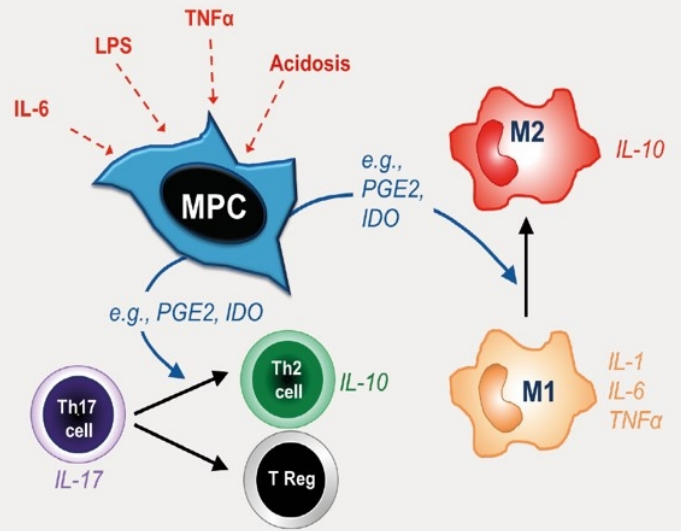
2. Decision Resources. Rheumatoid Arthritis Dec 2015

4. Bimbaum, H., Pike, C., Kaufman, R. (2010) Societal cost of rheumatoid arthritis patients in the US. Curr Med Res Opin. Jan;26(1):77-90

MPC-300-IV for treatment of Chronic Inflammatory Diseases through Immunomodulation

Inflammation induces production of immuno-modulatory factors by STRO-1+ Mesenchymal Precursor Cells (MPCs), which regulate multiple immune pathways concurrently

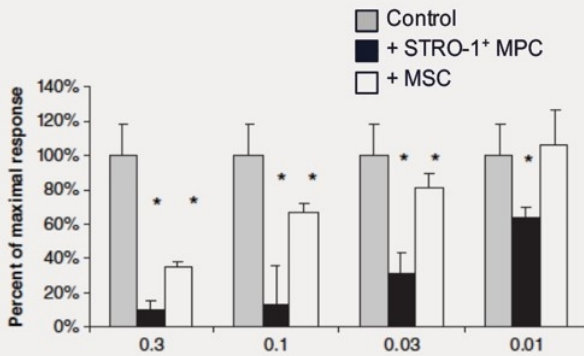
- MPCs have receptors that respond to inflammatory signals, resulting in release of anti-inflammatory mediators
- Mesoblast is developing MPC product candidates to target immune mediated diseases where multiple pathways are associated with treatment resistant disease
- MPCs have to date demonstrated a safe profile in terms of infectious or neoplastic complications



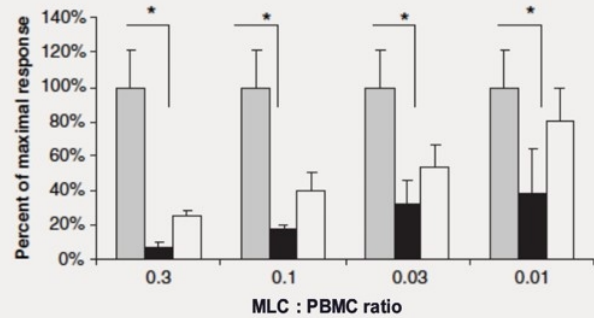
STRO-1+ MPCs are more immunosuppressive than plastic adherent mesenchymal lineage cells



A. Mixed Lymphocyte Culture



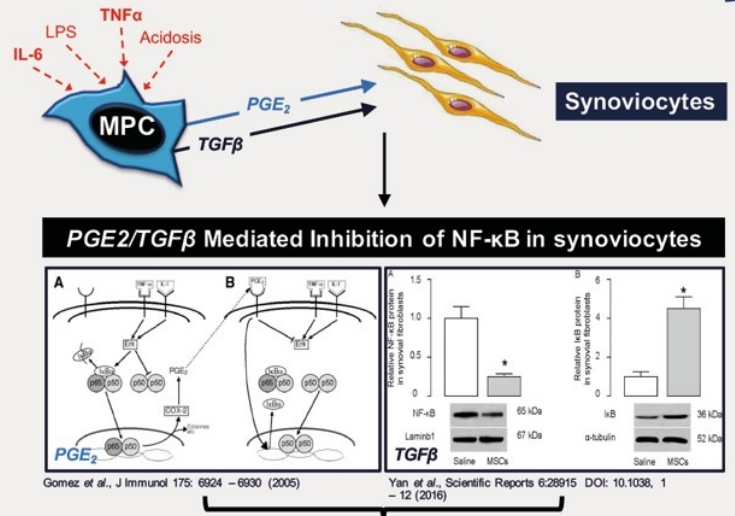
B. Mitogen Stimulation



- STRO-1 selected MPC elicit approximately 10-fold greater levels of inhibition of T-cell proliferation *in vitro* than MSC from the same donor
- Enhanced potency of STRO-1 selected cells correlated with increased expression of immunomodulatory factors (including IDO and HLA-G)

MPC-300-IV for modulation of Cytokine production by Synoviocytes/Synovial fibroblasts in Rheumatoid Arthritis

- PGE₂ and TGFβ secreted by MPCs following surface signaling in inflamed joint
- Both act directly on synovial fibroblasts to increase IκappaB and inhibit NFκappaB
- Secretion of inflammatory cytokines associated with joint pathology reduced



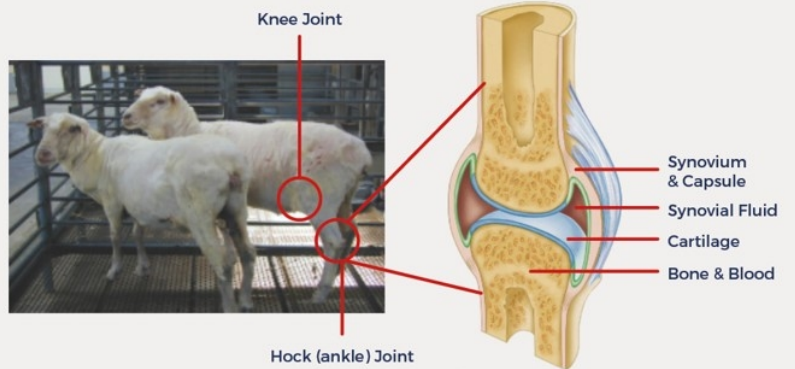
Reduced secretion of inflammatory mediators:
 TNFα, IL-1, IL-6, IL-8, MCP-1, MMP-3, MMP-13

A sheep model of Collagen-Induced Arthritis (CIA)*



Aim: to determine the anti-inflammatory effects and dose ranging of ovine MPCs in an ovine model of collagen-induced acute arthritis (CIA) and systemic inflammation

Dosed: administered by IV injection: 150 million ovine allogeneic MPC or placebo on day 29 in initial study (n=40) for clinical outcomes, and 25, 75, or 150 million ovine allogeneic MPCs or placebo on day 42 for second study (n=15) to evaluate joint cytokine levels

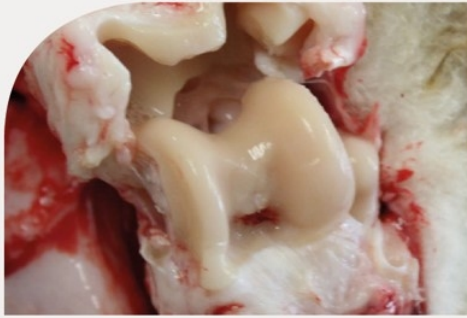


*Thorpe et al. *Clinical & Exp. Rheumatology* 10: 143-150 (1992)

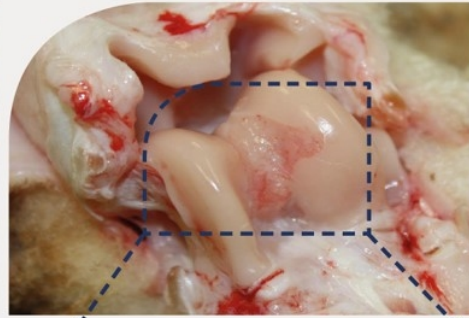
Features of CIA and Human RA: Invading Synovial Pannus and Cartilage Erosion



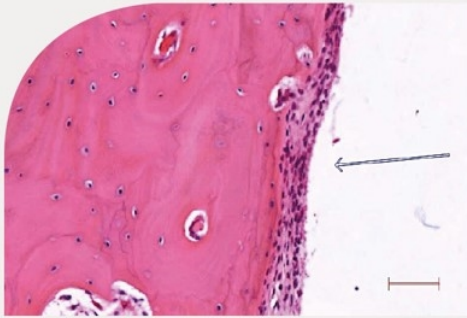
Normal joint



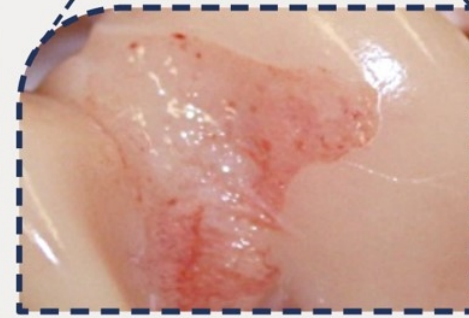
Col II Injected
Joint (Day 42)



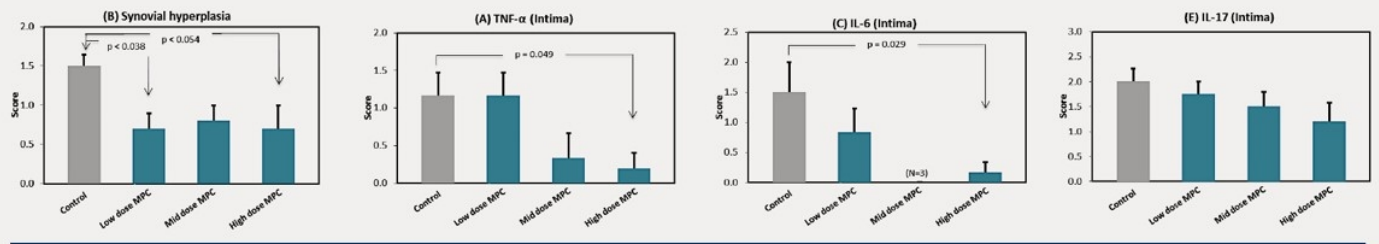
Inflammatory
Cell Pannus



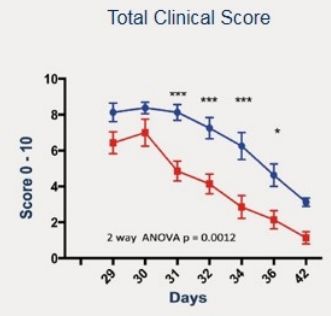
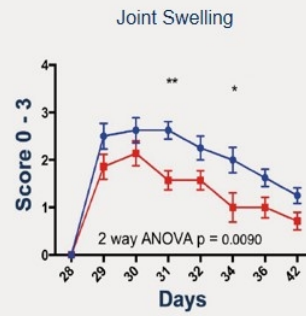
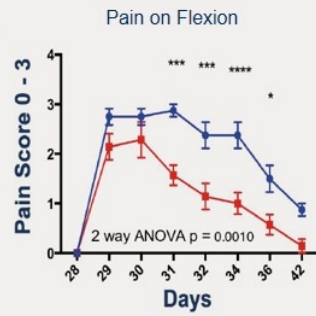
Erosion of
Cartilage



Allogeneic sheep MPCs reduce Synovial Pannus / Inflammatory Cytokines, improve symptoms in CIA



+ 150 million MPC (N = 7)
+ Control Saline (N = 8)



MSB-RA001:

Study design

- Phase 2 double-blind, randomized, placebo-controlled, dose-escalating study comparing a single infusion of two MPC doses (1M/kg and 2M/kg) with placebo in patients with active RA
 - *Inadequate response to at least 1 anti-TNF +/- other biologics*
 - *On a stable regimen methotrexate for >4 months +/- DMARDs for >3 months*
 - *+ RF and/or anti-CCP*; ≥ 4 swollen/tender joints; ESR or CRP > upper limit of normal*
- 48 patients enrolled at 14 sites in US and Australia**
 - *MPC 1 x 10⁶ cells/kg (N=16 active)*
 - *MPC 2 x 10⁶ cells/kg (N=16)*
 - *Placebo (N=16)*

*RF=Rheumatoid factor; anti-CCP=Cyclic citrullinated peptide antibody
** ClinicalTrials.gov Identifier: NCT01851070

MSB-RA001:

Study design

- Objectives

- Primary: Evaluate safety and tolerability of a single intravenous MPC infusion in biologic refractory RA patients through a 12-week primary endpoint
- Secondary: Evaluate clinical efficacy at week 4, 12, 39 and 52 and assess durability of clinical effects and safety through the full 52 week study
- Pre-specified efficacy endpoints include the American College of Rheumatology (ACR 20/50/70, ACR-N) composite clinical responses, the health assessment questionnaire-disability index (HAQ-DI), and the DAS28 composite measurement of disease activity; analyses were applied to the whole study population and the pre-specified exploratory subgroup based on whether the subjects had previously received 1-2 or ≥ 3 biologic agents.

MSB-RA001:

Safety conclusions through 39 weeks

- Infusions were well-tolerated without any acute infusion reactions or adverse events (AEs) reported either during infusion or the 6-h post-infusion monitoring period
- No treatment related SAEs reported during the 39 week period
- No discontinuations due to AEs during the 39-week study period
- Equivalent rates of AEs across treatment groups
- The safety profile over 39 weeks was comparable among the placebo and two MPC treatment groups

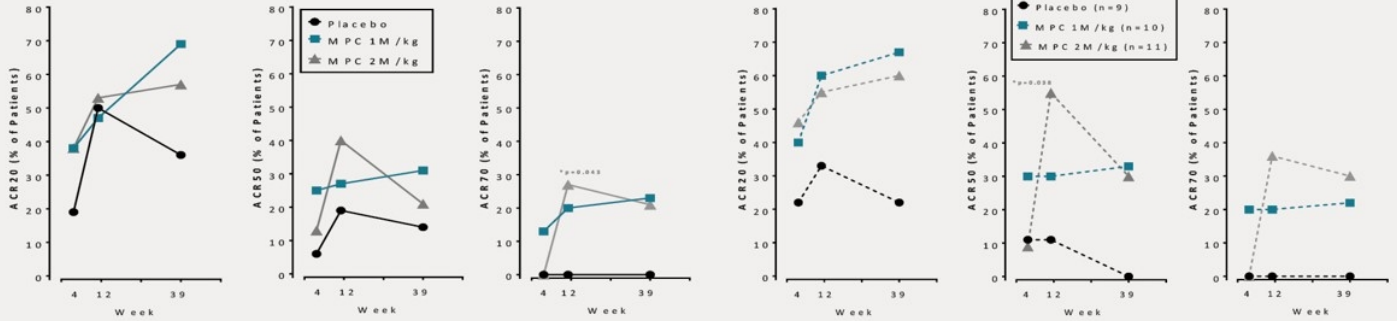
RA001:

Percent Achieving ACR20, 50 and 70 Response over 39 Weeks



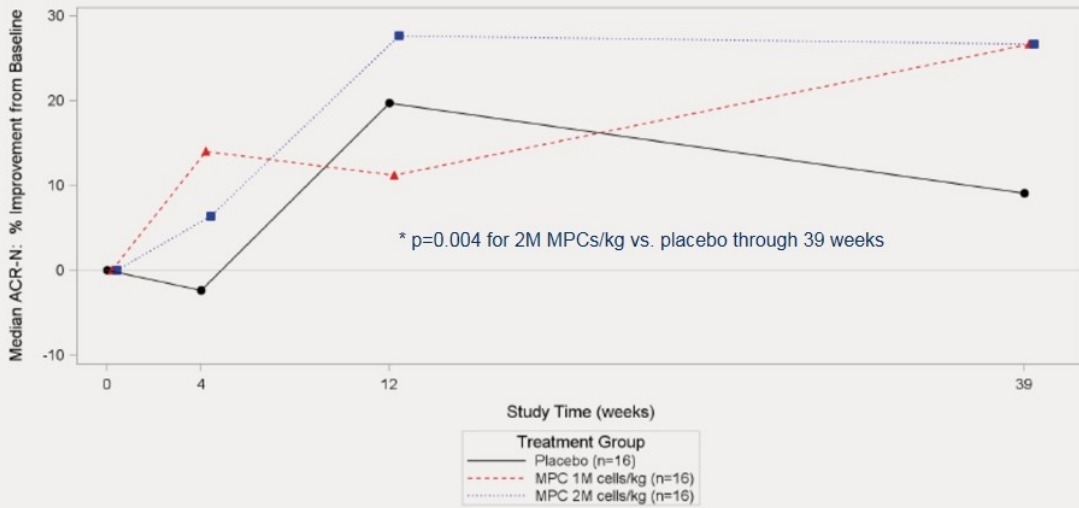
All Subjects

1-2 Prior Biologics



1. Values are observed n/N (%) at each time point
2. *P values vs. Placebo computed using Fisher exact test

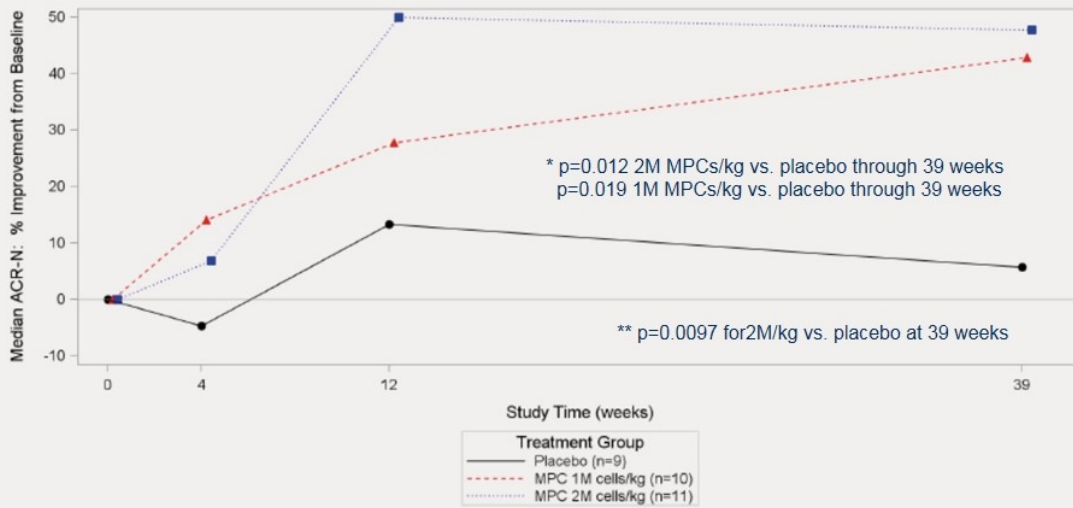
Analysis of ACR-N in all subjects



ACR-N = the lowest of 3 values: percent change in the number of swollen joints, percent change in the number of tender joints, and median of 5 measures in the American College of Rheumatology core data set 1) Patient's global assessment, 2) Physician's global assessment 3) Pain, 4) Physical function, and 5) Acute-phase reactants.
Missing values for individual components are replaced with carried forward values prior to ACR-N derivation.

* p-values vs. placebo for difference in Area Under the Curve (AUC) over 39 weeks using t-test on log-transformed geometric mean for ACR-N.
[Siegel JN, Zhen BG, Arthritis Rheum. 2005 Jun;52\(6\):1637-41.](#)

Analysis of ACR-N in subjects treated with 1-2 prior biologics



ACR-N = the lowest of 3 values: percent change in the number of swollen joints, percent change in the number of tender joints, and median of 5 measures in the American College of Rheumatology core data set 1) Patient's global assessment, 2) Physician's global assessment 3) Pain, 4) Physical function, and 5) Acute-phase reactants.
 Missing values for individual components are replaced with carried forward values prior to ACR-N derivation.

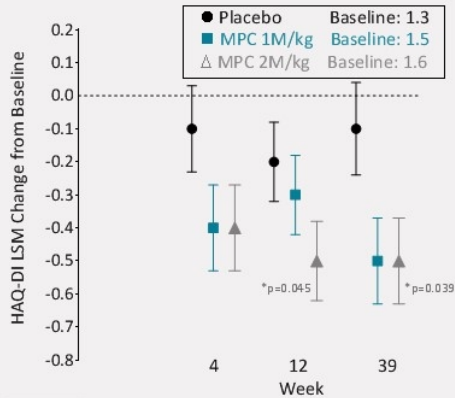
* p-values vs. placebo for difference in Area Under the Curve (AUC) over 39 weeks using t-test on log-transformed geometric mean for ACR-N;
 ** p-values vs. placebo for difference in median values at week 39 are from one-way ANOVA on ranks.

Health Assessment Questionnaire – Disability Index (HAQ-DI)

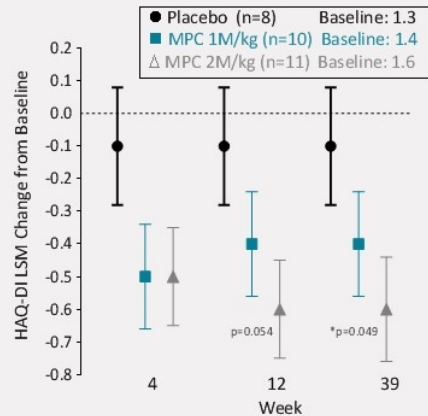
Least Squares Mean (SE) Change from Baseline at 4 , 12 and 39 Weeks



All Subjects



1-2 Prior Biologics



1. LS Mean= Least squares mean change from baseline from ANCOVA
2. HAQ-DI range is 0 to 3 (higher is worse)
3. *P value vs. Placebo from ANCOVA model using treatment as factor and baseline value as covariate

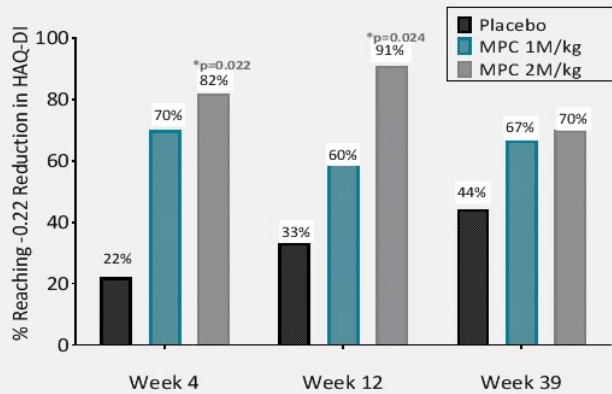
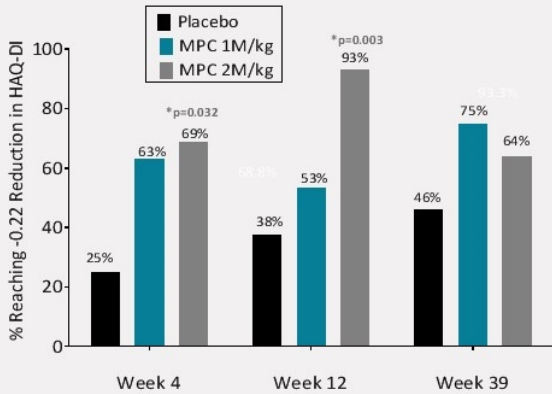
Health Assessment Questionnaire – Disability Index (HAQ-DI)

Percent that reached minimal clinically important reduction of -0.22 at 4, 12 and 39 weeks



All Subjects

1-2 Prior Biologics

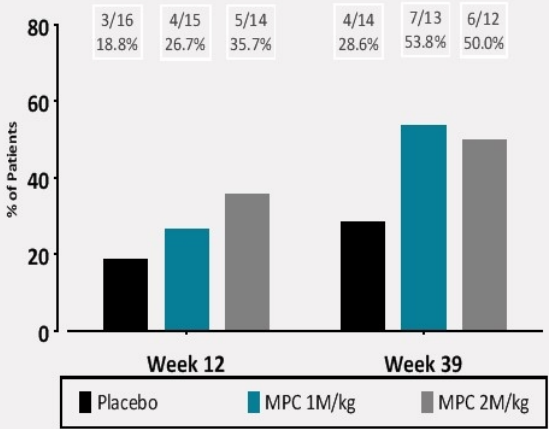


*P values vs. Placebo computed using Fisher's exact test (Observed values)

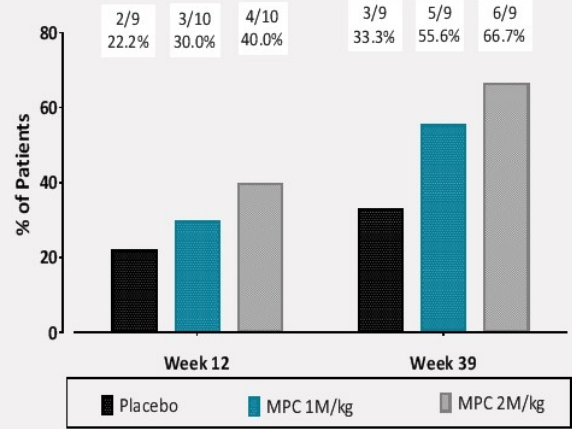
Percent of patients achieving Low Disease Activity Score (DAS28-CRP ≤ 3.2)



All Subjects



1-2 Prior Biologics



Summary of Key Efficacy Responses at 3 and 9 Months

All Subjects

	Week 12			Week 39		
	Placebo	1M/kg	2M/kg	Placebo	1M/kg	2M/kg
	N=16	N=16	N=16	N=16	N=16	N=16
ACR20	50%	47%	53%	36%	69%	57%
ACR50	19%	27%	40%	14%	31%	21%
ACR70	0%	20%	27%*	0%	23%	21%
ACR-N median	20%	11%	28%	9%	27%	27%
ACR-N mean Area Under Curve (AUC)	204.7	602.6	1476.3*	1952.4	3033.4	8326.4*
HAQ-DI <-0.22	38%	53%	93%*	46%	75%	64%
HAQ-DI (LS mean change from baseline)	-0.2	-0.3	-0.5*	-0.1	-0.5	-0.5*
DAS28-CRP (LS mean change from baseline)	-1.4	-1.3	-2.0	-1.8	-1.9	-2.4
DAS28-CRP ≤3.2	19%	27%	36%	29%	54%	50%

* p<0.05 with p-values vs. placebo from Fisher's exact test for frequencies, from ANCOVA model using treatment as factor and baseline value as covariate for mean change, from one-way ANOVA on ranks for median ACR-N, and from t-test on log-transformed geometric mean for ACR-N AUC.

Summary of Key Efficacy Responses at 3 and 9 Months

for Subgroup with Prior Use of 1-2 Biologics

	Week 12			Week 39		
	Placebo	1M/kg	2M/kg	Placebo	1M/kg	2M/kg
	N=9	N=10	N=11	N=9	N=10	N=11
ACR20	33%	60%	55%	22%	67%	60%
ACR50	11%	30%	55%	0%	33%	30%
ACR70	0%	20%	36%	0%	22%	30%
ACR-N median	13%	28%	50%	6%	43%	48% *
ACR-N mean Area Under Curve (AUC)	-393.0	1629.8	1713.8	-1567.0	7786.6*	10102.9*
HAQ-DI <-0.22	33%	60%	91%*	44%	67%	70%
HAQ-DI (LS mean change from baseline)	-0.1	-0.4	-0.6	-0.1	-0.4	-0.6*
DAS28-CRP (LS mean change from baseline)	-1.1	-1.8	-2.4	-1.8	-2.0	-2.8
DAS28-CRP ≤3.2	22%	30%	40%	33%	56%	67%

* p<0.05 with p-values vs. placebo from Fisher's exact test for frequencies, from ANCOVA model using treatment as factor and baseline value as covariate for mean change, from one-way ANOVA on ranks for median ACR-N, and from t-test on log-transformed geometric mean for ACR-N AUC.

MPC-300-IV:

Phase 2 Trial Results Update

- The Phase 2 trial of Mesoblast's allogeneic product candidate, MPC-300-IV, in biologic refractory rheumatoid arthritis will complete when all patients have been followed for 52 weeks
- A single intravenous MPC infusion in biologic refractory RA patients was without serious adverse events over 39 weeks, and resulted in dose-related improvements in clinical symptoms, function, and disease activity
- The 2 million MPC/kg dose showed the earliest and most sustained treatment benefit
- The clinical responses in this Phase 2 trial, together with the safety profile, position MPC-300-IV to become an early treatment option in RA patients who are resistant to or intolerant of anti-TNF or other biologic agents

Given the serious nature of anti-TNF resistant RA, we believe that MPC-300-IV is well-positioned to be developed as a regenerative advanced therapy to target this major unmet medical need.

Thank you



