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 2022

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 January 12, 2022, Mesoblast Limited filed with the Australian Securities Exchange a new release announcement and investor presentation, which are attached hereto as Exhibit 99.1 and Exhibit 99.2, and are 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/ Niva Sivakumar

Niva Sivakumar
Company Secretary

Dated: January 18, 2022

INDEX TO EXHIBITS

Item	
99.1	Press release of Mesoblast Ltd, dated January 12, 2022.
99.2	Investor presentation of Mesoblast Ltd, dated January 12, 2022.

asx announcement

mesoblast
the regenerative medicine company

SINGLE DOSE OF MESOBLAST'S ALLOGENEIC CELL THERAPY PROVIDES DURABLE PAIN REDUCTION FOR AT LEAST THREE YEARS IN PATIENTS WITH DEGENERATIVE DISC DISEASE

36-Month Results of Phase 3 Trial in Chronic Low Back Pain Presented at 2022 Biotech Showcase

Melbourne, Australia; January 12, and New York, USA; January 11, 2022: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today announced 36-month follow-up results from the 404-patient Phase 3 trial of its allogeneic cell therapy rexlemestrocel-L (MPC-06-ID) in patients with chronic low back pain (CLBP) associated with degenerative disc disease (DDD). Mesoblast Chief Executive Dr Silviu Itescu presented results from the three-arm trial at the 2022 Biotech Showcase event being held this week, which showed durable reduction in back pain lasting at least three years from a single intra-discal injection of rexlemestrocel-L+hyaluronic acid (HA) carrier.

There is a significant need for a safe, effective, and durable opioid-sparing treatment in patients with CLBP associated with degenerative disc disease. Results presented from this trial showed that:

- Durable reduction in pain through 36 months was greatest in the pre-specified population with CLBP of shorter duration than the study median of 68 months (n=194), suggesting that greatest benefits may be seen when the therapy is administered earlier in the disease process when there is active inflammation and before irreversible fibrosis of the intervertebral disc has occurred
- Pain reduction through 36 months was also seen in the subset of patients using opioids at baseline (n=168) with the rexlemestrocel-L+HA group having substantially greater reduction at all time points compared with saline controls
- Among patients on opioids at baseline, despite instructions to maintain existing therapies throughout the trial, at 36 months 28% who received rexlemestrocel-L + HA were not taking an opioid compared with 8% of saline treated controls (nominal p value 0.0075).

Mesoblast recently received feedback from the US Food & Drug Administration's (FDA) Office of Tissues and Advanced Therapies (OTAT) on the Phase 3 program for CLBP and plans to conduct an additional US Phase 3 trial which may support submissions for potential approval in both the US and EU. Following review of the completed Phase 3 trial data, OTAT agreed with Mesoblast's proposal for pain reduction at 12 months as the primary endpoint of the next trial, with functional improvement and reduction in opioid use as secondary endpoints.

The Biotech Showcase presentation materials have been lodged with the ASX.

About Mesoblast

Mesoblast is a world leader in developing allogeneic (off-the-shelf) cellular medicines for the treatment of severe and life-threatening inflammatory conditions. The Company has leveraged its proprietary mesenchymal lineage cell therapy technology platform to establish a broad portfolio of late-stage product candidates which respond to severe inflammation by releasing anti-inflammatory factors that counter and modulate multiple effector arms of the immune system, resulting in significant reduction of the damaging inflammatory process.

Mesoblast has a strong and extensive global intellectual property portfolio with protection extending through to at least 2041 in all major markets. The Company's proprietary manufacturing processes yield industrial-scale, cryopreserved, off-the-shelf, cellular medicines. These cell therapies, with defined pharmaceutical release criteria, are planned to be readily available to patients worldwide.

Mesoblast is developing product candidates for distinct indications based on its remestemcel-L and rexlemestrocel-L stromal cell technology platforms. Remestemcel-L is being developed for inflammatory diseases in children and adults including steroid refractory acute graft versus host disease and moderate to severe acute respiratory distress syndrome. Rexlemestrocel-L is in development for advanced chronic heart failure and chronic low back pain. Two products have been commercialized in Japan and Europe by Mesoblast's licensees, and the Company has established commercial partnerships in Europe and China for certain Phase 3 assets.

Mesoblast Limited
ABN 68 109 431 870

www.mesoblast.com

Corporate Headquarters
Level 38
55 Collins Street
Melbourne 3000
Victoria Australia

T +61 3 9639 6036
F +61 3 9639 6030

United States Operations
505 Fifth Avenue
Third Floor
New York, NY 10017
USA

T +1 212 880 2060
F +1 212 880 2061

Asia
21 Biopolis Road
#01-22 Nucleos (South Tower)
SINGAPORE 138567

T +65 6570 0635
F +65 6570 0176

Mesoblast has locations in Australia, the United States and Singapore and is listed on the Australian Securities Exchange (MSB) and on the Nasdaq (MESO). For more information, please see www.mesoblast.com, LinkedIn: Mesoblast Limited and Twitter: @Mesoblast

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. Forward-looking statements include, but are not limited to, statements about: the initiation, timing, progress and results of Mesoblast's preclinical and clinical studies, and Mesoblast's research and development programs; Mesoblast's ability to advance product candidates into, enroll and successfully complete, clinical studies, including multi-national clinical trials; Mesoblast's ability to advance its manufacturing capabilities; the timing or likelihood of regulatory filings and approvals (including BLA resubmission), manufacturing activities and product marketing activities, if any; the commercialization of Mesoblast's product candidates, if approved; regulatory or public perceptions and market acceptance surrounding the use of stem-cell based therapies; the potential for Mesoblast's product candidates, if any are approved, to be withdrawn from the market due to patient adverse events or deaths; the potential benefits of strategic collaboration agreements and Mesoblast's ability to enter into and maintain established strategic collaborations; Mesoblast's ability to establish and maintain intellectual property on its product candidates and Mesoblast's ability to successfully defend these in cases of alleged infringement; the scope of protection Mesoblast is able to establish and maintain for intellectual property rights covering its product candidates and technology; estimates of Mesoblast's expenses, future revenues, capital requirements and its needs for additional financing; Mesoblast's financial performance; developments relating to Mesoblast's competitors and industry; and the pricing and reimbursement of Mesoblast's product candidates, if approved. 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.

Release authorized by the Chief Executive.

For more information, please contact:

Corporate Communications / Investors
Paul Hughes
T: +61 3 9639 6036
E: investors@mesoblast.com

Media
Sumit Media
Grant Titmus
T: +61 419 388 161
E: grant@sumitmedia.com.au

Rubenstein
Nadine Woloshin
T: +1 917-699-9456
E: nwoloshin@rubenstein.com

Exhibit 99.2

mesoblast

Global Leader in Allogeneic Cellular Medicines for Inflammatory Diseases

Corporate Presentation
BIOTECH SHOWCASE 2022

JANUARY 2022

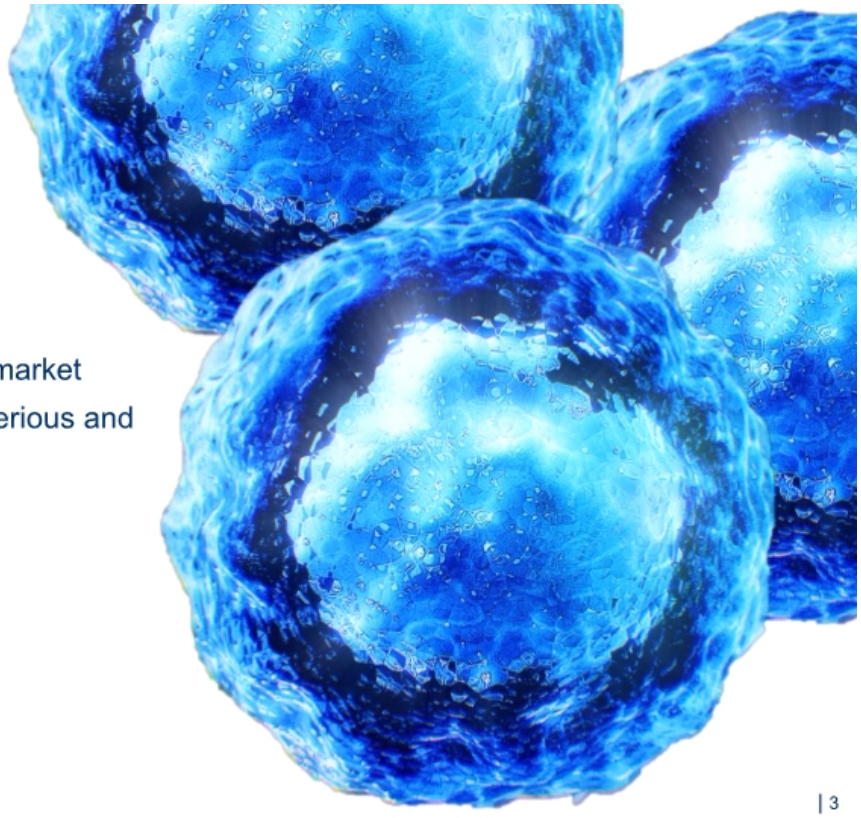
ASX: MSB; Nasdaq: MESO

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.

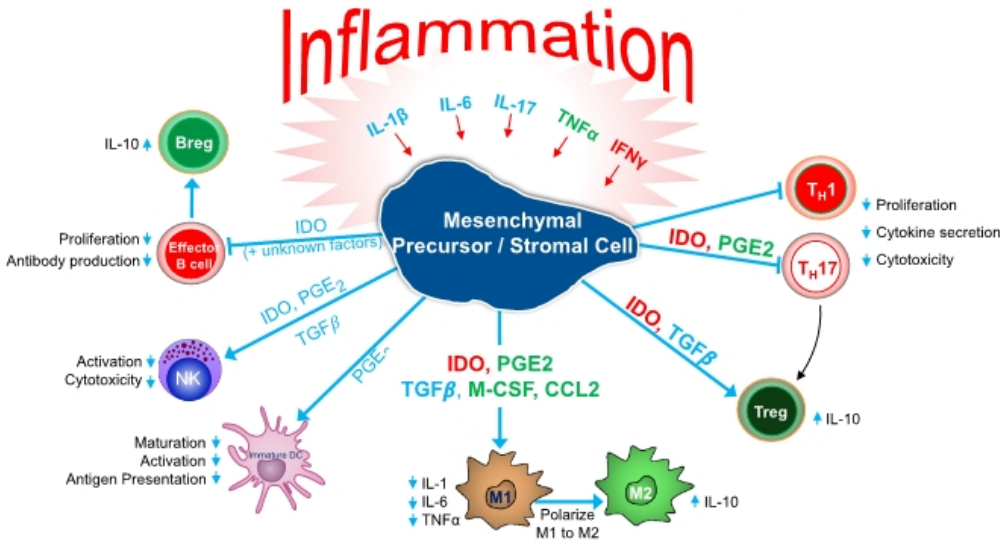
Our Mission

Mesoblast is committed to bringing to market innovative cellular medicines to treat serious and life-threatening illnesses



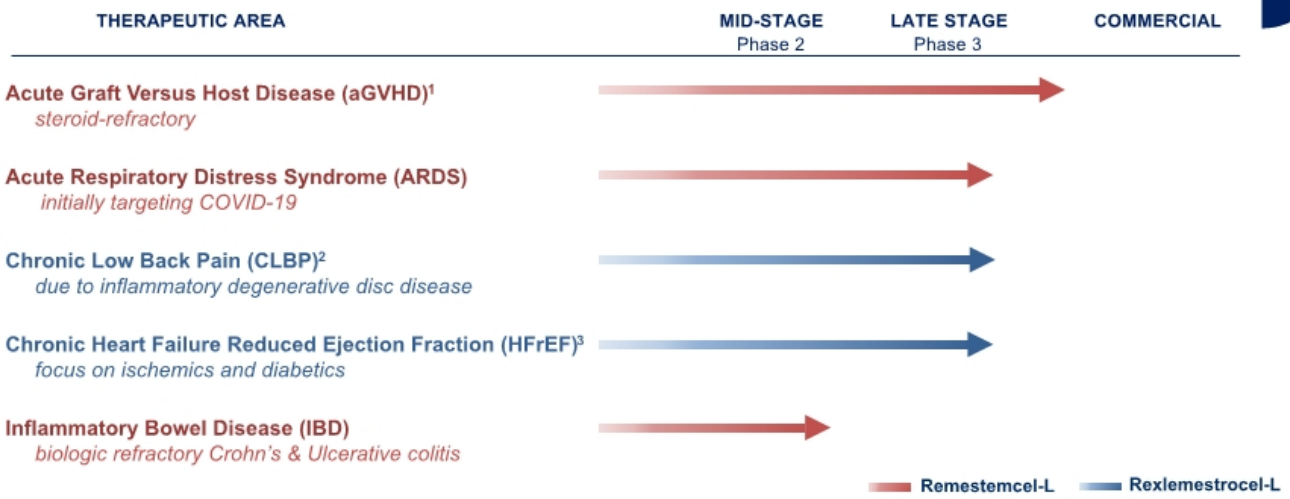
Platform Technology – Mechanism of Action

Our mesenchymal precursor/stromal cells respond to and are activated by multiple inflammatory cytokines through surface receptors, resulting in orchestration of an anti-inflammatory cascade



Source: Data on file

Late-Stage Clinical Pipeline

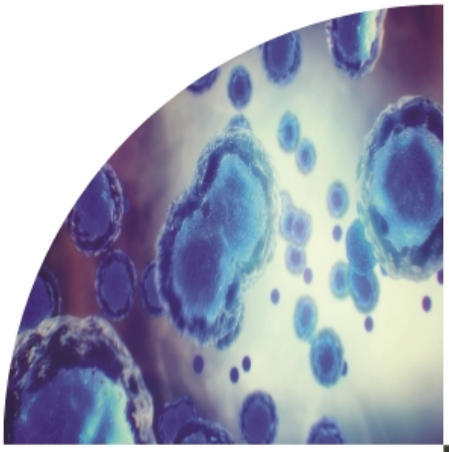


This chart is figurative and does not purport to show individual trial progress within a clinical program

1. JCR Pharmaceuticals Co., Ltd. (JCR), has the right to develop mesenchymal stromal cells (MSCs) in certain fields for the Japanese market, including for the treatment of hematological malignancies, such as Graft vs Host Disease, and for hypoxic ischemic encephalopathy (HIE). Mesoblast has the right to use safety and efficacy data generated by JCR to support its development and commercialization plans for remestemcel-L in the US and other major healthcare markets, including for GVHD and HIE
2. Grünenthal has an exclusive license to develop and commercialize rexlemestrocel-L for chronic low back pain in Europe and Latin America/Caribbean
3. Tasly Pharmaceuticals has exclusive rights for rexlemestrocel-L for the treatment or prevention of chronic heart failure in China

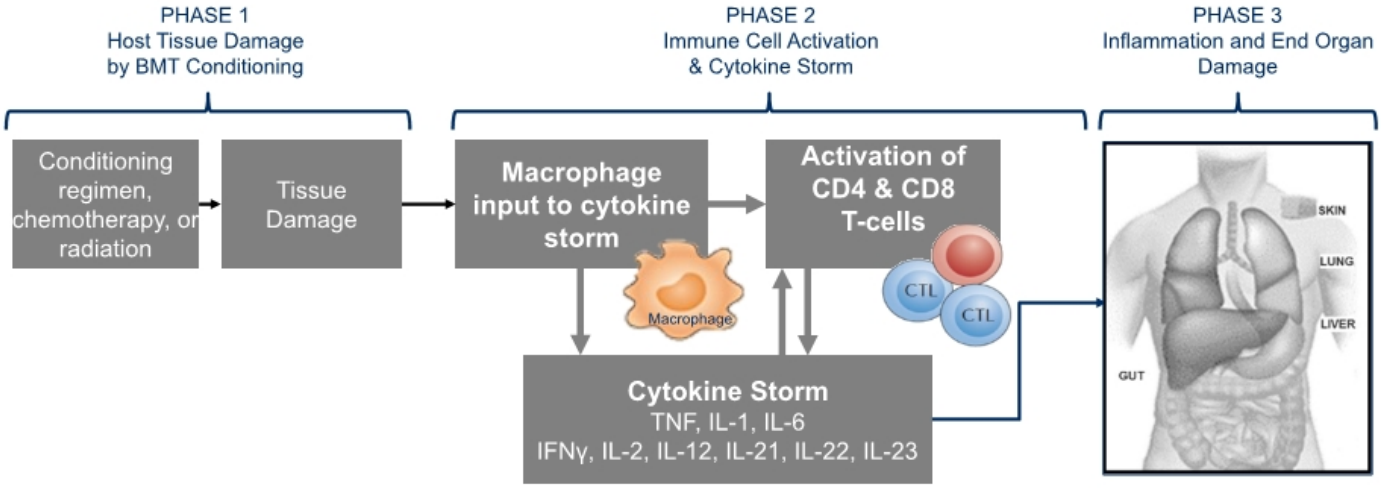
Remestemcel-L

Acute Graft versus Host Disease



Acute Graft versus Host Disease (aGVHD)

Serious and Fatal Complication of Allogeneic Bone Marrow Transplantation (BMT)



Modified from Blazar et al., Nature Reviews Immunology 12: 443 – 458

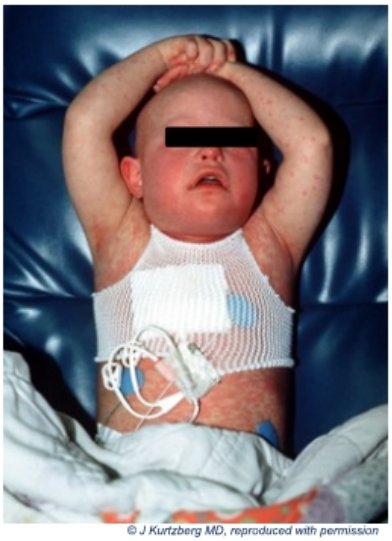
Children with Steroid-Refractory Acute GVHD at High Risk of Treatment Failure and Death

Extremely high unmet medical need

- More than 2,000 allogeneic BMTs in children and adolescents in US[1]
- Despite prophylaxis, ~50% will develop aGVHD[2]
- First-line treatment is corticosteroids
- Response rate is ~50%
- Children < 12 years of age have no approved treatment for steroid-refractory acute GVHD

Acute GVHD Primarily Affects Skin, GI Tract, and Liver

- Classic skin rash; Abdominal cramps; Large volumes of diarrhea
- Rising serum bilirubin (indicative of liver damage or disease)
- Mortality as high as 70 – 90%[2-5] when involving gut and liver



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1. HRSA Transplant Activity Report, CIBMTR, 2019; 2. Westin, J., Saliba, RM., Lima, M. (2011) Steroid-refractory acute GVHD: predictors and outcomes. Advances in Hematology; 3. MacMillan, M.L. et al. Pediatric acute GVHD: clinical phenotype and response to upfront steroids. Bone Marrow Transplant 55, 165–171 (2020); 4. Jagasia, M. et al. Risk factors for acute GVHD and survival after hematopoietic cell transplantation. Blood (2012) 119 (1): 296-307; 5. Axt L, Naumann A, Toennies J (2019) Retrospective single center analysis of outcome, risk factors and therapy in steroid refractory graft-versus-host disease after allogeneic hematopoietic cell transplantation. Bone Marrow Transplantation

Remestemcel-L: Prior Clinical Data in Children with SR-aGVHD

Consistent Efficacy and Safety Outcomes in a Total of 309 Children from Three Studies

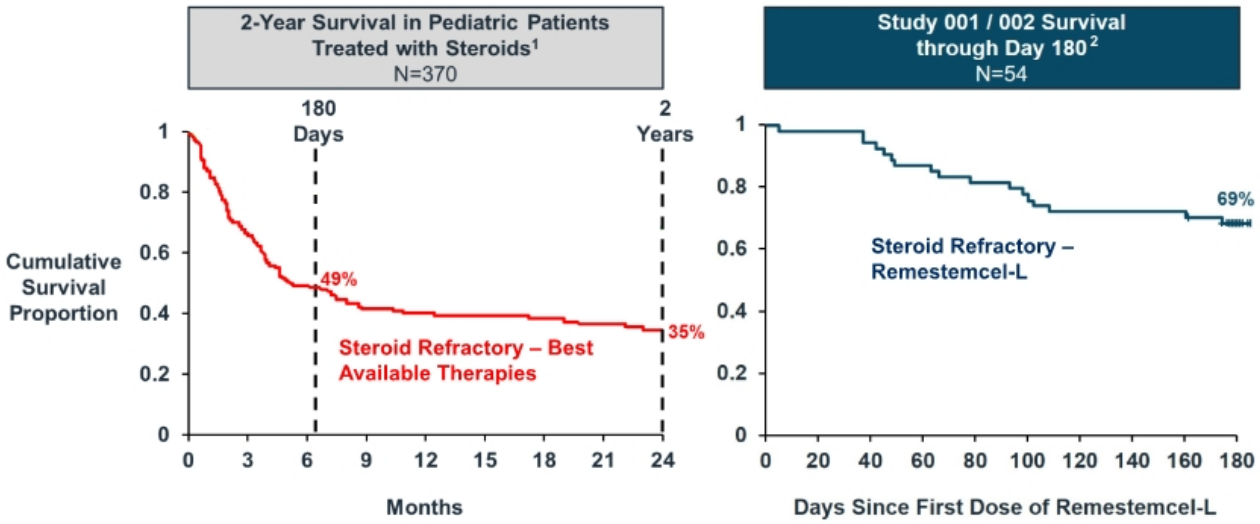
- Remestemcel-L was used as first-line therapy in a randomized controlled Phase 3 trial of 260 patients, with SR-aGVHD, including 27 children
- Remestemcel-L was used as salvage therapy in an expanded access program in 241 children with SR-aGVHD, 80% of whom had Grade C/D disease, and failed institutional standard of care
- Remestemcel-L was used as first-line therapy in Mesoblast's open-label Phase 3 trial in 54 children with SR-aGVHD, 89% of whom had Grade C/D disease

		Protocol 280 (pediatric)		EAP 275	Study 001
	MAGIC[1] N=30[2]	Placebo N=13	Remestemcel-L N=14	Remestemcel-L N=241	Remestemcel-L N=54[3]
Day 28 Overall Response	**43%**	**38%**	**64%**	**65%**	**69%**
Day 100 Survival	**57%**	**54%**	**79%**	**66%**	**74%**

Source: ODAC Advisory Committee Briefing Document and Presentation August 2020.

1. Mount Sinai Acute GVHD International Consortium (MAGIC) - a group of ten BMT centers throughout the US and Europe whose purpose is to conduct ground-breaking clinical trials in GVHD, including developing informative biorepositories that assist in developing treatments that can guide GVHD therapy; 2. Two subjects in the MAGIC cohort had follow-up <100 days; these subjects are excluded from the respective survival analyses; 3.GVHD001 had 55 randomized patients, however one patient dropped out before receiving any dose of remestemcel-L

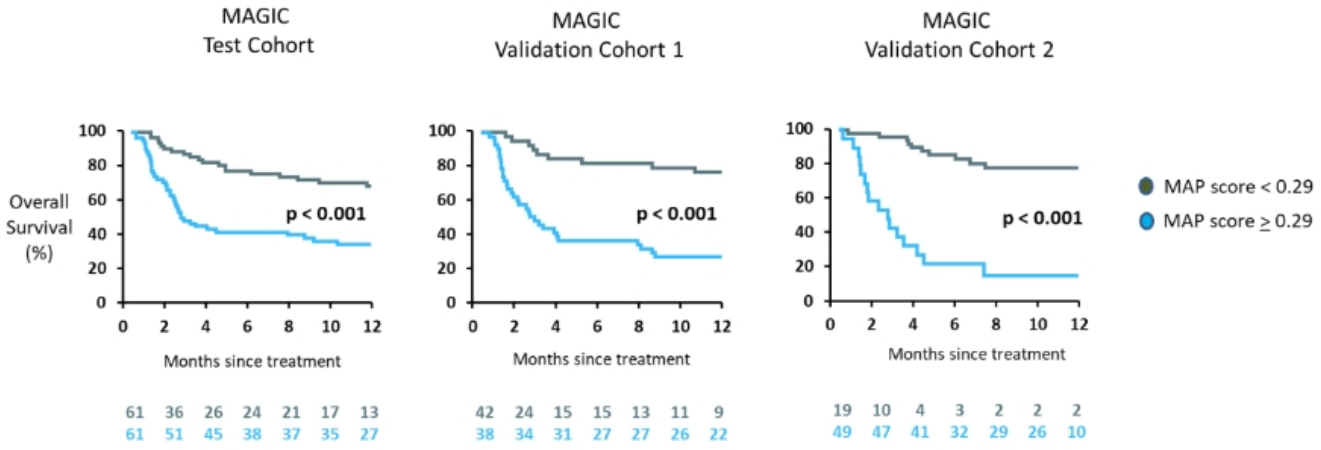
Remestemcel-L Improved Dismal Survival in Children with SR-aGVHD



1. Adapted and redrawn from Figure 2 of MacMillan, M.L. et al. Pediatric acute GVHD: clinical phenotype and response to upfront steroids. Bone Marrow Transplant 55, 165–171 (2020); 2. Kurtzberg, J. et al. A Phase 3, Single-Arm, Prospective Study of Remestemcel-L, Ex Vivo Culture-Expanded Adult Human Mesenchymal Stromal Cells for the Treatment of Pediatric Patients Who Failed to Respond to Steroid Treatment for Acute Graft-versus-Host Disease. Biol Blood Marrow Transplant 26 (2020) 845-854

Identifying Acute GVHD Patients at High Risk of Non-Response to Treatment and Death

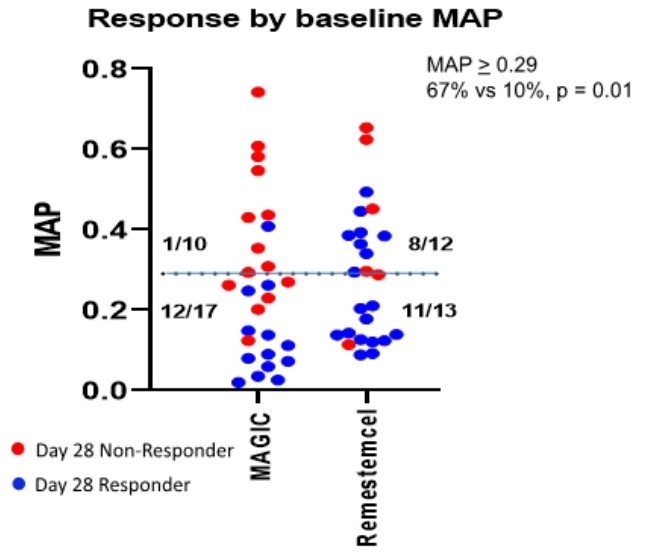
MAGIC Algorithm Probability Biomarker Score (MBS, MAP) > 0.29 is a Validated Threshold

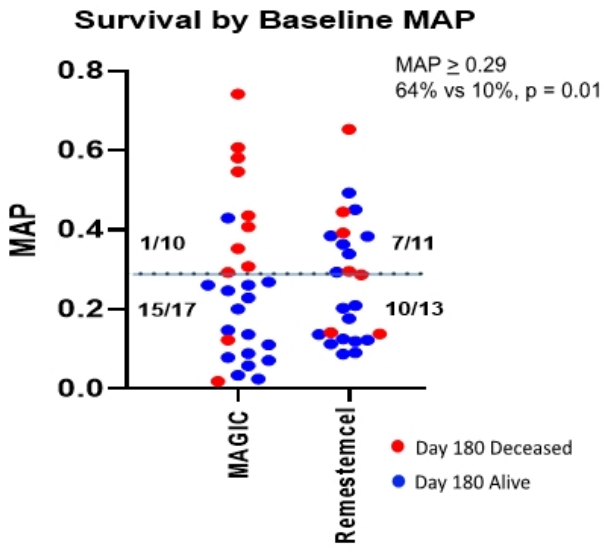


Major-Monfried H, et al. MAGIC biomarkers predict long-term outcomes for steroid-resistant acute GVHD. Blood 2018; 131 (25): 2846-2855

Remestemcel-L Treatment Outcomes

Significantly Greater Day 28 Overall Responses and Day 180 Survival in Steroid-Refractory Patients with Baseline MAP ≥ 0.29





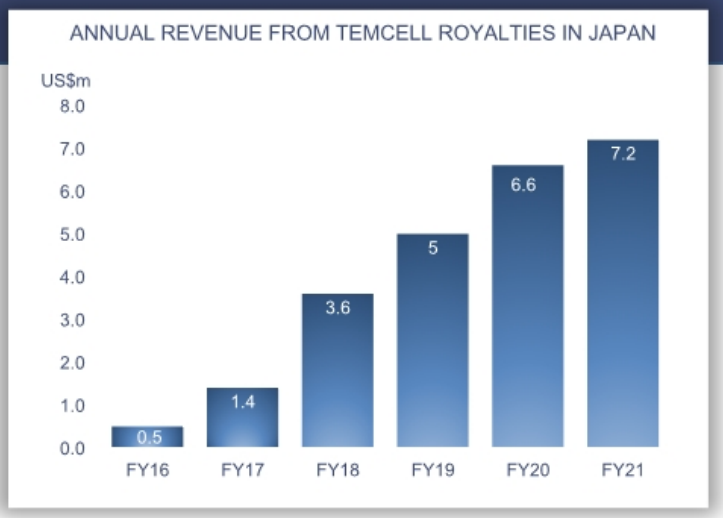
Kasikis S et al. Bone Marrow Transplantation 2021; 56:2869–2870.

Remestemcel-L: Regulatory & Commercial Update for SR-aGVHD

- Met with the FDA's OTAT November 2021
- OTAT indicated that Mesoblast's approach to address the outstanding CMC items is reasonable
- OTAT indicated that the in vitro immunomodulatory activity Mesoblast intends to measure for potency is a reasonable critical quality attribute (CQA) for the product, and the relevance of this activity to clinical outcomes should be established
- Mesoblast has now generated substantial new data that it believes establish the relevance of the proposed in vitro immunomodulatory activity of remestemcel-L to the in vivo clinical effect of the product in the Phase 3 trial in children with SR-aGVHD, including survival and biomarkers of in vivo activity
- Mesoblast will provide these new data to OTAT, and address other outstanding items as required for the Biologics License Application (BLA) resubmission
- Mesoblast continues to be in a well-established process with FDA's Center for Biologics Evaluation and Research (CBER), and if the resubmission is accepted, CBER will consider the adequacy of the clinical data in the context of the related CMC issues noted above

Continued Growth in Revenues from Sales of TEMCELL in Japan for SR-aGVHD

- JCR Pharmaceuticals has exclusive rights to Mesoblast's MSC technology for acute GVHD in Japan
- FY2021 revenue from TEMCELL® HS Inj[1] royalties increased by 10% from the prior year period to US$7.2 million
- Product adoption and reimbursement informs Mesoblast US commercial strategy for remestemcel-L in acute GVHD
- US addressable market for acute GVHD in children and adults is ~ eight-fold larger than Japan due to greater patient numbers, incidence and pharmacoeconomics



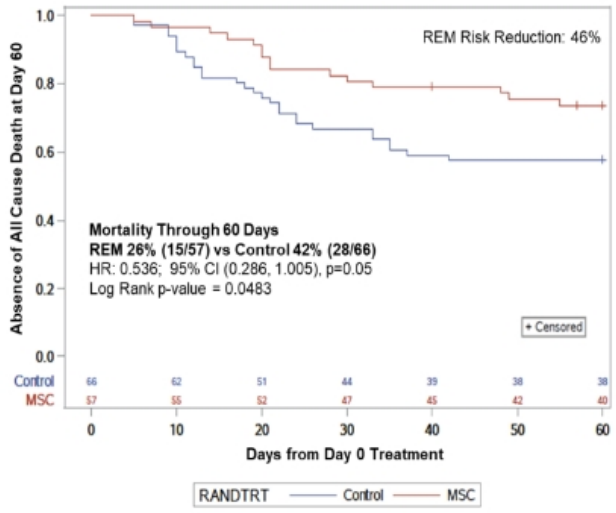
1. TEMCELL® Hs. Inj. is a registered trademark of JCR Pharmaceuticals Co Ltd.

Remestemcel-L

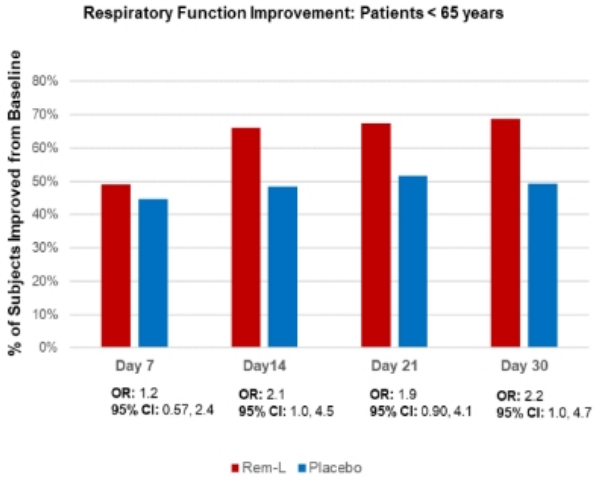
Acute Respiratory Distress Syndrome (ARDS) due to COVID-19

Greatest Mortality Reduction Improved ARDS Severity* Seen in Remestemcel-L Treated Patients < 65 years

Modified Intent to Treat (mITT) Patients **< 65 years old** (n=123)
Remestemcel-L vs Control



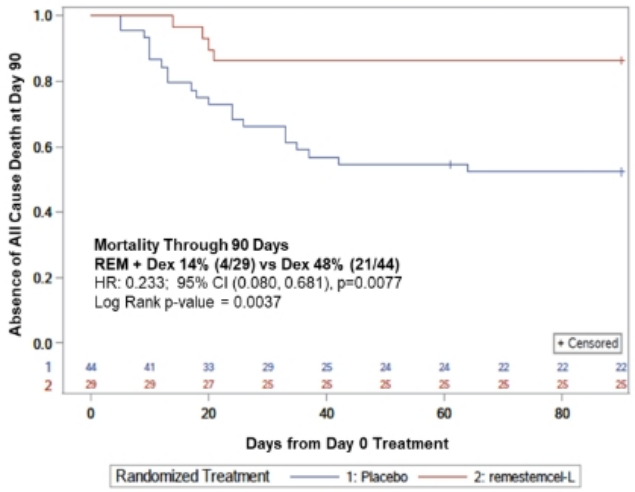
Treated Patients (mITT) **< 65 years old** (n=123)
Remestemcel-L vs Control



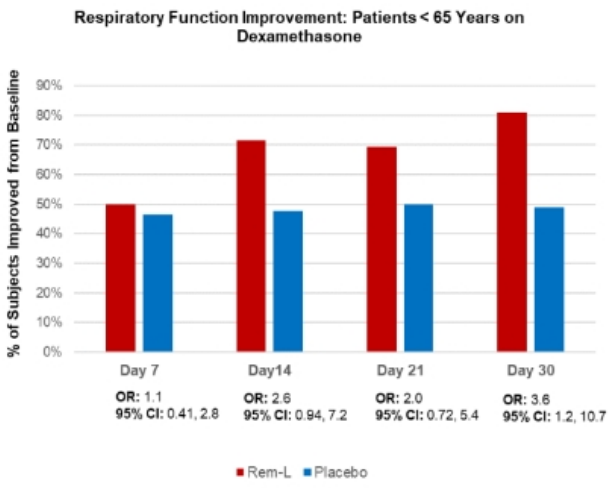
* Measured as resolution and/or improvement of ARDS as defined by the Berlin criteria at Days 7, 14, 21, and 30 post-randomizations

Remestemcel-L Plus Dexamethasone Shows Synergy in Mortality Reduction and Improvement in ARDS Severity in Exploratory Population < 65 years old

Treated Patients (mITT) < 65 years old on Dexamethasone (n=73) through 90-Days



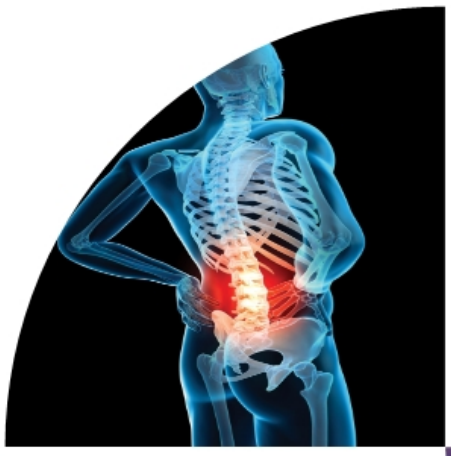
Treated Patients (mITT) < 65 years old on Dexamethasone (n=73)



* Respiratory Function Improvement measured as resolution and/or improvement of ARDS as defined by the Berlin criteria at Days 7, 14, 21, and 30 post-randomizations; Clinical Improvement was assessed based on a 7-point ordinal scale at baseline and on Days 7, 14, 21, and 30 and discharge from hospital

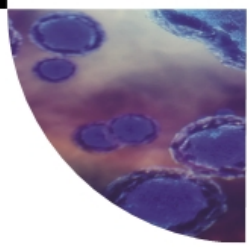
Remestemcel-L: Regulatory Pathway to Potential EUA for COVID-19 ARDS

- The FDA has advised Mesoblast that an additional clinical study in COVID ARDS, if statistically positive, could provide a dataset in conjunction with the recently completed 222 patient clinical study that might be sufficient to support an emergency use authorization (EUA)
- The 222 patient study was conducted by the US National Institutes of Health–funded Cardiothoracic Surgical Trials Network of investigators
- FDA indicated that potency assays must be established and agreed prior to commencement of the proposed Phase 3 clinical trial
- FDA provided guidance that the existing COVID ARDS Investigational New Drug (IND) file and future submissions for remestemcel-L in this indication may continue to cross-reference manufacturing and potency assay information in BLA for pediatric SR-aGVHD
- Mesoblast plans to move forward with an additional Phase 3 trial in COVID-19 ARDS with the next step being to agree on the final protocol with FDA and the trial clinical investigators



Rexlemestrocel-L

Chronic Low Back Pain (CLBP) due to Degenerative Disc Disease (DDD)



Rexlemestrocel-L

A New Paradigm for Treatment of Chronic Low Back Pain due to Degenerative Disc Disease

Burden of Illness

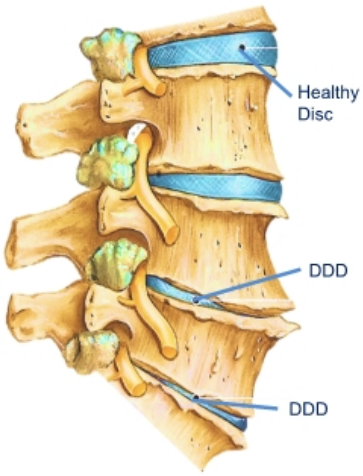
- Back pain causes more disability than any other condition[1]
- Inflicts substantial direct and indirect costs on the healthcare system[1], including excessive use of opioids in this patient population

Minimal Treatment Options

- Minimal treatment options for patients with chronic low back pain (CLBP) who fail conservative therapy include opioids and surgery
- 50% of opioid prescriptions are for CLBP[3]
- Durable improvement in pain has potential to reduce opioid use and prevent surgical intervention

Market Opportunity

- Over 7m patients are estimated to suffer from CLBP due to degenerative disc disease (DDD) in each of the U.S. and E.U.5 [3,4,5]
- MPC-06-ID development program targets over 3.2m patients in U.S. and 4m in E.U.5 with moderate to severe disease



1. Williams, J., NG, Nawi, Pelzter, 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(6): 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., 6. HealthCare Utilization and Cost of Discogenic Lower Back Pain in the US – Anthem/HealthCore.

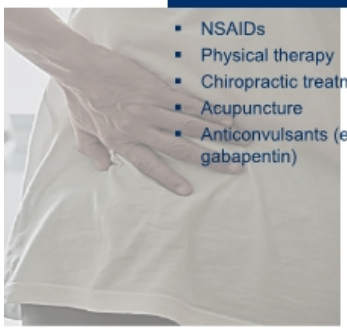
Current Patient Treatment Journey (US/EU) for Discogenic CLBP

Rexlemestrocel-L (MPC-06-ID) Potential for First-Line DCLBP Refractory to Conservative Treatment

Rexlemestrocel-L (MPC-06-ID) targeting moderate-to-severe DCLBP

Conservative treatments

- NSAIDs
- Physical therapy
- Chiropractic treatments
- Acupuncture
- Anticonvulsants (e.g., gabapentin)



Opioid analgesics

- Weak opioid analgesics (e.g., tramadol)
- Strong opioid analgesics (e.g., oxycodone)

Interventional therapies

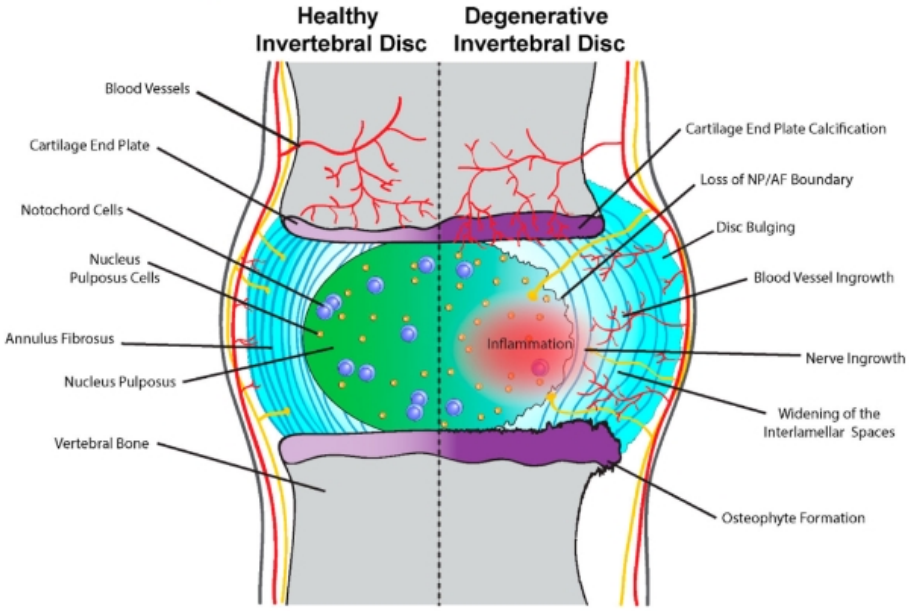
- Epidural steroid injections (off-label)
- Radio frequency ablation
- Spinal cord stimulation
- Intrathecal pumps

Surgeries

- Spinal fusion
- Disc replacement

Chronic Low Back Pain

Inflammation is at the Core of Degenerative Disc Disease

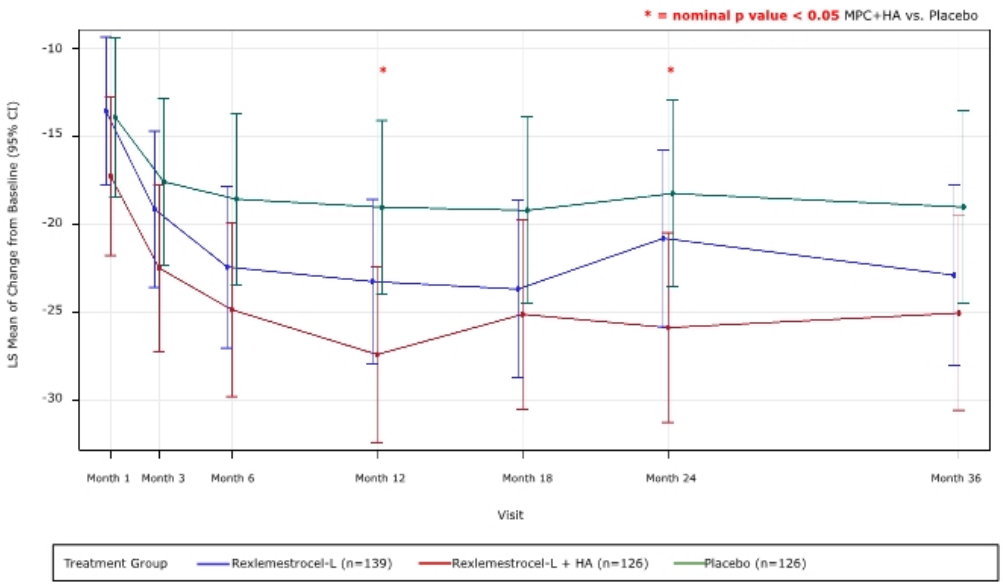


McCann MR and Seguin CA. Notochord Cells in Intervertebral Disc Development and Degeneration. J. Dev. Biol. **2016**, 4(1), 3

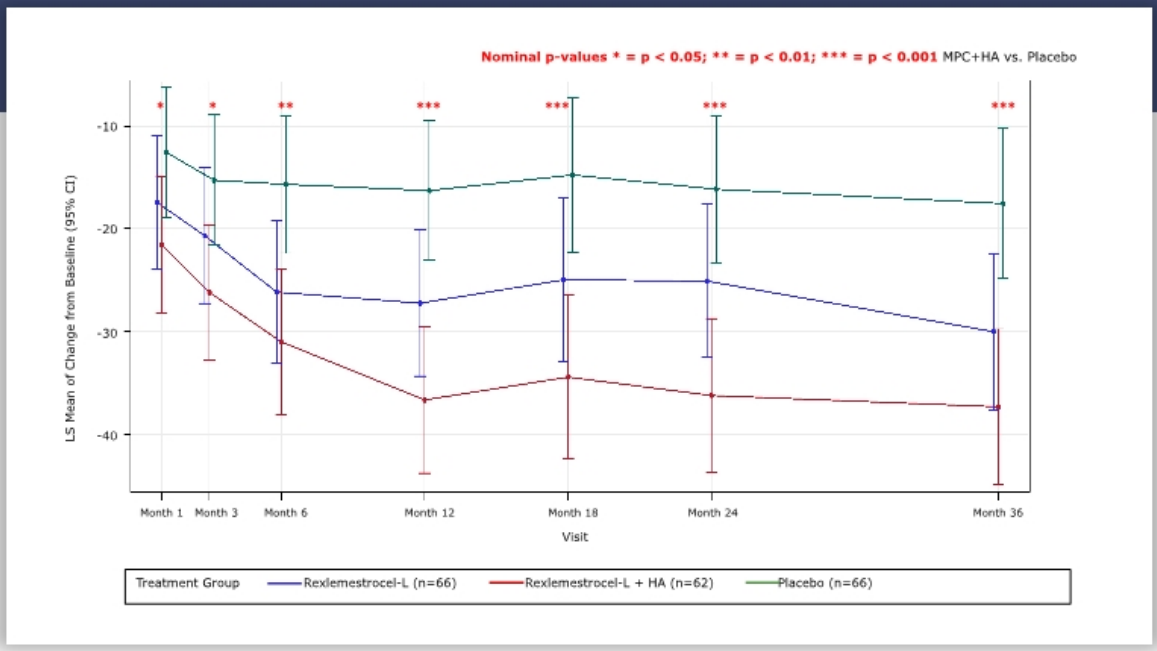
Results of 404-Patient Randomized Controlled Phase 3 Trial in CLBP: Single Injection of Rexlemestrocel-L + HA Results in >2 Years of Pain Reduction

- Positive results from a single injection of MPC + Hyaluronic Acid (HA) carrier include:
  - Achievement of significant and durable reductions in CLBP (mean change from baseline in back pain intensity) through 36 months across the entire evaluable study population (n=391) compared with saline controls
  - Greatest pain reduction was observed in the pre-specified population of subjects with CLBP duration shorter than the baseline study median of 68 months (n=194), significantly greater reduction (nominal p-value < 0.05) at all time points analyzed over 36 months compared with saline controls
  - Significantly greater pain reduction in the pre-specified patient subset of opioid users (n=168) at all time-points compared with saline controls and by 36 months there was a significant increase in the proportion of patients that came off opioids altogether

LS Mean Change in Low Back Pain from Baseline - Entire Study (n=391)

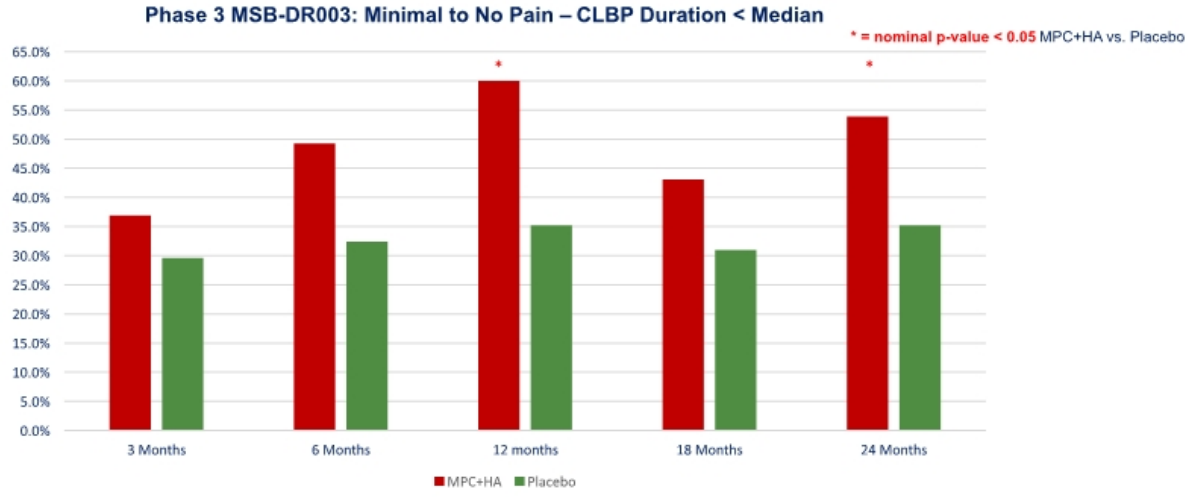


LS Mean VAS Change in Low Back Pain from Baseline - Duration CLBP < 68 Month Median (n=194)



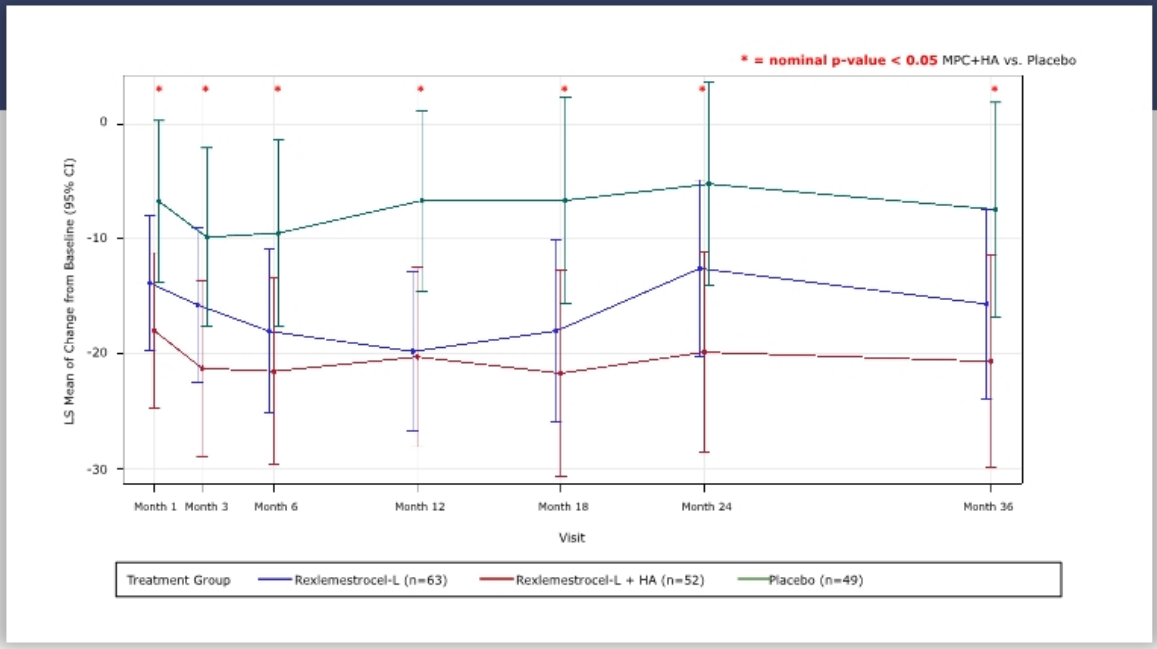
Subjects with Minimal to No Pain (VAS ≤ 20)

MPC + HA Increased Proportion of Patients with Minimal/No Pain (VAS <20) at 12 and 24 Months in those with Pain Duration < Median



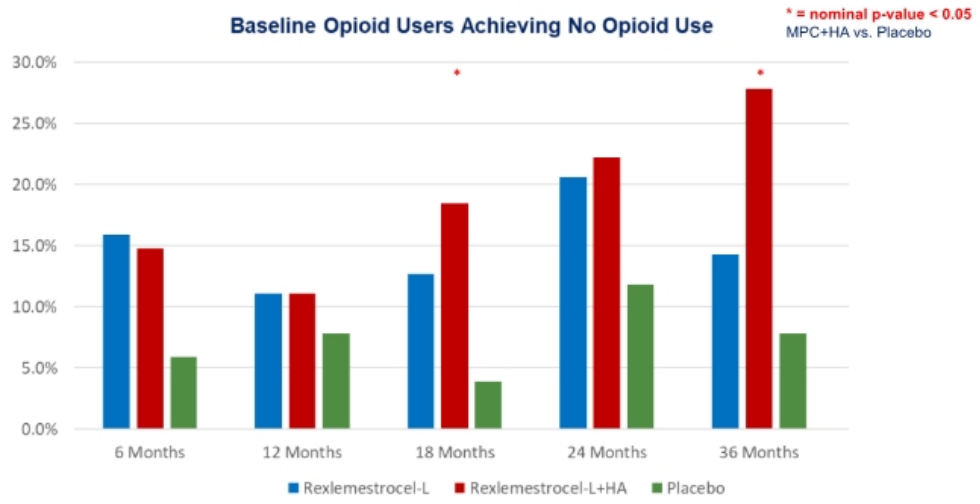
Minimal to No Pain – Subjects with a Low Back Pain VAS score ≤ 20 mm AND no post-treatment intervention through timepoint being evaluated. Subjects with missing data imputed as non-responders.

LS Mean VAS Change in Low Back Pain from Baseline - Opioid Users (n=168)



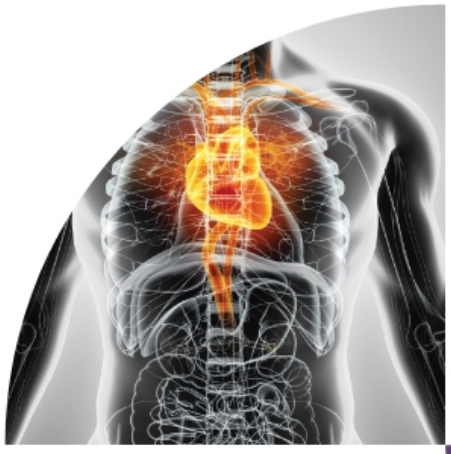
Pain Medication in Opioid Users

MPC + HA Increased the Proportion of Patients with Baseline Opioid Use Who Came Off Opioids Through 36 Months



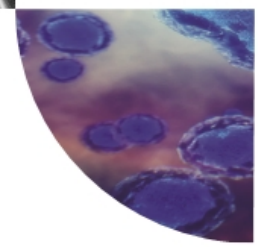
Next Steps for Rexlemestrocel-L in Chronic Low Back Pain

- Recently received feedback from the FDA Office of Tissues and Advanced Therapies (OTAT) on the Phase 3 program
- OTAT agreed with Mesoblast's proposal for mean pain reduction at 12 months to serve as the primary endpoint of the next trial, with mean functional improvement and reduction in opioid use as secondary endpoints
- A key objective is to demonstrate durable reduction in pain and position rexlemestrocel-L as a potential opioid-sparing agent
- The planned upcoming US trial will include at least 20% of subjects from the EU to support submissions to both FDA and EMA



Rexlemestrocel-L

Chronic Heart Failure with Reduced Ejection Fraction (HFrEF)

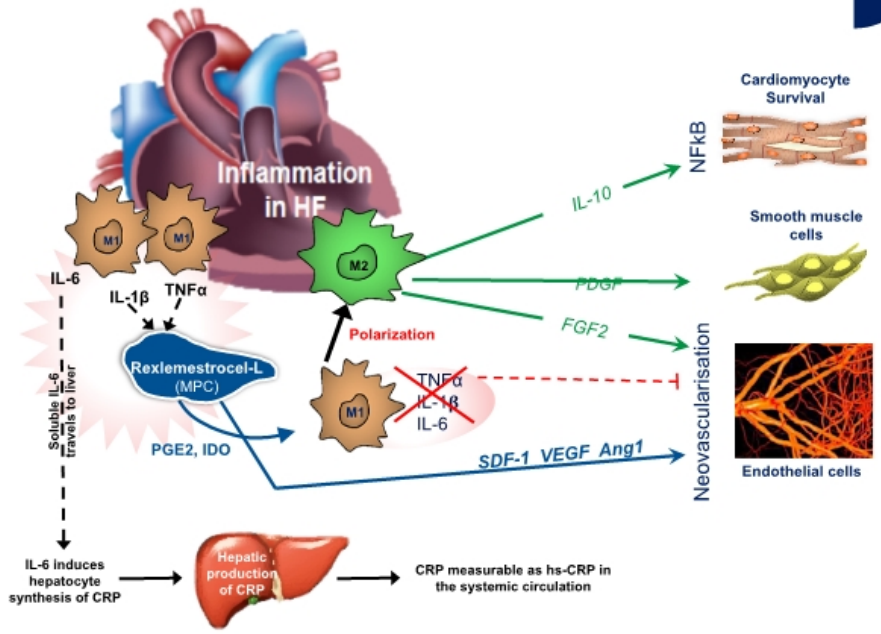


Proposed Mechanism of Action of Intra-Cardiac MPC Administration in Treatment of both Heart Failure & Large Vessel Atherosclerosis

Mesenchymal precursor cells (MPC) key mechanisms of action thought to beneficially impact the heart and the systemic vasculature:

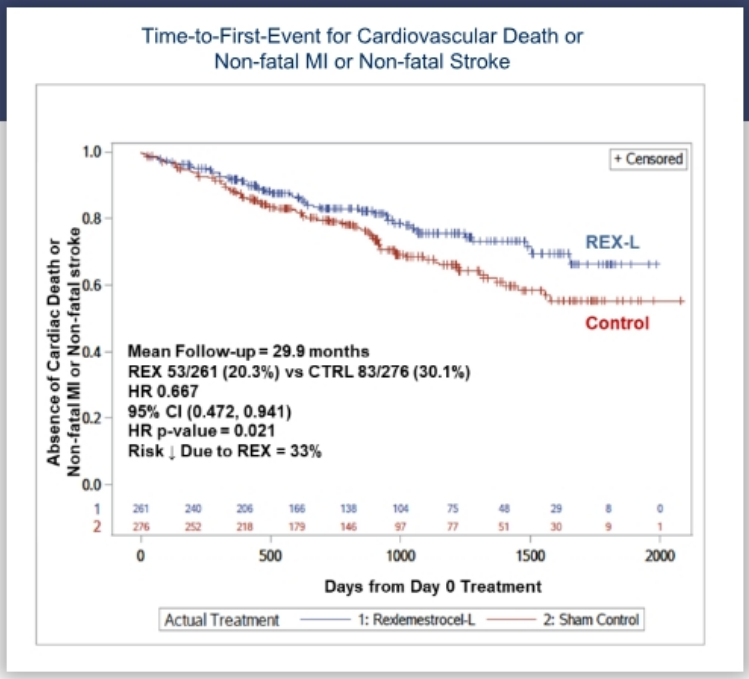
- Reduction in cardiac and systemic inflammation
- Reversal of endothelial dysfunction
- Induction of microvascular network within viable heart muscle
- Reduction in heart muscle death

hs-CRP synthesized in the liver is the systemic consequence of intra-cardiac IL-6 production



Modified from Borow KM, Yaroshinsky A, Greenberg B, Perin E. Phase 3 DREAM-HF Trial of Mesenchymal Precursor Cells in Chronic Heart Failure: A Review of Biological Plausibility and Implementation of Flexible Clinical Trial Design. *Circ Res.* 2019;125:265-281

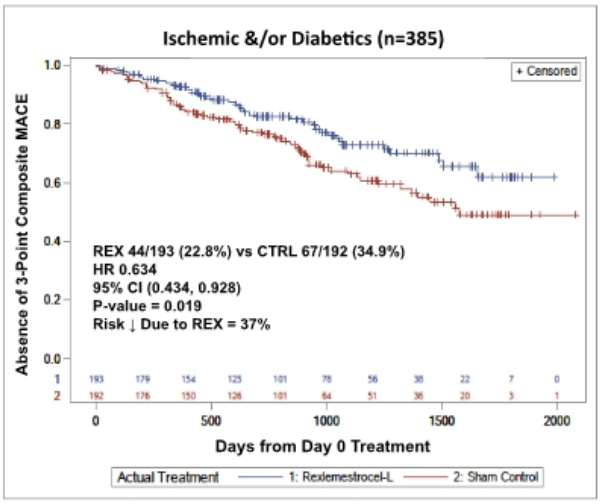
Rexlemestrocel-L Reduced Incidence of 3-Point Composite MACE (CV Death, MI or Stroke) Compared to Controls Across All 537 Treated Patients



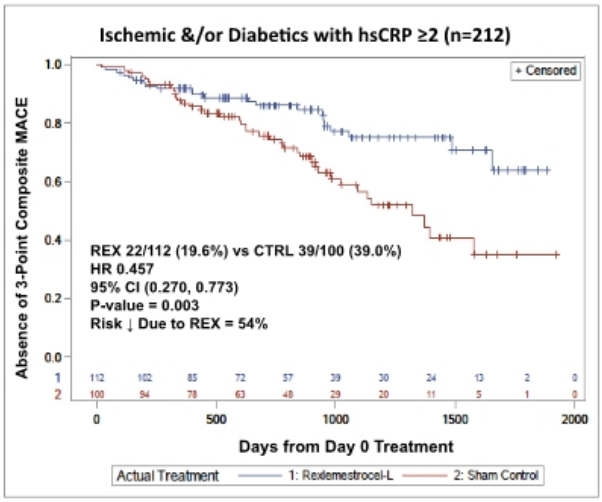
Kaplan-Meier log rank statistics

Composite 3-Point MACE and Inflammation

Rexlemestrocel-L Reduced Risk of 3-Point TTFE Composite IMM MACE in High-Risk Patients with Myocardial Ischemia &/or Diabetes by 37%



In Patients with Myocardial Ischemia and/or Diabetes with hsCRP≥2 mg/L Rexlemestrocel-L Reduced Risk of TTFE for 3-Point MACE by 54%



Kaplan-Meier log rank statistics

Investigational Agents Evaluated for Cardiovascular Risk Reduction Using 3-Point IMM MACE*: Comparison With Rexlemestrocel-L in Patients With Myocardial Ischemia &/or Diabetes

Medication	Drug Class	Clinical Trial	Hazard Ratio	Risk Reduction	95% CI	P-value	# Randomized Patients
Liraglutide	GLP-1 Receptor Agonist (RA)	LEADER	0.87	13%	0.78, 0.97	0.01	9,340
		Heart Failure Sub-group	0.94	6%	0.72, 1.21	-------	1,305
Dulaglutide	GLP-1 Receptor Agonist (RA)	REWIND	0.88	12%	0.79, 0.99	0.03	9,901
Empagliflozin	SGLT-2 Inhibitor	EMPA-REG	0.86	14%	0.74, 0.99	0.04	7,020
Canagliflozin	SGLT-2 Inhibitor	CANVAS + CANVAS-R	0.86	14%	0.75, 0.97	0.02	10,142
		Heart Failure Sub-group	0.80	20%	0.61, 1.05	-------	1,461
Dapagliflozin	SGLT-2 Inhibitor	DECLARE Timi 58	0.93	7%	0.84, 1.03	-------	17,160
		Heart Failure Sub-group	1.01	0%	0.81, 1.27	-------	1,724
Ertugliflozin	SGLT-2 Inhibitor	VERTIS CV	0.99	1%	0.88, 1.12	-------	8,246
Rexlemestrocel-L	**Mesenchymal Precursor Cells**	**DREAM HF Ischemics &/or Diabetics**	**0.63**	**37%**	**0.43, 0.93**	**0.019**	**385**
		Ischemics &/or Diabetics With Baseline hsCRP≥2mg/L	**0.46**	**54%**	**0.27, 0.77**	**0.003**	**212**

* TTFE Composite for Cardiovascular Death or Non-fatal MI or Non-fatal Stroke

Wang CCL et al. Circulation 2019; 139: 1741-1743. McGuire DK et al. JAMA Cardiol. 2021; 6:148-158.

Rexlemestrocel-L: Conclusion & Key Next Steps for HFrEF

1. Transendocardial delivery of 150 million allogeneic MPCs (rexlemestrocel-L) was safe and did not elicit any clinically meaningful immune-related responses
2. Over a mean follow-up of 30 months, a single rexlemestrocel-L dose on top of maximal standard of care significantly reduced:
   - Composite of cardiovascular death or non-fatal MI or non-fatal stroke in all 537 patients
   - A hierarchical analysis of pre-specified risk stratification showed greatest benefit in patients with myocardial ischemia and/or diabetes (72% of total treated population)
   - In controls (treated with maximal current therapies for heart failure), the presence of myocardial ischemia and/or diabetes resulted in 1.9-fold greater risk of 3-Point MACE versus other control patients with heart failure
   - Rexlemestrocel-L reduced 3-Point MACE in myocardial ischemics and/or diabetics by 37%
   - Greatest benefit in patients with elevated CRP at baseline with reduction in 3-Point MACE of 54% (n = 212)
3. Mesoblast to formally submit to FDA its new analyses of outcomes in high-risk HFrEF patients with diabetes and/or myocardial ischemia to agree on a potential pathway to approval


mesoblast
Thank You