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 August 2016

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 o

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 o 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 o No ☑

INFORMATION CONTAINED ON THIS REPORT ON FORM 6-K

On August 9, 2016, 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 August 9, 2016, Mesoblast Limited filed with the Australian Securities Exchange an investor presentation, which is attached hereto as Exhibit 99.2, 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: August 10, 2016

INDEX TO EXHIBITS

Item	
99.1	Press release of Mesoblast Ltd, dated August 9, 2016.
99.2	Investor presentation of Mesoblast Ltd, dated August 9, 2016

asx announcement

mesoblast
the regenerative medicine company

PHASE 2 TRIAL RESULTS OF MESOBLAST'S CELL THERAPY SHOW DOSE-RELATED IMPROVEMENTS IN BIOLOGIC REFRACTORY RHEUMATOID ARTHRITIS

Key points:

- The biologic refractory rheumatoid arthritis (RA) population accounts for approximately one-third of all RA patients who have received anti-TNF or other biologic agents, is the fastest growing branded market segment, the hardest to treat, and requires new therapies that are both effective and safe
- Intravenous infusions of allogeneic Mesenchymal Precursor Cells (MPCs) were well tolerated in biologic refractory RA patients and were without serious adverse events over 12 weeks
- A single intravenous MPC infusion in biologic refractory RA patients resulted in dose-related improvements in clinical symptoms, function, and disease activity, with the 2 million MPCs/kg dose providing the greatest benefit
- Importantly, ACR70, the most meaningful measure of clinical improvement, was achieved by significantly more of the high dose MPC-treated than placebo-treated patients at 12 weeks
- In patients who had previously received 1-2 biologics, a single infusion of 2 million MPC/kg resulted in 55% and 36% ACR50 and ACR70 responses, respectively, compared with 11% and 0% of placebo treated patients, and in 91% of patients achieving the minimum clinically important improvement in physical function, defined as a reduction of at least -0.22 in the HAQ-DI, compared with 33% placebo treated patients
- The safety and efficacy results of this trial provide support for the potential of Mesoblast's allogeneic MPCs to be positioned as a first-line treatment option in RA patients who have previously received a prior anti-TNF or other biologic agent
- Given the large market opportunity, Mesoblast's Tier 1 product candidate, MPC-300-IV, is well-positioned to advance through a strategic partnership into Phase 3 development for biologic refractory rheumatoid arthritis

New York; USA; and Melbourne, Australia; 9 August 2016: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), today announced that a single intravenous infusion of its proprietary allogeneic Mesenchymal Precursor Cell (MPC) product candidate, MPC-300-IV, was well tolerated and demonstrated a dose-related improvement in clinical symptoms, physical function, and disease activity relative to placebo through the 12 week primary endpoint in its Phase 2 trial in biologic refractory rheumatoid arthritis.
Dr Allan Gibofsky, Professor of Medicine and Public Health at Weill Cornell Medical College and Attending Rheumatologist at Hospital for Special Surgery in New York, commented: "The safety and efficacy results of this study are very encouraging and suggest that Mesoblast's cell therapy has the potential to fill the major unmet medical need of the biologic refractory RA population, where agents that provide consistent durable effects without the risk of opportunistic infections or malignancies are sorely needed."

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-Tumor Necrosis Factor (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 with a 40 week follow-up for a study total 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 primary 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 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 70%, 50% or 20% improvement from baseline,

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the health assessment questionnaire-disability index (HAQ-DI), a standardized measure of functional status, and the DAS28 composite measurement of disease activity. Analyses were performed for the whole study population and for the pre-specified exploratory subgroup based on whether the subjects had previously received 1-2 or more than 2 biologic agents.

Key results at week 12, shown in detail in the table below, were:

1. Safety:

- Cell infusions were well tolerated with no infusion-related adverse events. There were no serious adverse events, and the safety profile over 12 weeks was comparable among placebo and MPC treatment groups.

2. ACR70/50/20 composite scores measuring degree of clinical responses to treatment:

- There was a dose-related improvement in many of the individual components of the ACR composite following MPC treatment; the 2M/kg group who had previously received 1-2 biologics showed significant improvement over placebo in each of the following categories: swollen joint counts, investigator global assessment, patient global assessment, and patient pain scores.
- ACR70 responses overall showed a dose-related effect after a single MPC infusion, with the greatest effect seen in the 2M/kg group who had previously received 1-2 biologics (36% vs 0% placebo).
- ACR50 responses overall showed a dose-related effect after a single MPC infusion, with the greatest effect seen in the 2M/kg group who had previously received 1-2 biologics (55% vs 11% placebo).
- ACR20 responses were greater in both the 2M/kg and 1M/kg group who had previously received 1-2 biologics than placebo (55% and 60%, respectively, vs 33% placebo).

3. HAQ-DI score measuring functional improvement following treatment:

- A single MPC infusion resulted in a dose-related improvement in function, based on reduction in mean HAQ-DI levels as early as week 4 and sustained reduction in mean HAQ-DI through 12 weeks; maximal effect was seen in the 2M/kg group who had previously received 1-2 biologics (-0.7 vs -0.1 placebo).
- At 12 weeks, MPC treatment resulted in a dose-related increase in the number of patients achieving a minimum clinically important improvement in physical function, defined as a reduction of at least -0.22 in the HAQ-DI; the greatest effect was seen in the 2M/kg group who had previously received 1-2 biologics (91% vs 33% placebo).

4. DAS28 composite score measuring overall disease activity following treatment:

- A single MPC infusion resulted in a dose-related reduction in the mean DAS28 activity score relative to placebo, and in an increase in the number of patients achieving the biologically-meaningful target of low disease activity state, defined as DAS28-CRP $\leq$3.2.

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Summary of Key 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 $\leq$3.2	19%	27%	36%	*>0.1*	22%	30%	40%	*>0.1*

Major advances in the treatment of RA using biologic agents have resulted in a $15 billion global market in 2015, which is projected to grow to over $18 billion in 2024. Over two million patients were treated for RA in the United States alone in 2015, with three million more people in the five major European markets and Japan. Despite the substantial advances in RA treatment using biologic agents such as anti-TNF agents, approximately one third of patients either do not respond sufficiently or cannot tolerate these agents due to infectious or other complications. In the United States, 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 biosimilars.

Mesoblast Chief Executive Silviu Itescu said: “The Phase 2 trial results have indicated a strong efficacy signal and consistent effects of a single MPC infusion on clinical symptoms, functional abilities, and disease activity, without any serious adverse events. These results support the potential of our allogeneic cell therapy to be positioned as a first-line treatment option for biologic refractory patients, where there is a clear need for safe and effective treatments. Given the large market opportunity, our Tier 1 product candidate, MPC-300-IV, is well-positioned to advance through a strategic partnership into Phase 3 development for biologic refractory rheumatoid arthritis.”

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 ACR70/50/20 response is a composite measure based on achieving 70%/50%/20% improvement in tender joint or swollen joint counts plus improvement in three of the following:

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- 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)

The patient and physician global assessments and pain assessment are measured using a visual analogue scale on a scale of 0-100. 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.

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

Mesoblast's Tier 1 product candidate, MPC-300-IV, comprises 2 million immunoselected and culture-expanded Mesenchymal Precursor Cells (MPCs)/kilogram which are intravenously delivered. Existing biologic therapies target individual cytokine pathways thought to be involved in RA disease pathogenesis, including TNF-alpha, interleukin-6, or interleukin-17, but not concomitantly. There are at least two mechanisms of action (MOA) by which MPC-300-IV may impact on clinical rheumatoid arthritis outcomes through concomitant inhibition of multiple cytokine networks:

1. *Immunomodulatory MOA*: Pro-inflammatory monocytes/macrophages and activated T cells are involved in the pathogenesis of RA via joint inflammation and secretion of multiple pro-inflammatory cytokines. In preclinical studies, activation of MPCs by these pro-inflammatory cytokines through specific surface receptors results in release by MPCs of anti-inflammatory mediators including PGE2 and IDO which act on inflammatory target cells. Allogeneic human MPCs secreting PGE2 and IDO, when co-cultured with donor immune cells, switch pro-inflammatory monocytes producing TNF-alpha or IL-6 to an anti-inflammatory phenotype producing IL-10, and switch pro-inflammatory T cells producing IL-17 to anti-inflammatory FoxP3 Tregs producing IL-10.
2. *Synoviocyte Inhibitory MOA*: Pro-inflammatory synoviocytes in the RA joint proliferate highly and secrete multiple cytokines involved in RA disease pathogenesis. The biomolecules PGE2 and TGF-beta, secreted by MPCs following cell surface signalling by inflammatory cytokines, act directly on RA synoviocytes to inhibit the pleiotropic signalling molecule NFkappaB, resulting in reduced synoviocyte proliferation and decreased production by the synoviocytes of the pro-inflammatory factors TNF-alpha, IL-1, IL-6, IL-8, MCP-1, and various metalloproteinases involved in joint inflammation and destructive pathology.

In large animal studies, a single intravenous infusion of Mesoblast's allogeneic MPCs resulted in concomitant inhibition of TNF-alpha, IL-6 and IL-17 inflammatory pathways in the inflamed joints, and substantially ameliorated clinical disease. Biologic refractory RA patients who have received prior anti-TNF or other biologic agents continue to have active inflammatory pathways, and the broad, concomitant targeting of multiple cytokine networks by MPCs may result in clinically meaningful outcomes in this patient group.

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 conditions, orthopedic disorders, immunologic and inflammatory disorders and oncologic/hematologic conditions.

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Conference Call and Webcast Details
Mesoblast will provide a corporate update beginning at 9:00 am Australian Eastern Standard Time on Tuesday 9 August 2016 / 7:00 pm Eastern Daylight Time on Monday 8 August 2016.

The live webcast can be accessed via: http://webcasting.boardroom.media/broadcast/579ff85b557172a161ada516
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 445377.

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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Exhibit 99.2

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the regenerative medicine company

Rheumatoid Arthritis Program: Top-line Phase 2 Results

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 Quarterly Report on Form 6-K 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 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 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. 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.

Greatest Unmet Need in Rheumatoid Arthritis: Biologic Refractory Patients

- In 2016, over 5m individuals are impacted by rheumatoid arthritis (RA) across the 7 major pharmaceutical markets (7MM) with ~70% suffering from moderate to severe disease[1,2]

- Major advances in the treatment of RA using biologic agents have resulted in a $15 billion global market in 2015, which is projected to grow to over $18 billion in 2024
  - Anti-TNFα therapy is the most common first line class of biologic agents across the 7 major markets for moderate-to-severe RA patients who have failed conventional DMARDs

- ~30% of patients do not respond to anti-TNFα therapy or fail to maintain an initial good response over time or experience adverse events leading to treatment discontinuation[3,4]
  - On average, maintenance rates for anti-TNFα therapy at 1 year is ~65% and drops to ~40% at 5 years
  - Switching to a second or third anti-TNFα product results in significantly lower efficacy than is seen with an anti-TNF agent in biologically naive patients

- In the United States, the anti-TNFα refractory population is the fastest growing branded market segment, projected to increase by 8% annually from 2015 to 2024[5]
  - Estimated 90k RA patients in the US are anti-TNFα refractor and receive a non-TNFα inhibitor/Jak Inhibitor representing ~ $2bn USD in 2015. This target population is expected to grow to ~178K in 2024 representing over $3.6bn USD.

[1] GlobalData Rheumatoid Arthritis Global Forecast 2013-2023
[2] Decision Resources: Disease Landscape & Forecast Immune and Inflammatory Disorders – Rheumatoid Arthritis January 2016
[3] Favalli, EG., Biggioggero, M., Marchesoni, A, et. al. (2014) Survival on treatment with second-line biologic therapy: a cohort study comparing cycling and swap strategies. Rheumatology 2014: 53:1664-1668
[4] Flouri, I, Markatseli, TE., Voulgari, P., et. al. (2014) Comparative effectiveness and survival of infliximab, adalimumab, and etanercept for rheumatoid arthritis patients in the Helllenic Registry of Biologics: Low rates of remission and 5-year drug survival
[5] Estimated from Decision Resources: Pharmacon– Rheumatoid Arthritis 2015

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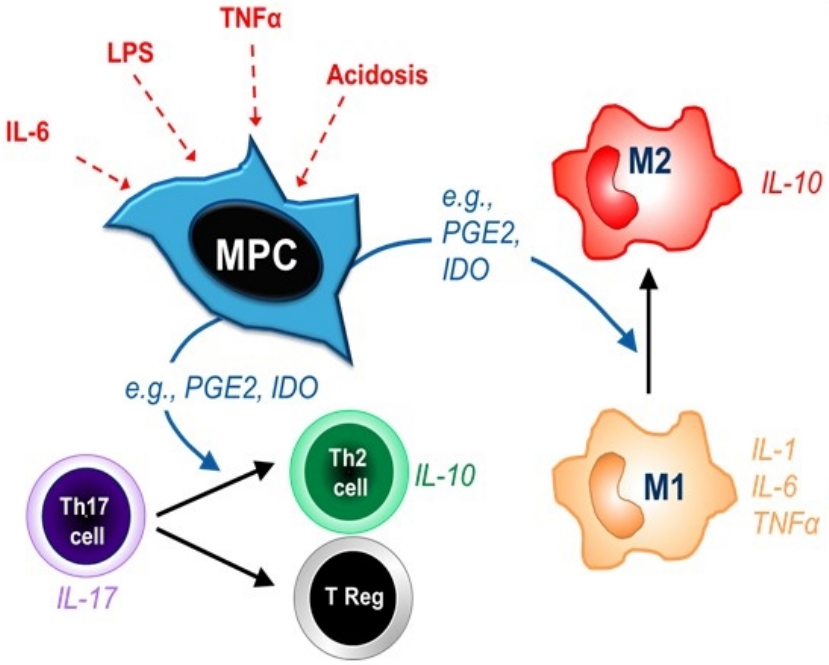
MPC-300-IV for Treatment of Chronic Inflammatory Diseases Through Immunomodulation

Inflammation induces production of immuno-modulatory factors by 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:
  - Biologic refractory rheumatoid arthritis
  - Diabetic kidney disease
  - Biologic refractory Crohn's disease
- MPCs have to date demonstrated a safe profile in terms of infectious or neoplastic complications

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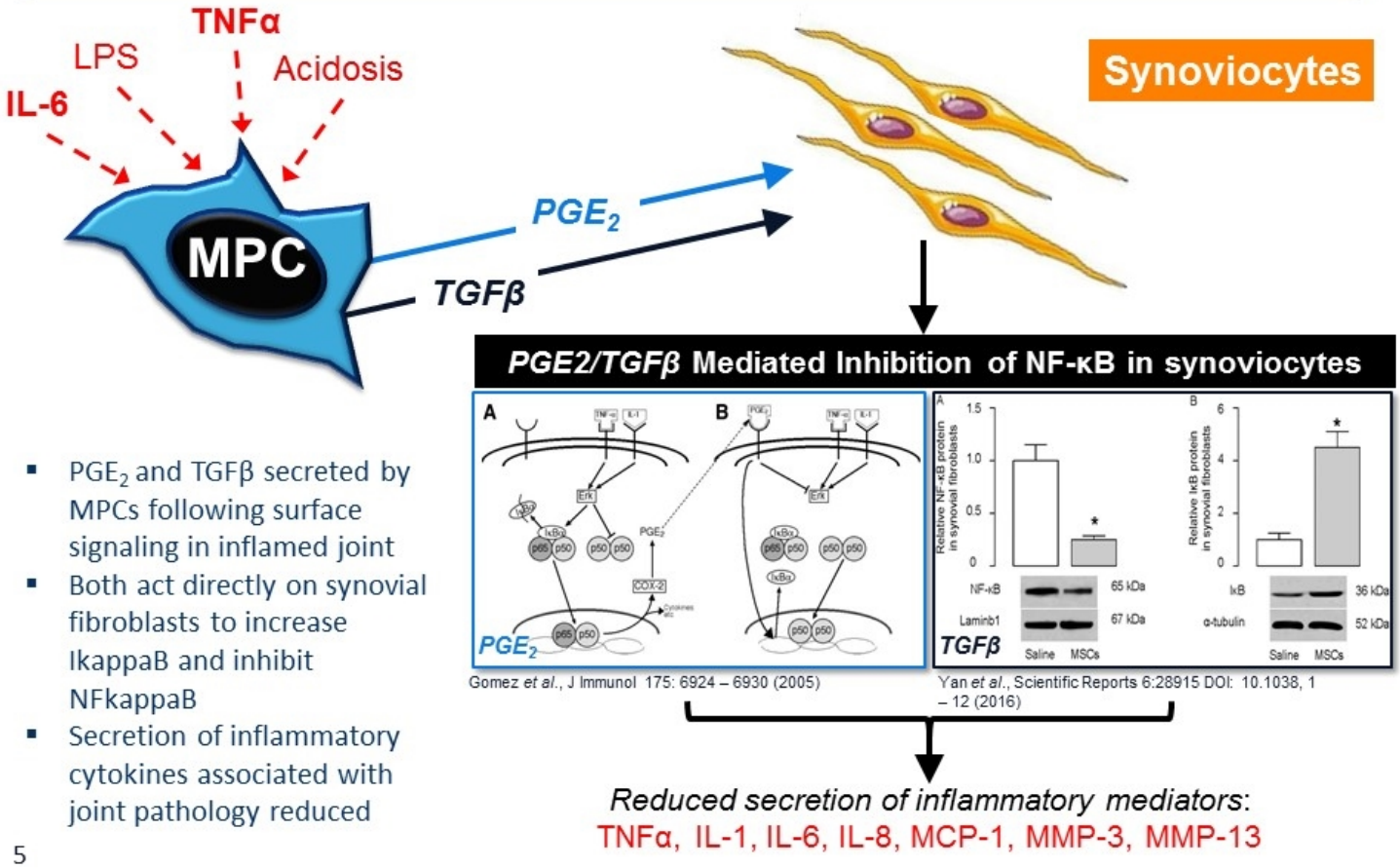
MPC-300-IV for Modulation Of Cytokine Production By Synoviocytes/Synovial Fibroblasts In Rheumatoid Arthritis



- PGE_2 and TGFβ secreted by MPCs following surface signaling in inflamed joint
- Both act directly on synovial fibroblasts to increase IkappaB and inhibit NFkappaB
- Secretion of inflammatory cytokines associated with joint pathology reduced

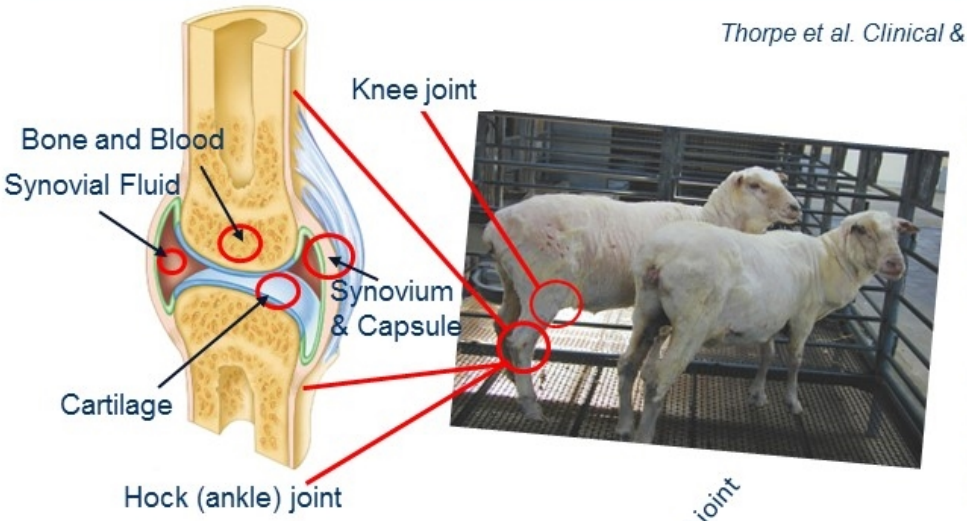
Gomez *et al.*, J Immunol 175: 6924 – 6930 (2005)

Yan *et al.*, Scientific Reports 6:28915 DOI: 10.1038, 1 – 12 (2016)

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

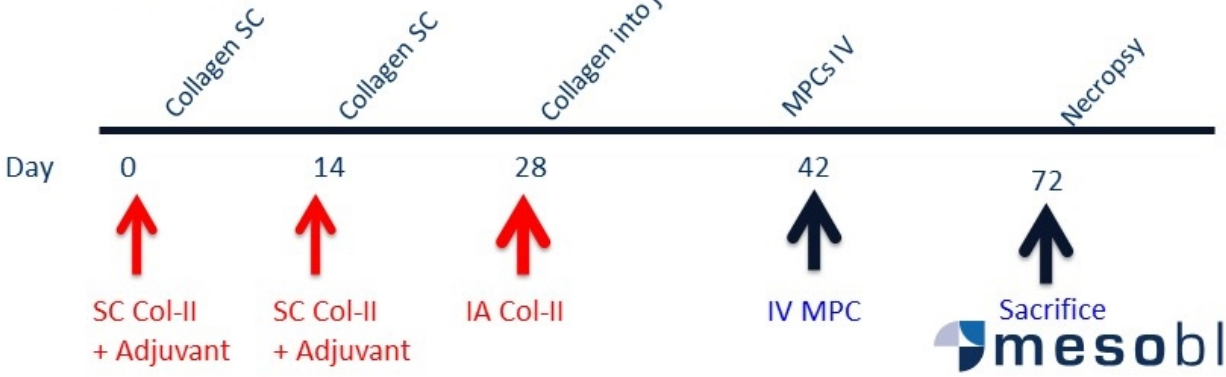
A Sheep Model of Collagen-Induced Arthritis (CIA)

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



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

Doses: 25, 75, 150 million cryopreserved ovine MPCs administered by IV injection via the jugular vein



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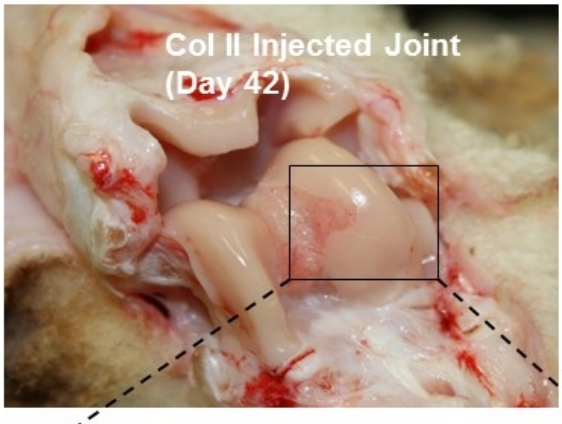
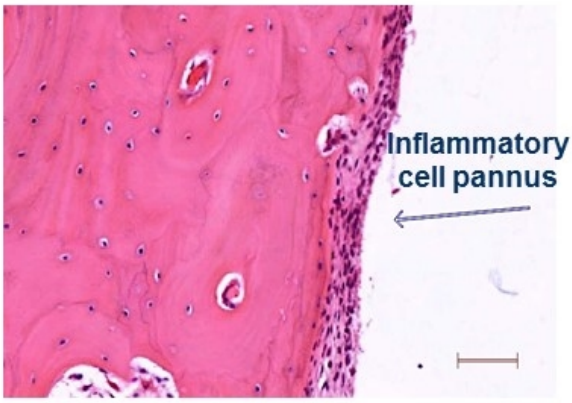
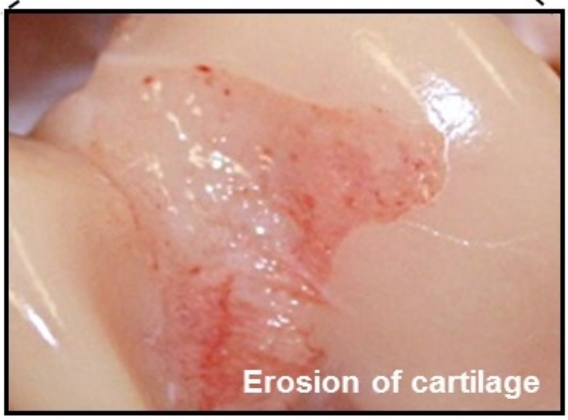
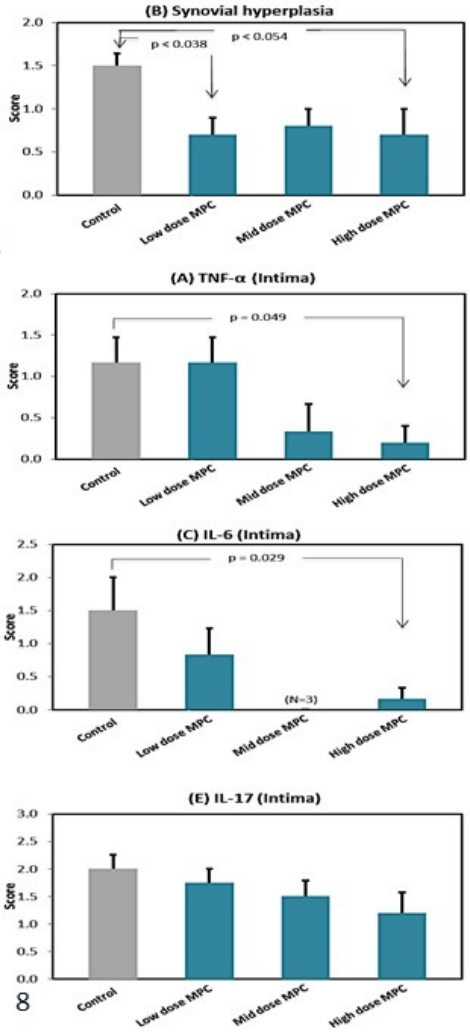
Features Of CIA And Human RA: Invading Synovial Pannus And Cartilage Erosion

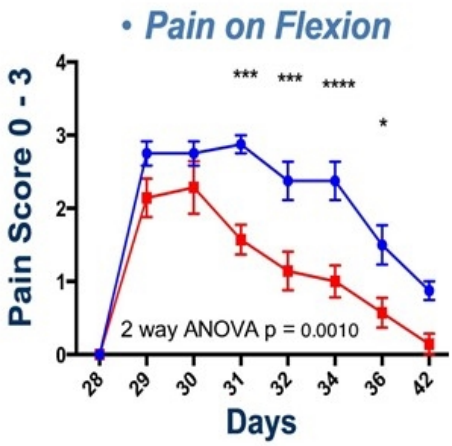


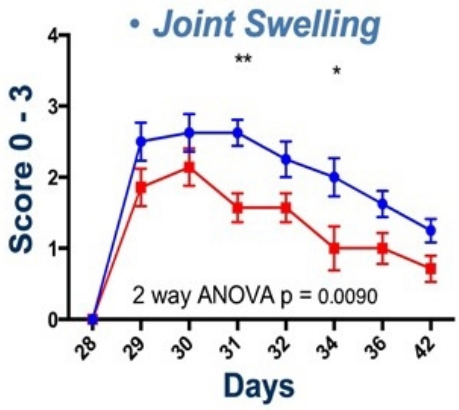


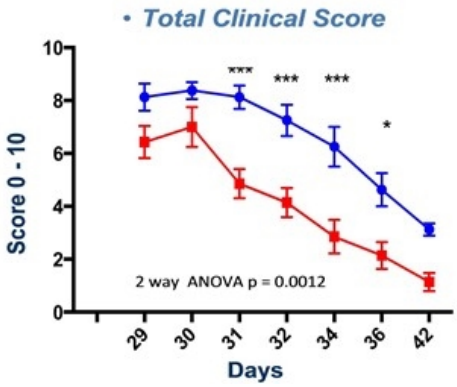


Allogeneic Sheep MPCs Reduce Synovial Pannus/ Inflammatory Cytokines, Improve Symptoms in CIA









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

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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 10^6 cells/kg (N=16 active)
  - MPC 2 x 10^6 cells/kg (N=16)
  - Placebo (N=16)

- 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 through the 12-week primary endpoint 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) composite clinical response, 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.

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

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MSB-RA001 : Safety Summary

- All 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 serious AEs (SAEs) were reported during the 12- week primary study period
- No discontinuations due to AEs during the 12-week primary study period
- Treatment-emergent adverse events (TEAEs) reported by 12 (75%), 13 (81%) and 10 (63%) of patients in the placebo and MPC 1M/kg and 2M/kg groups, respectively
- The safety profile over 12 weeks was comparable among the placebo and two MPC treatment groups

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Profile of Marketed Non-TNFα/JAK Inhibitors Suggest Clinical Need for Agents with Reduced Safety Risk

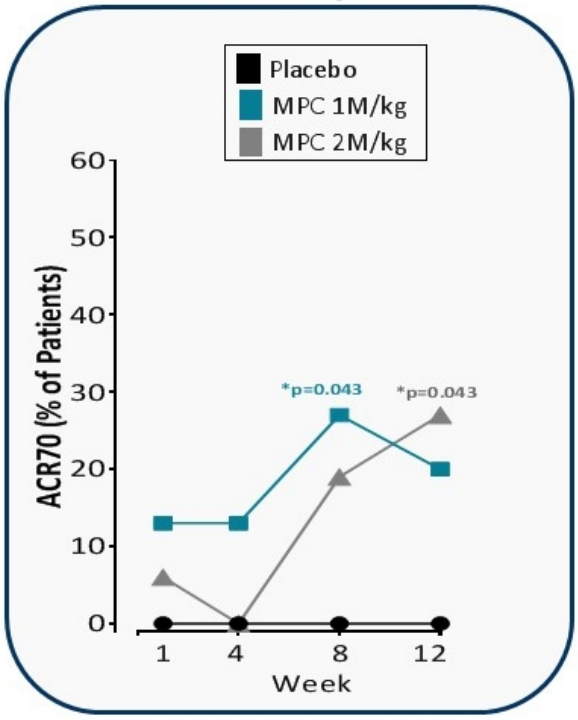
- To date, no safety concerns have been identified with MPC-300-IV across multiple therapeutic indications, including in biologic refractory RA patients
- Currently marketed non-TNFα Inhibitors are associated with serious adverse events such as serious infections, malignancies, cardiovascular, and hepatic abnormalities that may limit initiation of therapy and/or lead to discontinuation
- Given the risk profile of non-TNFα Inhibitors, ongoing clinical need exists for new agents that are efficacious and offer a reduced safety profile in the biologic refractory population
- Mesoblast MPC-300-IV has the potential to address this unmet medical need

*Source: FDA Package Insert

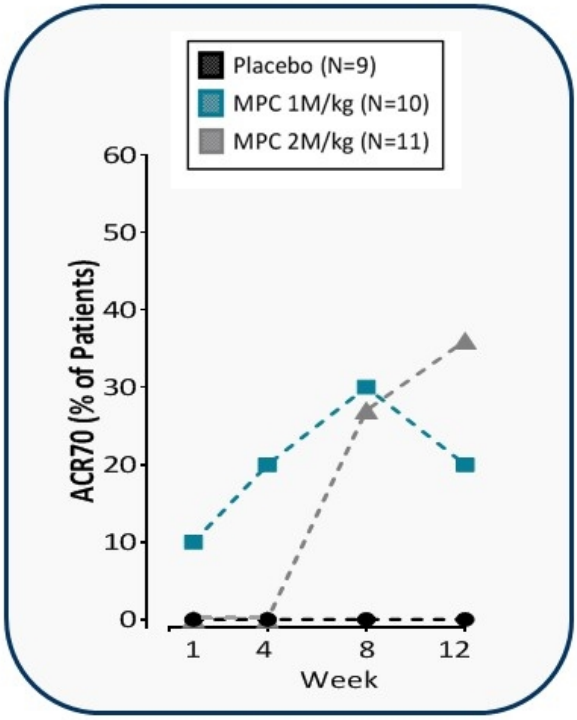
RA001: ACR70 Response (%) over 12 Weeks

All Subjects and Subgroup of 1-2 Prior Biologics[1,2]

All Subjects



1-2 Prior Biologics



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

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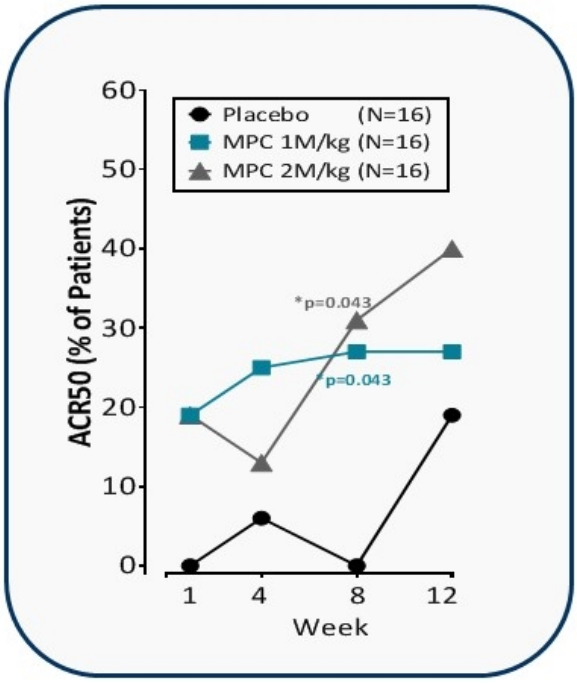
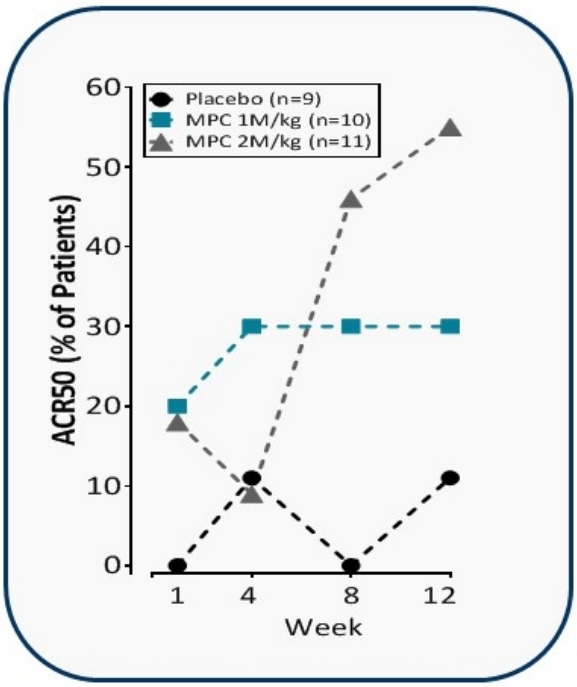
RA001: ACR50 Response (%) over 12 Weeks

All Subjects and Subgroup of 1-2 Prior Biologics[1,2]

All Subjects



1-2 Prior Biologics



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

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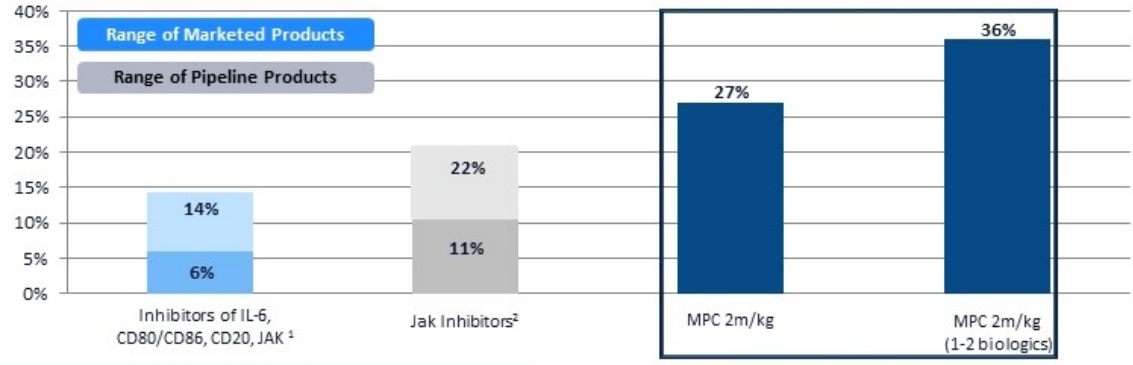
One Dose of MPC-300-IV Provides Compelling Efficacy at 12 weeks in the Biologic Refractory Population*

ACR70 @ 3 Months



ACR50 @ 3 Months

*Source: See References

[1] Inhibitors 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

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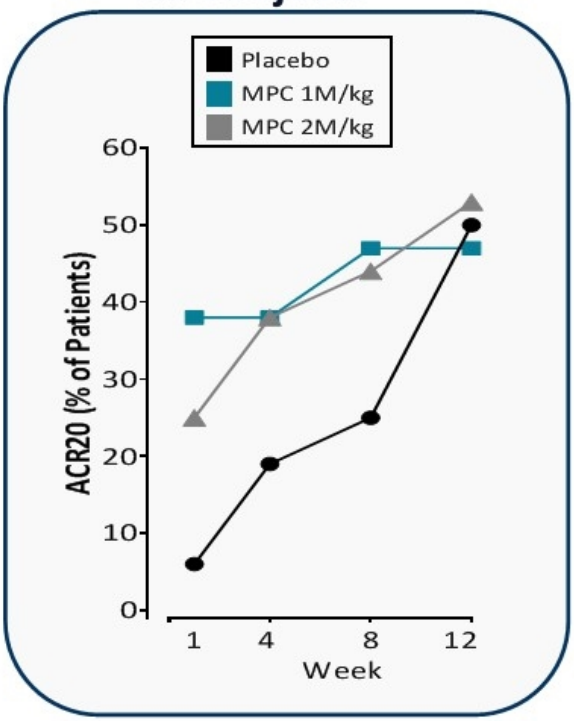
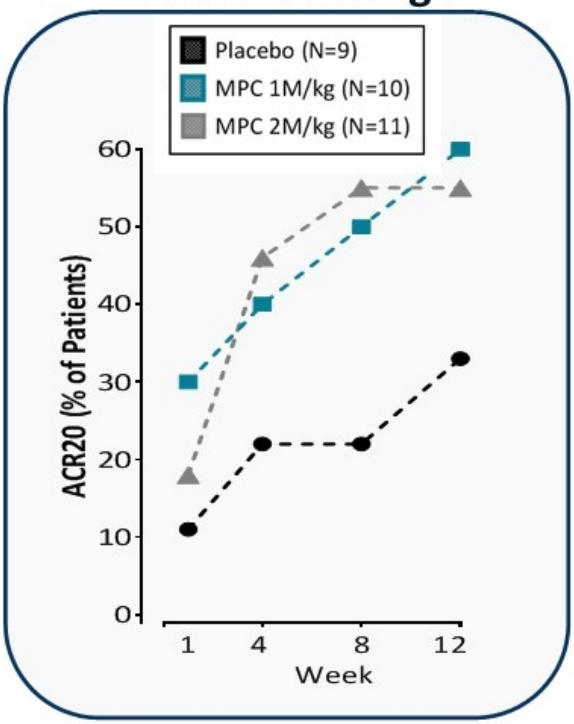
RA001: ACR20 Response (%) over 12 Weeks

All Subjects and Subgroup of 1-2 Prior Biologics[1,2]

All Subjects



1-2 Prior Biologics



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

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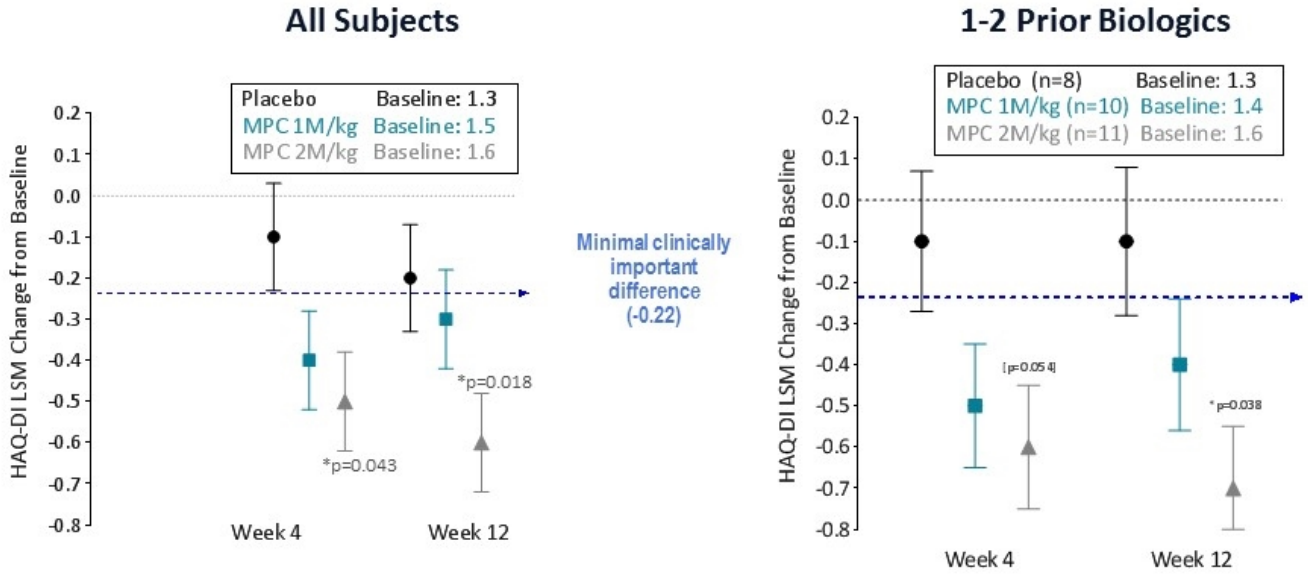
Health Assessment Questionnaire – Disability Index (HAQ-DI)
Least Squares Mean (SE) Change from Baseline at 4 and 12 Weeks
All Subjects and Subgroup of 1-2 Prior Biologics[1,2,3]



Significant dose-related improvement in physical function in 2M/kg MPC group vs. placebo

NOTE: 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

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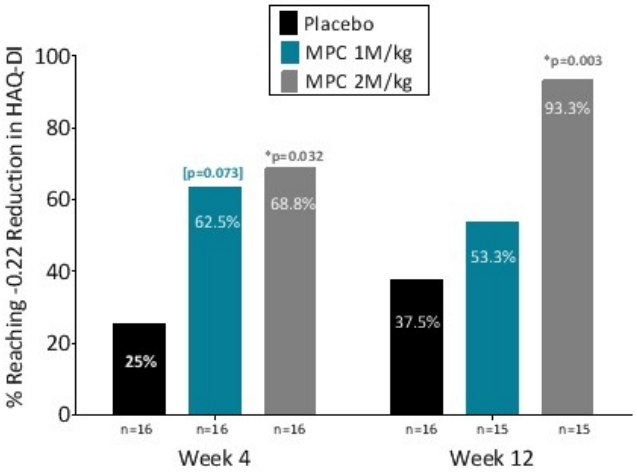
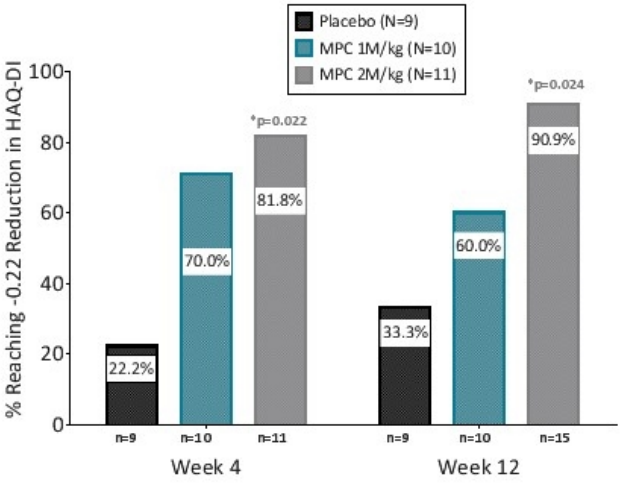
Health Assessment Questionnaire – Disability Index (HAQ-DI)
Percent that reached minimal clinically important reduction of -0.22 at 4 and 12 weeks
All Subjects and Subgroup of 1-2 Prior Biologics[1]

All Subjects



1-2 Prior Biologics

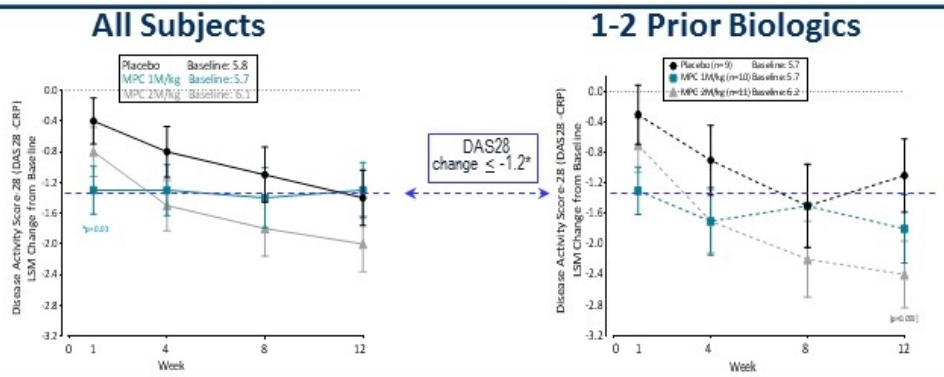


Significantly more MPC patients achieved clinically important improvement in physical function

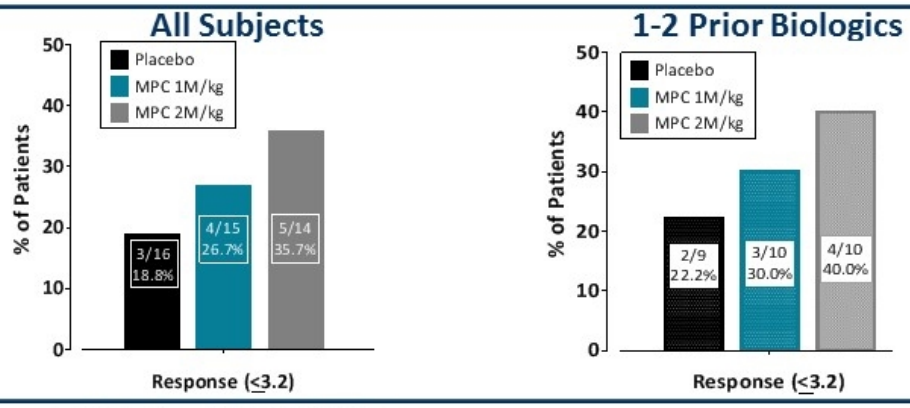
NOTE: 1) *P values vs. Placebo computed using Fisher exact test (observed values)

Disease Activity Score-28 –CRP (DAS28-CRP) at Week 12
LS mean change from baseline and proportion of patients that achieved low disease activity state (defined as DAS28 ≤3.2)
All Subjects and Subgroup of 1-2 Prior Biologics

Least Squares Mean Change from Baseline



Response: ≤3.2



* Clinically relevant improvement ≤-1.2 Ann Rheum Dis 2009;68:954–60

MPC-300-IV: Conclusions

- The biologic refractory rheumatoid arthritis (RA) population accounts for approximately one-third of all RA patients who have received anti-TNF or other biologic agents, is the hardest to treat, and requires new therapies that are both effective and safe, without the risk of serious infections or malignancies
- Intravenous infusions of allogeneic Mesenchymal Precursor Cells (MPCs) were well tolerated in biologic refractory RA patients and were without serious adverse events over 12 weeks
- A single intravenous MPC infusion in biologic refractory RA patients resulted in dose-related improvements in clinical symptoms, function, and disease activity, with the 2 million MPCs/kg dose providing the greatest benefit
- Importantly, ACR70, the most meaningful measure of clinical improvement, was achieved by significantly more of the high dose MPC-treated than placebo-treated patients
- In patients who had previously received 1-2 biologics, a single infusion of 2 million MPC/kg resulted in 55% and 36% ACR50 and ACR70 responses, respectively, compared with 11% and 0% of placebo treated patients, and in 91% of patients achieving the minimum clinically important improvement in physical function, defined as a reduction of at least -0.22 in the HAQ-DI, compared with 33% placebo treated patients
- The safety and efficacy results of this trial provide support for the potential of Mesoblast's allogeneic MPCs to be positioned as first-line treatment option in RA patients who have previously received a prior anti-TNF or other biologic agent

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