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 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 February 25, 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: February 25, 2022

INDEX TO EXHIBITS

Item	
99.1	Press release of Mesoblast Ltd, dated February 25, 2022.
99.2	Investor presentation of Mesoblast Ltd, dated February 25, 2022.

asx announcement

mesoblast
the regenerative medicine company

OPERATIONAL HIGHLIGHTS AND FINANCIAL RESULTS FOR THE PERIOD ENDED DECEMBER 31, 2021

Mesoblast Prepares for Resubmission of Biologics License Application

Melbourne, Australia; February 25 and New York, USA; February 24, 2022: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today reported financial results and operational highlights for the period ended December 31, 2021.

Financial Highlights

- Mesoblast completed a refinancing of its senior secured debt facility with a new US$90 million five-year facility provided by funds managed by Oaktree Capital Management, L.P.
- Cash on hand at the end of the quarter was US$94.8 million, with up to an additional US$40 million available to be drawn down from existing financing facilities subject to certain milestones
- Total Operating Activities saw a 40% reduction in net cash usage on the comparative quarter last year, to US$18.2 million in the current quarter
- Regulatory and manufacturing activities related to the planned Biologics License Application (BLA) resubmission for remestemcel-L in steroid-refractory acute graft versus host disease (SR-aGVHD) in children accounted for over half of this cash usage
- Revenues in the quarter were US$2.4 million, primarily from TEMCELL® HS Inj.[1] royalties on sales for SR-aGvHD in Japan, which increased 7% on the comparative quarter last year

Operational Highlights

Activities supporting potential resubmission of the Biologics License Application (BLA) for remestemcel-L in the treatment of children with steroid-refractory acute graft versus host disease (SR-aGVHD):

- Appointed Dr. Eric Rose as the Company's Chief Medical Officer (CMO). Dr. Rose brings to Mesoblast an extensive record of excellence in clinical development and successful interactions at the highest levels with key regulatory, industry and government stakeholders including the United States Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Biomedical Advanced Research and Development Authority (BARDA)
- Held meeting with the FDA's Office of Tissues and Advanced Therapies (OTAT) to address potency assay and chemistry, manufacturing, and controls (CMC) items identified in the complete response letter (CRL) for remestemcel-L in the treatment of SR-aGVHD in children
- FDA indicated that the *in vitro* immunomodulatory activity Mesoblast intends to measure for potency of the product is reasonable and that 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 potency assay measuring remestemcel-L's *in vitro* anti-inflammatory and immunomodulatory activity 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 FDA and address all other outstanding items as required for resubmission of the BLA

- 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, FDA will consider the adequacy of the clinical data in the context of the related CMC issues noted above.

Activities regarding the rexlemestrocel-L Phase 3 programs in chronic low back pain (CLBP) and chronic heart failure (CHF):

- During the period, Mesoblast received feedback from the FDA's 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
- Received feedback from FDA's OTAT confirming that reduction in major adverse cardiovascular events (MACE) of cardiovascular mortality or irreversible morbidity (non-fatal heart attack or stroke) is an acceptable clinically meaningful endpoint for determining the treatment benefit of rexlemestrocel-L for patients with chronic heart failure and low ejection fraction (HFrEF)
- Preparing formal submission to FDA of the detailed analyses of outcomes in high-risk HFrEF patients with diabetes and/or myocardial ischemia to agree on a potential pathway to approval

Board Update

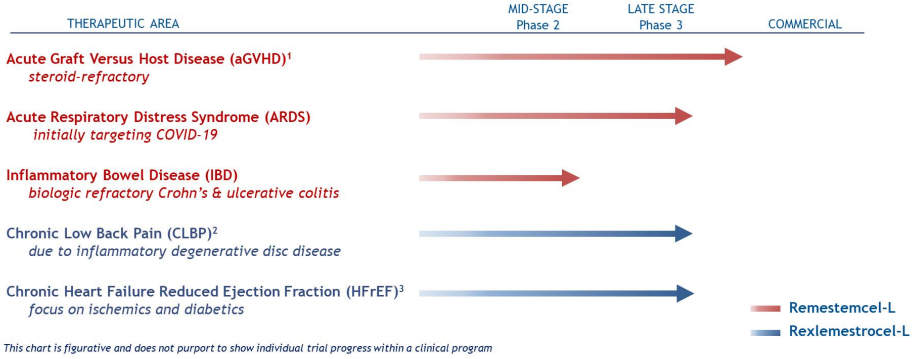
As foreshadowed at the Annual General Meeting in November 2021, the two long standing Australia-based non-executive directors will retire from the Board over a 6-12 month period. As such, Mr Donal O'Dwyer retires from the Board today.

Mesoblast's Chief Executive, Silviu Itescu said "I would like to thank Donal for his tenure since 2004 and specifically his vision, dedication, and commitment in supporting Mesoblast's objectives to bring important and potentially life-saving therapies to market."

The Mesoblast Board and management team wish to thank Donal for his invaluable contributions and wish him well in the future.

DETAILED PRODUCT ACTIVITIES FOR THE PERIOD

Late-Stage Clinical Pipeline



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

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Remestemcel-L

Steroid-refractory acute graft versus host disease (SR-aGVHD) in children:

Mesoblast met with FDA's OTAT to address the appropriateness of a potency assay related to remestemcel-L's proposed immunomodulatory mechanism of action as well as the approach to outstanding CMC items identified in the CRL. OTAT indicated that Mesoblast's approach to address outstanding CMC items is reasonable, that the *in vitro* immunomodulatory activity of remestemcel-L proposed by Mesoblast as a measure of its potency is a reasonable critical quality attribute (CQA) for the product in the treatment of children with SR-aGVHD, and the relevance of this immunomodulatory activity to clinical outcomes should be established.

The relevance of remestemcel-L's activity on severe inflammation was most recently shown in results from an investigator-initiated study, published in the peer-reviewed journal *Bone Marrow Transplantation*[2], in children with SR-aGVHD stratified by baseline levels of inflammatory biomarkers. The study compared outcomes in 25 children from Mesoblast's Phase 3 trial of remestemcel-L in SR-aGVHD with 27 closely matched children from the Mount Sinai Acute GVHD International Consortium (MAGIC)[3] who participated in a prospective natural history study and were matched for the Phase 3 trial entry criteria. The objective of the study was to evaluate whether remestemcel-L improved outcomes in children with highest risk of death, namely those with baseline MAGIC Algorithm Probability (MAP) biomarker levels ≥0.29, a level associated with significant GI inflammation and damage, and which is predictive of poor treatment responses and very high mortality in SR-aGVHD.

In children with MAP ≥0.29, treatment with remestemcel-L resulted in 67% Day 28 Overall Response and 64% Day 180 overall survival compared with 10% Day 28 Overall Response and 10% Day 180 survival in the MAGIC cohort (both p=0.01) when treated with various biologics, including ruxolitinib. These results showed that remestemcel-L provided a significant benefit in terms of both response and survival in children with the highest levels of inflammation and at greatest risk of death.

Mesoblast has now generated substantial new data that it believes establish the relevance of the proposed potency assay measuring remestemcel-L's *in vitro* anti-inflammatory and immunomodulatory activity 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 all other outstanding items as required for resubmission of the BLA.

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.

Inflammatory Bowel Disease (IBD) - Ulcerative Colitis & Crohn's Colitis

The immunomodulatory effects of remestemcel-L on GI inflammation is being further evaluated in a randomized, controlled study of remestemcel-L by direct endoscopic delivery to areas of inflammation in patients with medically refractory ulcerative colitis or Crohn's colitis. Results from an interim analysis of the first patient cohort showed that a single local delivery of remestemcel-L by colonoscopy resulted in rapid mucosal healing and disease remission in these refractory patients at high risk of progression to surgery. These results were presented at the 17th Congress of European Crohn's and Colitis Organisation (ECCO) by the trial's lead investigator Dr. Amy L. Lightner, Associate Professor of Surgery in the Department of Colon and Rectal Surgery at Cleveland Clinic and were published in the *Journal of Crohn's and Colitis*.[4,5]

The study at Cleveland Clinic will randomize up to 48 patients with medically refractory ulcerative colitis or Crohn's colitis in a 2:1 fashion to receive a single intervention with remestemcel-L or placebo. Medically refractory ulcerative colitis and Crohn's colitis patients are defined as having active disease for at least 6 months and having lost response to at least one monoclonal antibody (anti-TNF or anti-integrin).[6,7]

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Key results of the interim analysis performed in the first 12 enrolled patients were as follows:

- Colonoscopic delivery of remestemcel-L was not associated with any treatment-related adverse events
- All ulcerative colitis patients treated with remestemcel-L had improved clinical and endoscopy scores within two weeks, as defined by the Mayo clinical score and Mayo endoscopic severity (MES) score, and all achieved clinical and endoscopic remission by six weeks
- All ulcerative colitis patients were extremely satisfied or satisfied with remestemcel-L treatment at three months, based on the inflammatory bowel disease patient reported treatment impact (IBD-PRTI), and response was described as excellent or good in all patients
- All Crohn's colitis patients treated with remestemcel-L showed treatment remissions or responses by three months, as measured by the Simple Endoscopy Score for Crohn's Disease (SES-CD) (mean score 17 at baseline decreased to 5 at three months)
- Remestemcel-L treatment resulted in reduction of fecal calprotectin, a validated biomarker of disease activity,[8] from mean of 231 at baseline to 67 at three months, indicative of remission
- In controls with ulcerative colitis and Crohn's colitis over three months, endoscopy scores increased, fecal calprotectin levels increased from a mean of 330 to 505, and clinical responses were described as poor or unchanged

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

High infection rates continue and new variants of COVID-19 are emerging globally. Hospitalizations remain high with significant numbers of patients in ICU and on ventilators. The ongoing mortality rates underline the high unmet clinical need for new therapies in hospitalized patients who are at risk of developing ARDS.

Mesoblast has met with the FDA in regard to potential emergency use authorization (EUA) for remestemcel-L in the treatment of ventilator-dependent patients with moderate or severe ARDS due to COVID-19. The FDA advised Mesoblast that an additional clinical study in COVID ARDS would be required which, if statistically positive, could provide a dataset in conjunction with the recently completed 222 patient clinical study that might be sufficient to support an EUA. Mesoblast intends to move forward with the pivotal trial for EUA, with reference to the aGVHD BLA for product potency assay in place prior to trial commencement.

Rexlemestrocel-L

Chronic Low Back Pain (CLBP) associated with Degenerative Disc Disease (DDD)

There is a significant need for a safe, effective, and durable opioid-sparing treatment in patients with CLBP associated with degenerative disc disease. Mesoblast recently presented 36-month follow-up results from the 404-patient, three-arm, Phase 3 trial in patients with CLBP associated with DDD, 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.

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)

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During the period, Mesoblast received feedback from the FDA's 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.

Chronic Heart Failure

Data from the landmark DREAM-HF randomized, controlled Phase 3 trial of rexlemestrocel-L in 565 patients with chronic heart failure and low ejection fraction (HFrEF) were presented as a late breaking presentation at the AHA annual Scientific Sessions during a featured program titled 'Building on the Foundations of Treatment: Advances in Heart Failure Therapy.'

The trial's co-principal investigator Dr Emerson Perin, Medical Director of Texas Heart Institute, and Clinical Professor, Baylor College of Medicine, presented new results from the landmark study showing a significant relationship between presence of systemic inflammation as quantified by high-sensitivity C-reactive protein (hs-CRP) and treatment benefit with rexlemestrocel-L on risk of major adverse cardiovascular events (MACE) of cardiovascular mortality, heart attack or stroke.

In addition, FDA provided guidance that confirmed a reduction in incidence of cardiovascular mortality or irreversible morbidity (non-fatal heart attack or stroke) is a clinically meaningful acceptable endpoint in patients with chronic HFrEF and encouraged Mesoblast to identify the highest-risk group with greatest likelihood of beneficial response to intervention with rexlemestrocel-L in the DREAM-HF Phase 3 trial.

In line with this guidance, Mesoblast performed additional analyses of MACE outcomes in pre-specified high-risk patient groups from the landmark DREAM-HF trial, and the results were presented in December at the 18th Global CardioVascular Clinical Trialists Forum (CVCT) in Washington DC.

The data showed that:

- While a single rexlemestrocel-L dose on top of maximal standard of care therapies reduced the composite 3-point MACE in all 537 patients by 33% (p=0.02) over a mean follow-up of 30 months, a hierarchical analysis across pre-specified high-risk subgroups showed greatest benefit in patients with diabetes and/or myocardial ischemia (hazard ratio 0.63, p=0.019)
- Among control patients with HFrEF (n=276) all of whom were treated with maximal available standard of care therapies, risk of 3-point MACE was 1.9-fold higher in controls with diabetes and/or myocardial ischemia (n=192) than controls with neither diabetes nor myocardial ischemia (n=84), p=0.02. This confirmed the ongoing high-risk of 3-point MACE in control patients with diabetes and/or myocardial ischemia due to micro- and macro-vascular disease despite receiving optimal standard of care therapies
- Compared to control patients, rexlemestrocel-L reduced the incidence of 3-point MACE by 37% overall in NYHA class II or III HFrEF patients with diabetes and/or myocardial ischemia (n=385, p=0.02) and by 54% in those with diabetes and/or myocardial ischemia who had evidence of systemic inflammation, as defined by elevated baseline levels of hs-CRP >2mg/L (n=212, p=0.003).

Diabetes Mellitus is not only a significant risk factor in the onset of heart failure, it also increases the risk of mortality and morbidity in patients who have existing heart failure.[9-11] Type 2 diabetes causes structural heart disease and heart failure through myocardial ischemia involving small and large vessels. Importantly, inflammation which is a critical component of the pathophysiology of the disease is also known to accelerate large vessel atherosclerosis.[9]

Mesoblast will submit for formal FDA review the new data analyses showing the reduction in mortality and irreversible morbidity by rexlemestrocel-L in HFrEF patients with diabetes and/or myocardial ischemia, to agree on a potential pathway to approval.

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FINANCIAL RESULTS FOR THE PERIOD ENDED DECEMBER 31, 2021 (SECOND QUARTER FY2022)

- **Total Revenue** was US$2.4 million for the second quarter FY2022, primarily from TEMCELL® HS Inj.[1] royalties on sales for SR-aGvHD in Japan, which increased 7% on the comparative quarter last year
- In November Mesoblast completed a refinancing of its senior secured debt facility with a new US$90 million five-year facility provided by funds managed by Oaktree Capital Management, L.P.
- **Cash on hand** at the end of the quarter was US$94.8 million, with up to an additional US$40 million available to be drawn down from existing financing facilities subject to certain milestones.
- **Net operating cash** usage was US$18.2 million for the second quarter FY2022, a reduction of 40% or US$12.4 million on the comparative quarter.
- **Research & Development expenses** reduced by US$4.0 million (28%), down to US$10.2 million for the second quarter FY2022 from US$14.2 million for the second quarter FY2021 as clinical trial activities for our COVID-19 ARDS, CLBP and CHF product candidates reduced given clinical trial recruitment and data analysis is now complete.
- **Manufacturing expense** were US$6.6 million for the second quarter FY2022, compared to US$6.5 million for the second quarter FY2021. During the quarter we continued to build our pre-launch inventory levels of remestemcel-L to support the long-term commercial supply for SR-aGVHD and COVID ARDS.

  We expect to recognize the US$28.0 million balance of remestemcel-L pre-launch inventory, and the balance of any further production completed at that time, on our balance sheet if we receive FDA approval.
- **Management and Administration** expenses were stable at US$7.8 million and US$7.9m for the second quarters FY2022 and FY2021 respectively.
- **Remeasurement of Contingent Consideration** reduced to a loss of US$0.3 million for the second quarter FY2022 whereas a gain of US$1.5 million was recognized in the second quarter FY2021 as a result of revaluing future third party payments.
- **Fair value movement of warrants** a gain of US$2.2 million in the second quarter FY2022, compared to Nil for the second quarter FY2021.
- **Finance Costs** for borrowing arrangements with Hercules, NovaQuest and Oaktree were US$5.4 million for the second quarter FY2022, compared to US$1.1 million for the second quarter FY2021. The increase was primarily due to the recognition of a non-cash gain on revaluation of our borrowings in the comparative quarter.

Loss after tax for the second quarter FY2022 was US$25.9 million compared to US$25.7 million for the second quarter FY2021.The net loss attributable to ordinary shareholders was 4.00 US cents per share for the second quarter FY2022, compared with 4.38 US cents per share for the second quarter FY2021.

Conference Call

There will be a webcast today, beginning at 9.00am AEDT (Friday, February 25); 5.00pm EST (Thursday, February 24). It can be accessed via: https://webcast.openbriefing.com/8499/

The archived webcast will be available on the Investor page of the Company's website: www.mesoblast.com

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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 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

References / Footnotes

1. TEMCELL® HS Inj. is a registered trademark of JCR Pharmaceuticals Co. Ltd.
2. Kasikis S., et al. Mesenchymal stromal cell therapy induces high responses and survival in children with steroid refractory GVHD and poor risk. *Bone Marrow Transplantation* 2021; https://doi.org/10.1038/s41409-021-01442-3
3. 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
4. Lightner A., et al. A Phase IB/IIA study of remestemcel-L, an allogeneic bone marrow derived mesenchymal stem cell product, for the treatment of medically refractory Crohn's colitis: A preliminary analysis. *Journal of Crohn's and Colitis*, Volume 16, Issue Supplement_1, January 2022, Pages i412–i413, https://doi.org/10.1093/ecco-jcc/jjab232.555
5. Lightner A., et al. A Phase IB/IIA study of remestemcel-L, an allogeneic bone marrow derived mesenchymal stem cell product, for the treatment of medically refractory ulcerative colitis: An interim analysis. *Journal of Crohn's and Colitis*, Volume 16, Issue Supplement_1, January 2022, Pages i398–i399, https://doi.org/10.1093/ecco-jcc/jjab232.534
6. Abreu MT and Sandborn WJ. Defining Endpoints and Biomarkers in Inflammatory Bowel Disease: Moving the Needle Through Clinical Trial Design. *Gastroenterology* 2020;159:2013–2018
7. Daperno M, et al. Development and validation of a new, simplified endoscopic activity score for Crohn's disease: the SES-CD. *Gastrointest Endosc* 2004;60:505–512.
8. Pathirana GW, et al. Faecal Calprotectin. *Clin Biochem Rev.* 2018 Aug; 39(3): 77–90.
9. Dunlay SM., et al. Circulation. 2019;140:e294–e324
10. Wang CCL et al. Circulation 2019; 139: 1741-1743.
11. McGuire DK et al. JAMA Cardiol. 2021; 6:148-158.

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

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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.

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mesoblast
the regenerative medicine company

Consolidated Income Statement

(in U.S. dollars, in thousands, except per share amount)	Three Months Ended December 31, 2021	Three Months Ended December 31, 2020	Six Months Ended December 31, 2021	Six Months Ended December 31, 2020
Revenue	2,383	2,241	5,977	3,546
Research & development	(10,198)	(14,238)	(19,526)	(33,516)
Manufacturing commercialization	(6,590)	(6,450)	(14,127)	(18,374)
Management and administration	(7,814)	(7,867)	(13,692)	(15,546)
Fair value remeasurement of contingent consideration	(351)	1,462	(71)	16,569
Fair value remeasurement of warrant liability	2,152	—	2,152	—
Other operating income and expenses	(227)	296	(405)	395
Finance costs	(5,380)	(1,062)	(9,040)	(3,966)
Loss before income tax	**(26,025)**	**(25,618)**	**(48,732)**	**(50,892)**
Income tax benefit/(expense)	80	(74)	142	656
Loss attributable to the owners of Mesoblast Limited	**(25,945)**	**(25,692)**	**(48,590)**	**(50,236)**
Losses per share from continuing operations attributable to the ordinary equity holders of the Group:	**Cents**	**Cents**	**Cents**	**Cents**
Basic - losses per share	(4.00)	(4.38)	(7.50)	(8.60)
Diluted - losses per share	(4.00)	(4.38)	(7.50)	(8.60)

Consolidated Statement of Comprehensive Income

(in U.S. dollars, in thousands)	Three Months Ended December 31, 2021	Three Months Ended December 31, 2020	Six Months Ended December 31, 2021	Six Months Ended December 31, 2020
Loss for the period	**(25,945)**	**(25,692)**	**(48,590)**	**(50,236)**
Other comprehensive (loss)/income				
Items that may be reclassified to profit and loss				
Exchange differences on translation of foreign operations	166	904	(183)	1,312
Items that will not be reclassified to profit and loss				
Financial assets at fair value through other comprehensive income	112	(53)	266	28
Other comprehensive (loss)/income for the period, net of tax	**278**	**851**	**83**	**1,340**
Total comprehensive losses attributable to the owners of Mesoblast Limited	**(25,667)**	**(24,841)**	**(48,507)**	**(48,896)**

Consolidated Balance Sheet

(in U.S. dollars, in thousands)	As of December 31, 2021	As of June 30, 2021
Assets		
Current Assets		
Cash & cash equivalents	94,849	136,881
Trade & other receivables	6,048	4,842
Prepayments	7,900	6,504
Total Current Assets	**108,797**	**148,227**
Non-Current Assets		
Property, plant and equipment	2,470	3,021
Right-of-use assets	9,033	9,119
Financial assets at fair value through other comprehensive income	2,347	2,080
Other non-current assets	1,956	1,724
Intangible assets	579,836	580,546
Total Non-Current Assets	**595,642**	**596,490**
Total Assets	**704,439**	**744,717**
Liabilities		
Current Liabilities		
Trade and other payables	20,919	19,598
Provisions	22,288	18,710
Borrowings	5,203	53,200
Lease liabilities	3,489	2,765
Warrant liability	6,055	—
Total Current Liabilities	**57,954**	**94,273**
Non-Current Liabilities		
Deferred tax liability	—	—
Provisions	13,992	17,017
Borrowings	86,542	41,045
Lease liabilities	7,942	8,485
Deferred consideration	2,500	2,500
Total Non-Current Liabilities	**110,976**	**69,047**
Total Liabilities	**168,930**	**163,320**
Net Assets	**535,509**	**581,397**
Equity		
Issued Capital	1,163,586	1,163,153
Reserves	68,082	65,813
(Accumulated losses)/retained earnings	(696,159)	(647,569)
Total Equity	**535,509**	**581,397**

Mesoblast Limited
ABN 68 109 431 870

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Consolidated Statement of Cash Flows

(in U.S. dollars, in thousands)	Six Months Ended December 31, 2021	2020
Cash flows from operating activities		
Commercialization revenue received	5,531	1,972
Government grants and tax incentives received	24	17
Payments to suppliers and employees (inclusive of goods and services tax)	(41,977)	(59,357)
Interest received	4	16
Income taxes paid	—	(6)
Net cash (outflows) in operating activities	**(36,418)**	**(57,358)**
Cash flows from investing activities		
Investment in fixed assets	(103)	(488)
Payments for intellectual property	(26)	—
Net cash (outflows) in investing activities	**(129)**	**(488)**
Cash flows from financing activities		
Proceeds from borrowings	51,919	—
Repayment of borrowings	(55,458)	—
Payment of transaction costs from borrowings	(5,453)	—
Interest and other costs of finance paid	(2,951)	(2,771)
Proceeds from issue of shares	209	9,565
Proceeds from issue of warrants	8,081	—
Payments for share issue costs	(216)	(905)
Payments for lease liabilities	(1,214)	(1,480)
Net cash inflows/(outflows) by financing activities	**(5,083)**	**4,409**
Net decrease in cash and cash equivalents	(41,630)	(53,437)
Cash and cash equivalents at beginning of period	136,881	129,328
FX gain/(losses) on the translation of foreign bank accounts	(402)	1,637
Cash and cash equivalents at end of period	**94,849**	**77,528**

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(in U.S. dollars, in thousands)	Three Months Ended December 31, 2021	2020
Cash flows from operating activities		
Commercialization revenue received	3,536	1,290
Government grants and tax incentives received	—	—
Payments to suppliers and employees (inclusive of goods and services tax)	(21,755)	(31,873)
Interest received	—	3
Income taxes paid	—	—
Net cash (outflows) in operating activities	**(18,219)**	**(30,580)**
Cash flows from investing activities		
Investment in fixed assets	(4)	(407)
Payments for intellectual property	(26)	—
Net cash (outflows) in investing activities	**(30)**	**(407)**
Cash flows from financing activities		
Proceeds from borrowings	51,919	—
Repayment of borrowings	(55,458)	—
Payment of transaction costs from borrowings	(5,353)	—
Interest and other costs of finance paid	(1,544)	(1,382)
Proceeds from issue of shares	62	1,431
Proceeds from issue of warrants	8,081	—
Payments for share issue costs	(112)	(8)
Payments for lease liabilities	(528)	(785)
Net cash inflows/(outflows) by financing activities	**(2,933)**	**(744)**
Net decrease in cash and cash equivalents	(21,182)	(31,731)
Cash and cash equivalents at beginning of period (October 1)	115,956	108,123
FX gain/(losses) on the translation of foreign bank accounts	75	1,136
Cash and cash equivalents at end of period	**94,849**	**77,528**

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Exhibit 99.2

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Global Leader in Allogeneic Cellular Medicines for Inflammatory Diseases

Operational Highlights & Financial Results for the Period Ended December 31, 2021

February 2022

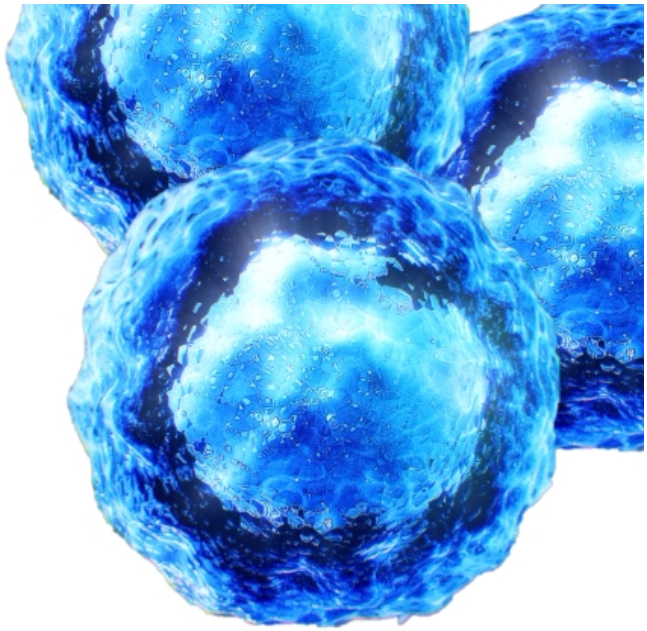
ASX: MSB; Nasdaq: MESO

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.

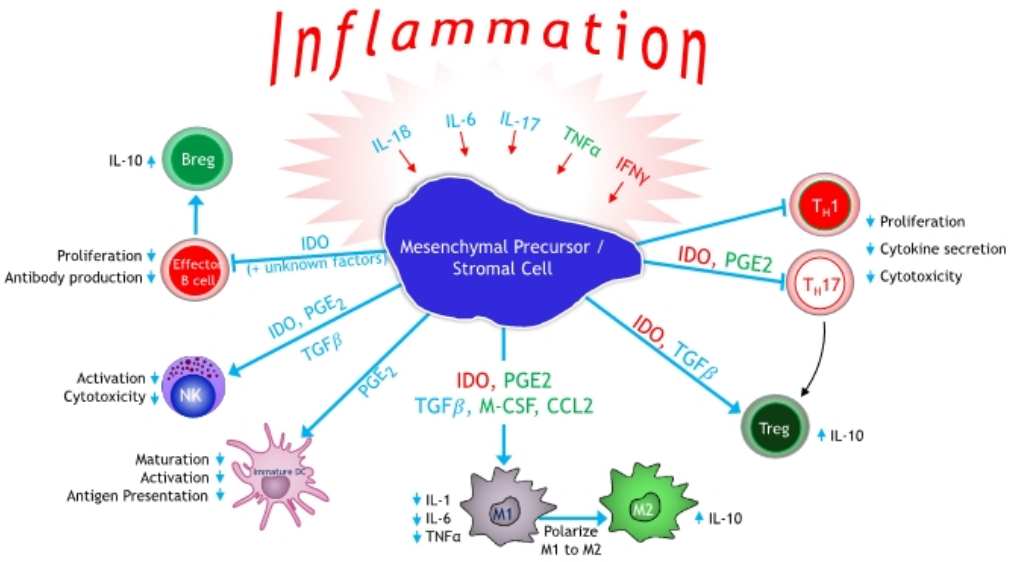
Our Mission

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

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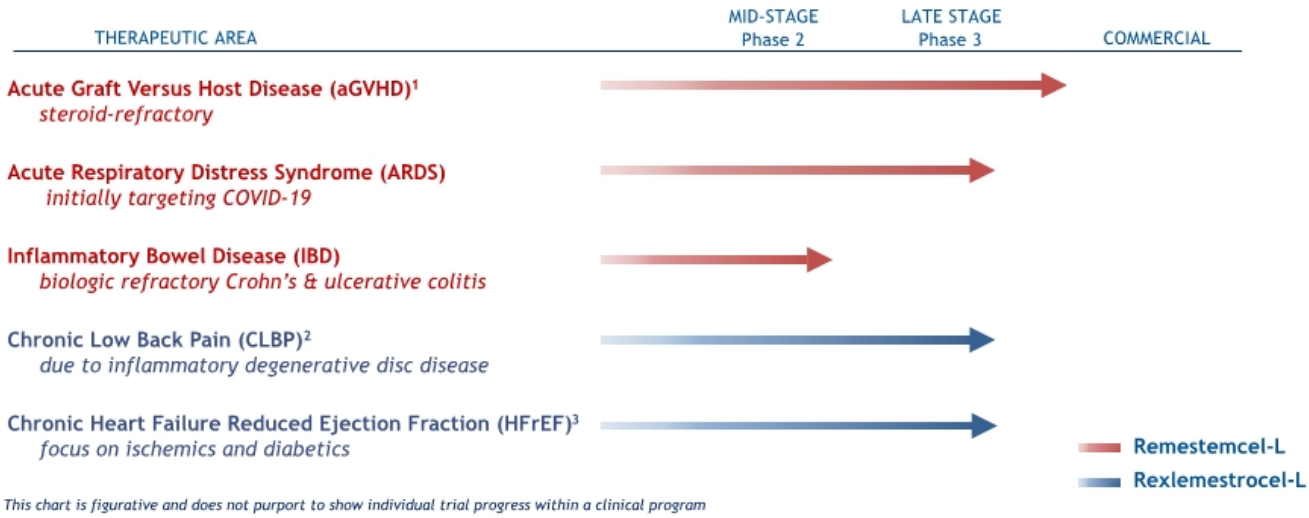
Late-Stage Clinical Pipeline



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

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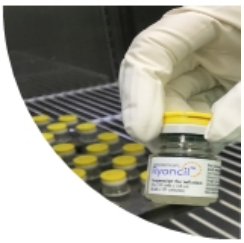

Financial Results

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Financial Highlights

- Revenues in the quarter were US$2.4 million, primarily from TEMCELL® HS Inj.[1] royalties on sales for SR-aGvHD in Japan, which increased 7% on the comparative quarter last year
- Cash on hand at the end of the quarter was US$94.8 million, with up to an additional US$40 million available to be drawn down from existing financing facilities subject to certain milestones
- Mesoblast completed a refinancing of its senior secured debt facility with a new US$90 million five-year facility provided by funds managed by Oaktree Capital Management, L.P.
- Total Operating Activities saw a 40% reduction in net cash usage on the comparative quarter last year, to US$18.2 million in the current quarter
- Regulatory and manufacturing activities related to the planned Biologics License Application (BLA) resubmission for remestemcel-L in steroid-refractory acute graft versus host disease (SR-aGVHD) in children accounted for over half of this cash usage

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

Reduction in R&D Spend; Steady Investment in Manufacturing

P&L for the 3 months ended (US$m)	Dec 31, 2021 (2nd Qtr FY2022)	Dec 31, 2020 (2nd Qtr FY2021)
Commercialization revenue	2.4	2.2
Total Revenue	**2.4**	**2.2**
Research and development	(10.2)	(14.2)
Manufacturing	(6.6)	(6.5)
Management & administration	(7.8)	(7.9)
Revaluation of contingent consideration	(0.3)	1.5
Revaluation of warrant liability	2.2	-
Other operating income & expenses	(0.2)	0.3
Finance costs	(5.4)	(1.1)
Loss before tax	**(26.0)**	**(25.6)**
Income tax benefit	0.1	(0.1)
Loss after tax	**(25.9)**	**(25.7)**

- **Decreased R&D Spend:**
  28% reduction ($4.0m) predominantly due to reduced spend on clinical trial activities.

- **Steady Investment in Manufacturing:**
  Continued build of pre-launch inventory of remestemcel-L to support the long-term commercial supply for SR-aGVHD, COVID-19 ARDS & IBD.

  On FDA approval, remestemcel-L inventory will be recognized on the balance sheet, currently at US$28.0 million.

- **Non-cash Movements in Finance Costs:**
  $4.3m increase was primarily due to the recognition of a non-cash gain on revaluation of our borrowings **in the comparative quarter.**

Remestemcel-L

Acute Graft Versus Host Disease (aGVHD)

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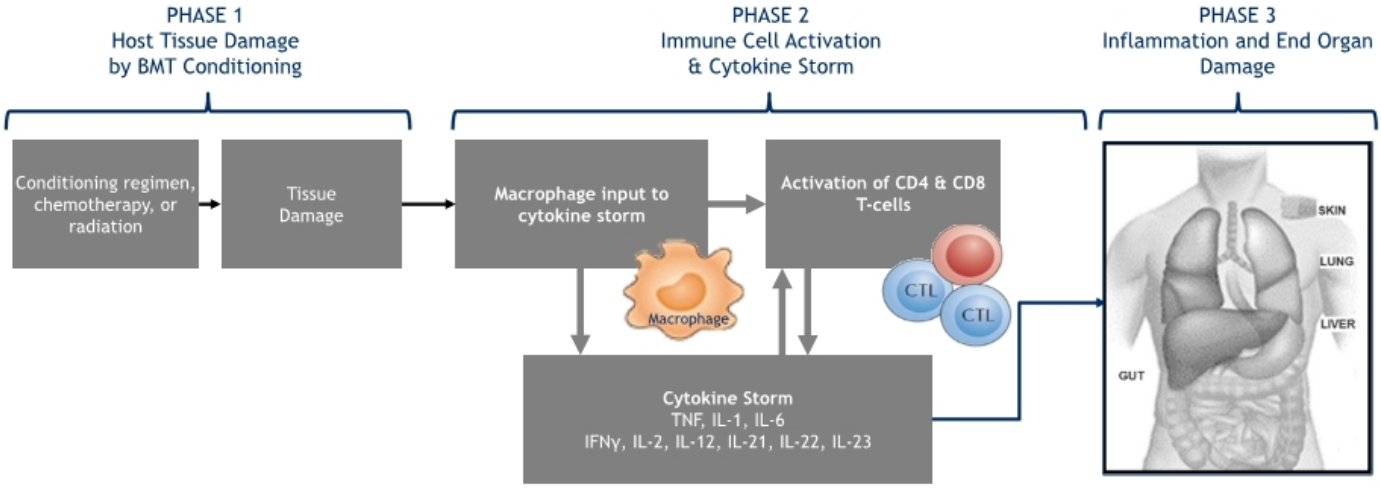
Acute Graft Versus Host Disease (aGVHD)

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



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

Acute Graft Versus Host Disease (aGVHD)

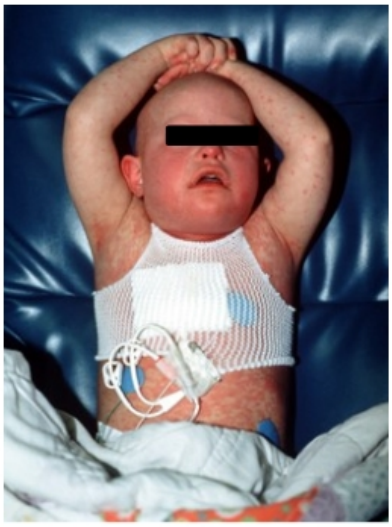
Serious and Fatal Complication of Allogeneic Bone Marrow Transplantation (BMT)

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



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

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

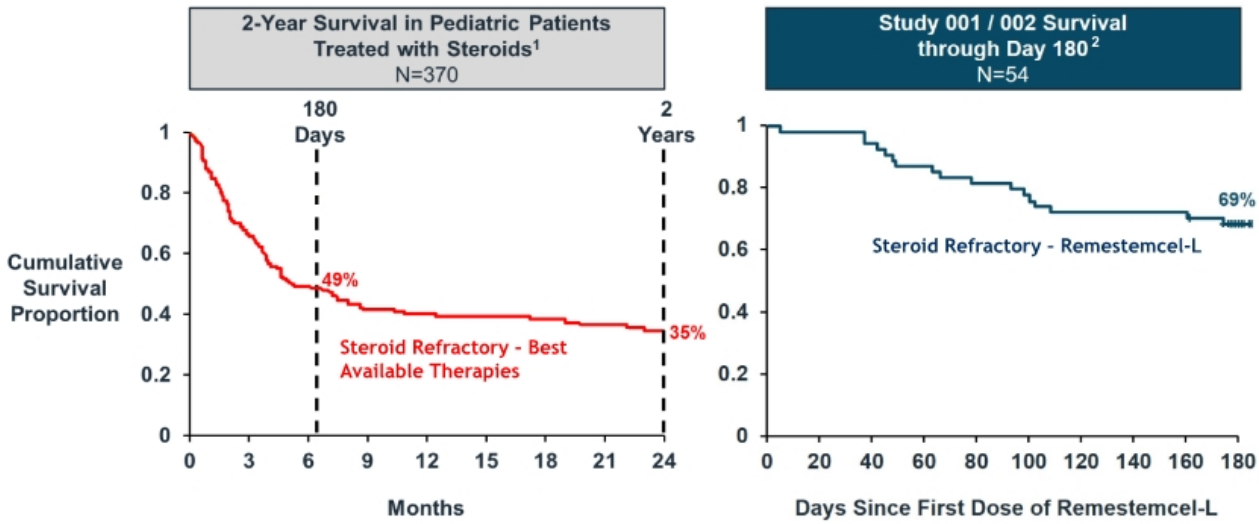
Consistent Efficacy and Safety Outcomes in a Total of 309 Children from Three Studies

- 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%

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

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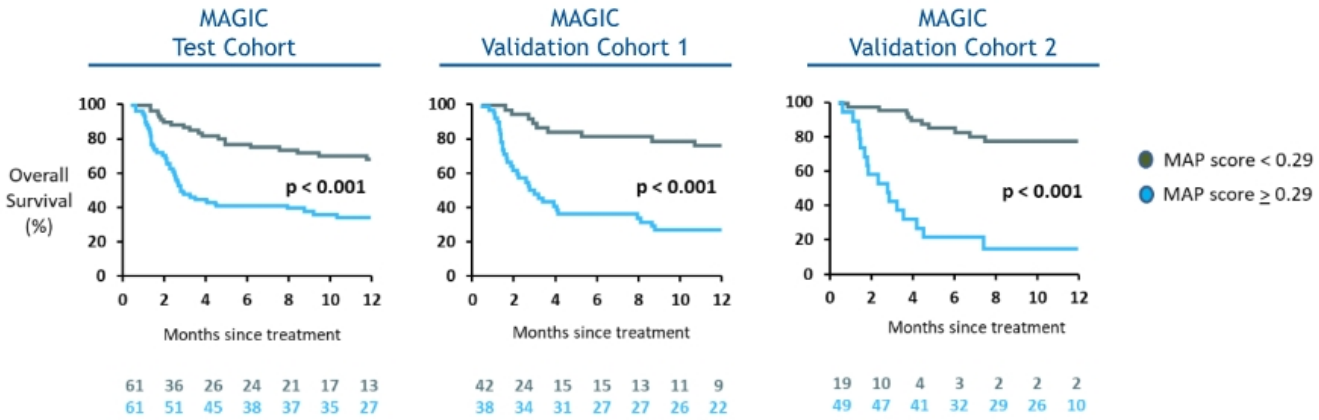
Identifying Acute GVHD Patients at High Risk of Non-Response to Treatment and Death

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

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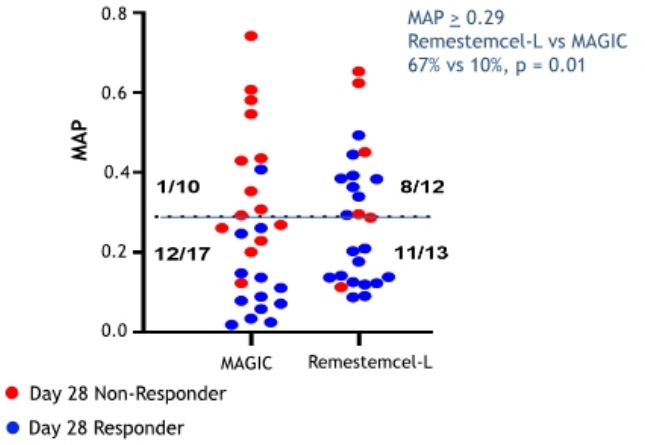
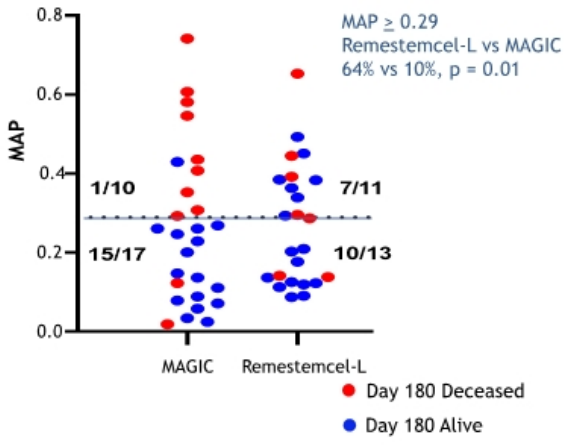
Remestemcel-L Treatment Outcomes

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

Response by Baseline MAP



Survival by Baseline MAP



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

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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

Remestemcel-L

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

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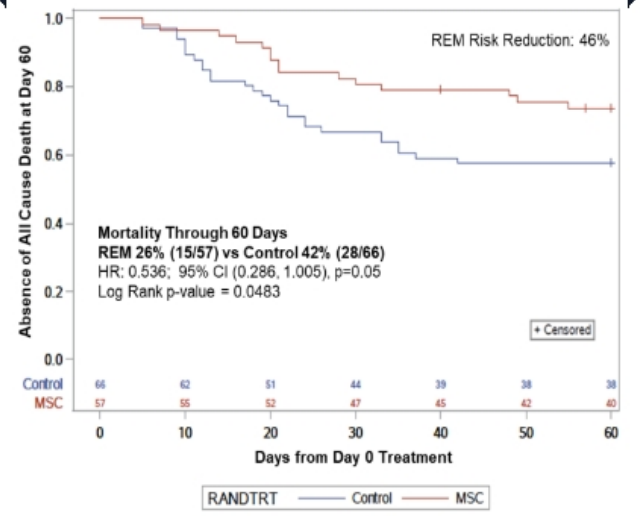
Remestemcel-L: Acute Respiratory Distress Syndrome (ARDS) due to COVID-19

Clinical Need for Therapeutic Remains High

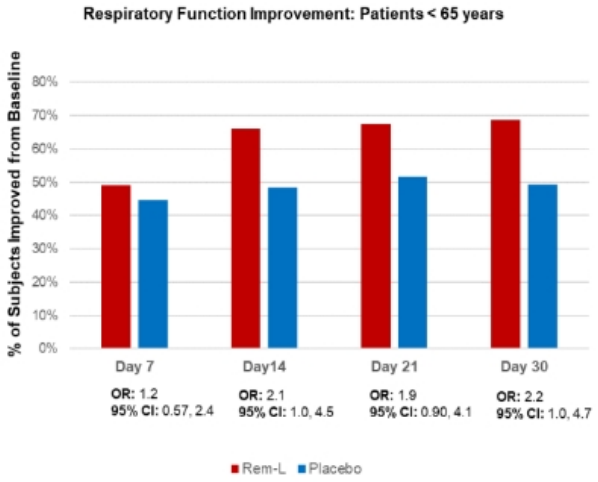
- COVID-19 is a respiratory virus with a high mortality due to a severe inflammatory condition of the lungs called acute respiratory disease syndrome (ARDS)
- ARDS is caused by cytokine storm in lungs of patients infected with COVID-19 and is the primary cause of death
- High infection rates continue and new variants of COVID-19 are emerging globally. Hospitalizations remain high with significant numbers of patients in ICU and on ventilators
- The ongoing mortality rates underline the high unmet clinical need for new therapies in hospitalized patients who are at risk of developing ARDS
- Remestemcel-L has the potential to tame the cytokine storm in ARDS and may offer a life-saving treatment for those suffering from COVID-19
- Mesoblast intends to move forward with the pivotal trial for EUA, with reference to the aGVHD BLA for product potency assay in place prior to trial commencement

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

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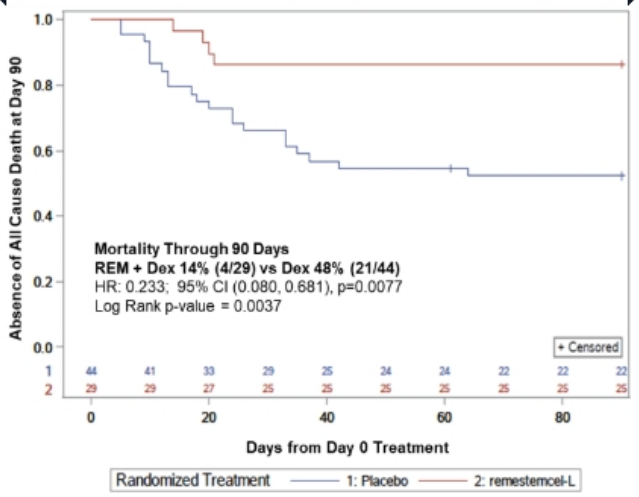
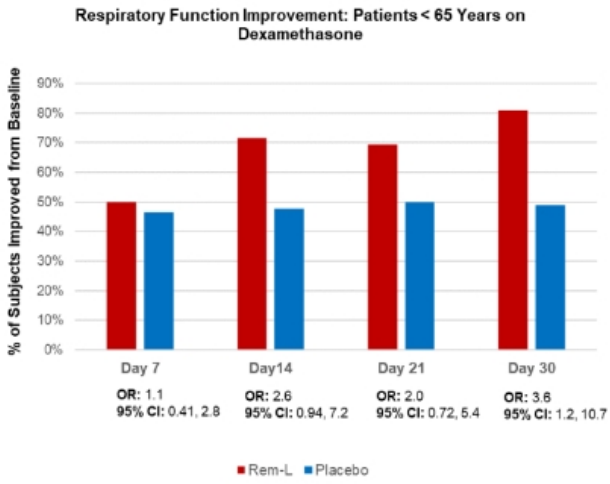
Remestemcel-L Plus Dexamethasone Shows Synergy in Mortality Reduction and Improvement in ARDS Severity* in Exploratory Population < 65 years old

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



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



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

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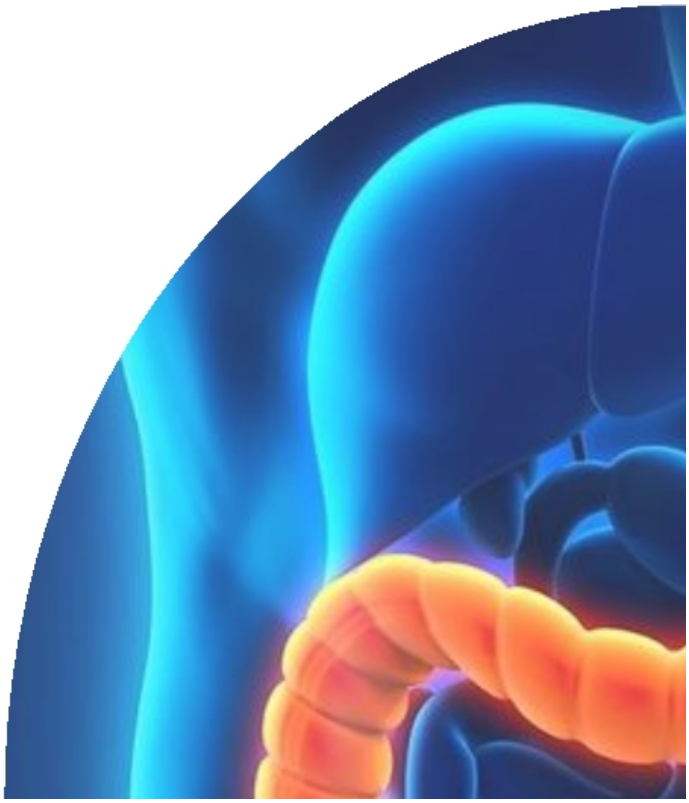
Remestemcel-L: Regulatory Pathway to Potential EUA for COVID-19 ARDS

- 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

Remestemcel-L

Inflammatory Bowel Disease

Ulcerative Colitis & Crohn's Disease



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Remestemcel-L: Inflammatory Bowel Disease

Potential Localized Treatment for Ulcerative Colitis & Crohn's Colitis Refractory to Biologics - High Unmet Need

Treatment Options

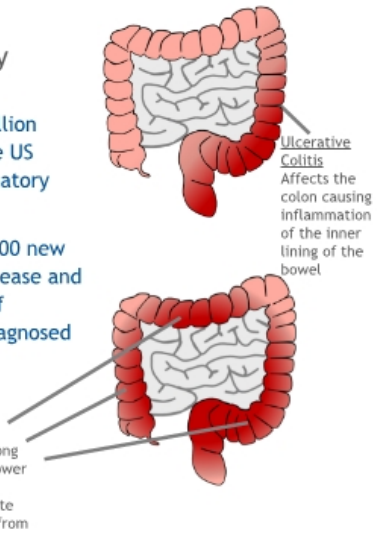
- Despite recent advances, approximately 30% of patients are primarily unresponsive to anti-TNFα agents
- Among responders, up to 10% will lose their response to the drug every year[1,2]

Burden of Illness

- Up to 80% of patients with medically-refractory Crohn's disease and 20% of patients with medically-refractory ulcerative colitis eventually require surgical treatment of their disease[1,2]
- Which can have a devastating impact on quality of life

Market Opportunity

- More than three million people (1.3%) in the US alone have inflammatory bowel disease[1]
- Approximately 33,000 new cases of Crohn's disease and 38,000 new cases of ulcerative colitis diagnosed every year[3-5]



1. Crohn's and Colitis Foundation; 2. Lightner AL. Surgery for Inflammatory Bowel Disease in the ERA of Biologics. J Gastroinest Surg. 2020 Vol 24: 1430-1435; 3. CDC Facts and Figures 2015; 4. Globaldata Pharmapoint 2018; 5. Dahlhamer JM, MMWR Morb Mortal Wkly Rep. 2016;65(42):1166-1169

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Remestemcel-L: Ulcerative Colitis & Crohn's Colitis

Results of First Patient Cohort from Randomized Controlled Study Presented at Congress of European Crohn's and Colitis Organisation (ECCO)

- The immunomodulatory effects of remestemcel-L on GI inflammation is being further evaluated in a randomized, controlled study of remestemcel-L by direct endoscopic delivery to areas of inflammation in patients with medically refractory ulcerative colitis or Crohn's colitis
- A single local delivery of remestemcel-L by colonoscopy resulted in rapid mucosal healing and disease remission in these refractory patients at high risk of progression to surgery
- The study at Cleveland Clinic will randomize up to 48 patients with medically refractory ulcerative colitis or Crohn's colitis in a 2:1 fashion to receive a single intervention with remestemcel-L or placebo.
- Medically refractory ulcerative colitis and Crohn's colitis patients are defined as having active disease for at least 6 months and having lost response to at least one monoclonal antibody (anti-TNF or anti-integrin)

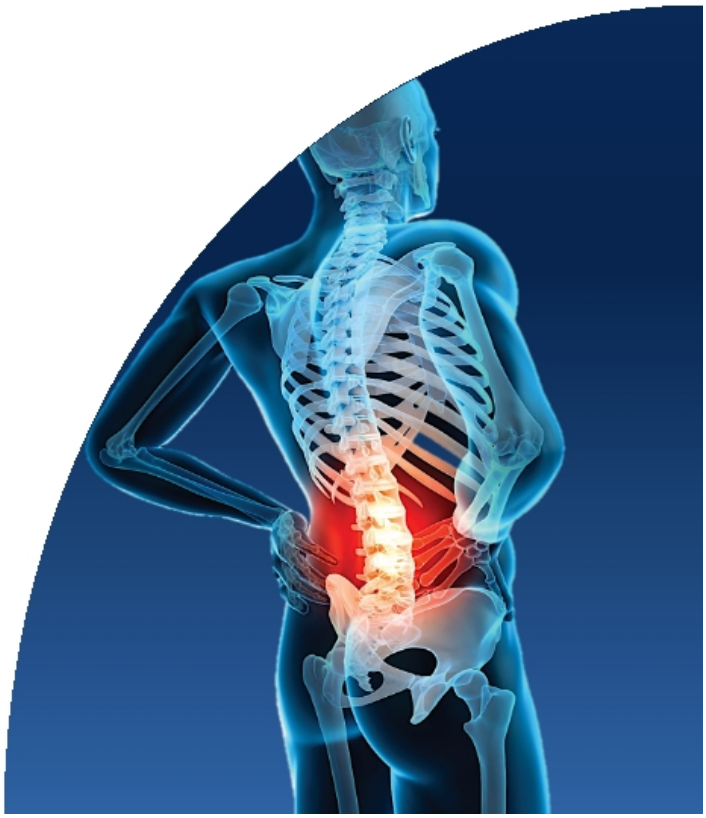
Remestemcel-L: Ulcerative Colitis & Crohn's Colitis

Results of First Patient Cohort from Randomized Controlled Study Presented at Congress of European Crohn's and Colitis Organisation (ECCO)

- Key results of the interim analysis performed in the first 12 enrolled patients were as follows:
  - All UC patients treated with remestemcel-L had improved clinical and endoscopy scores within 2 weeks, as defined by the Mayo clinical score and Mayo endoscopic severity (MES) score, and all achieved clinical and endoscopic remission by 2 weeks
  - All UC patients were extremely satisfied or satisfied with remestemcel-L treatment at 3 months, based on the inflammatory bowel disease patient reported treatment impact (IBD-PRTI), and response was described as excellent or good in all patients
  - All Crohn's colitis patients treated with remestemcel-L showed treatment remissions or responses by three months, as measured by the Simple Endoscopy Score for Crohn's Disease (SES-CD) (mean score 17 at baseline decreased to 5 at 3 months)
  - Remestemcel-L treatment resulted in reduction of fecal calprotectin, a validated biomarker of disease activity,10 from mean of 231 at baseline to 67 at 3 months, indicative of remission
  - In controls with UC and Crohn's colitis over 3 months, endoscopy scores increased, fecal calprotectin levels increased from a mean of 330 to 505, and clinical responses were described as poor or unchanged

Rexlemestrocel-L

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



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Rexlemestrocel-L

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

Burden of Illness

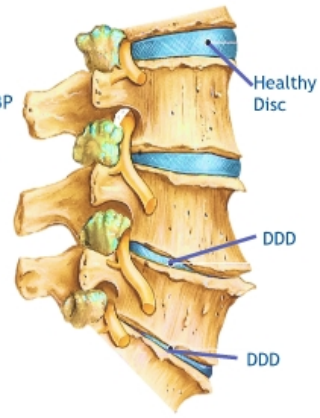
- Back pain causes more disability than any other condition[1]
- Inflicts substantial direct and indirect costs on the healthcare system,[1] including excessive use of opioids in this patient population

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]



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.

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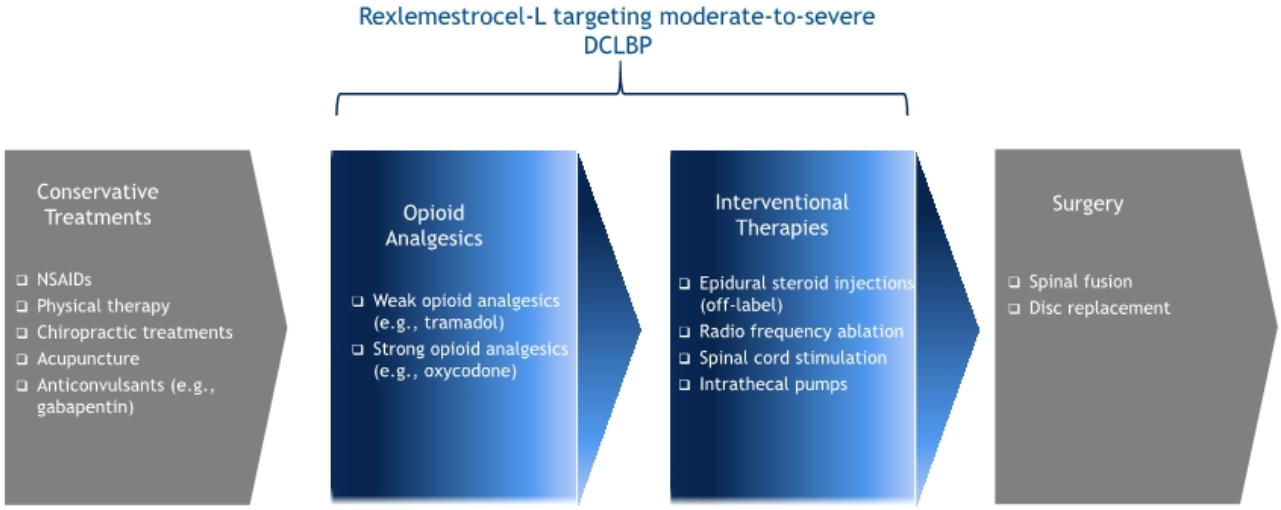
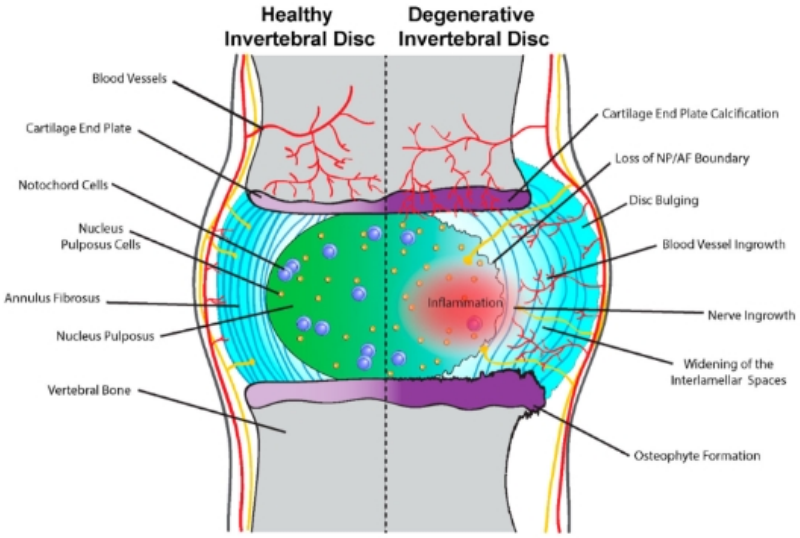
The Patient Treatment Journey

Rexlemestrocel-L Potential for First-Line CLBP associated with DDD, Refractory to Conservative Treatment



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

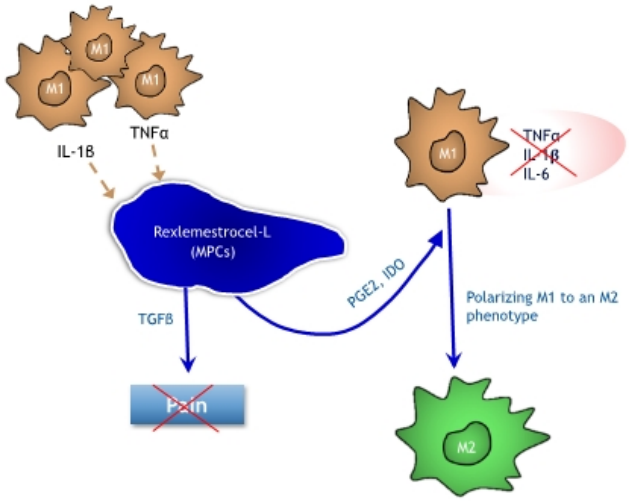
Technology Platform – Mesenchymal Precursor Cells (MPC)

Potential Mechanisms of Action in Treating Inflammatory Disc Disease

Rexlemestrocel-L

Mesenchymal precursor cells (MPC) beneficially act in the inflamed disc:

1. Reduce neurite ingrowth
2. Reduce neuropathic pain
3. Increase structural integrity of annulus
4. Increase proteoglycans in nucleus



M1=pro-inflammatory macrophage; IL-1B=interleukin-1 beta (pro-inflammatory cytokine); TNFα=Tumour Necrosis Factor alpha (pro-inflammatory cytokine); M2=anti-inflammatory macrophage

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Phase 3 Trial Outcomes – Rexlemestrocel-L for Chronic Low Back Pain

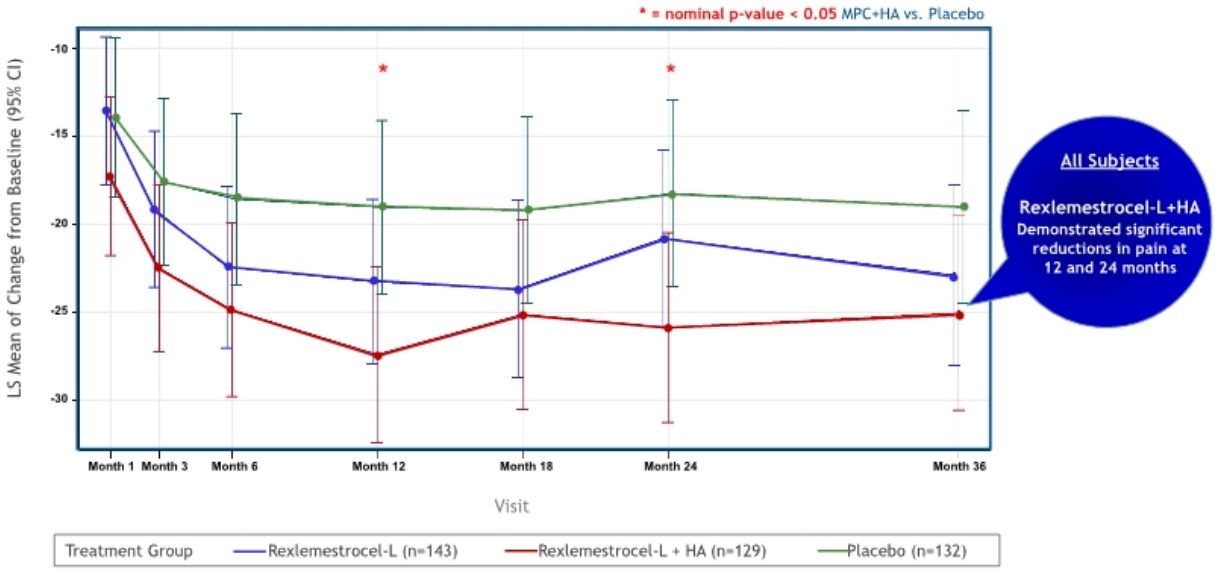
Single Injection of Rexlemestrocel-L + HA Results in >Three Years of Pain Reduction

Positive results from a single injection of MPC + Hyaluronic Acid (HA) carrier include:

- No appreciable differences in the safety profile of subjects treated with Rexlemestrocel-L, Rexlemestrocel-L+HA or saline control
- 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=404) 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=202) with 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

Phase 3 Trial: Outcome

LS Mean Change in Low Back Pain from Baseline - Entire Study (n=404)



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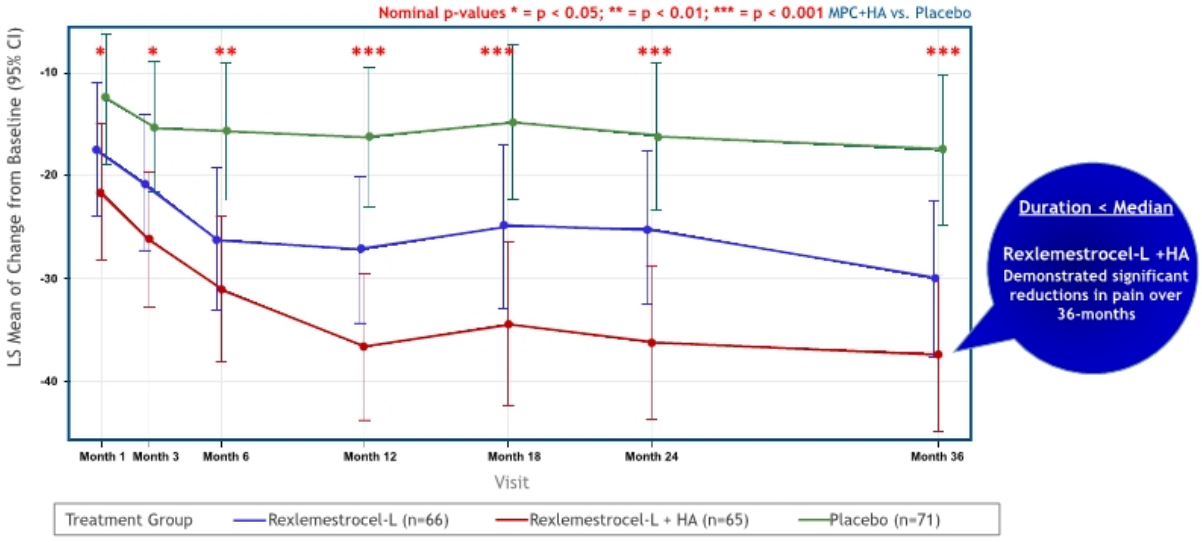
Phase 3 Trial: Outcome

LS Mean VAS Change in Low Back Pain from Baseline - Duration CLBP < 68 Month Median Baseline Duration (n=202)



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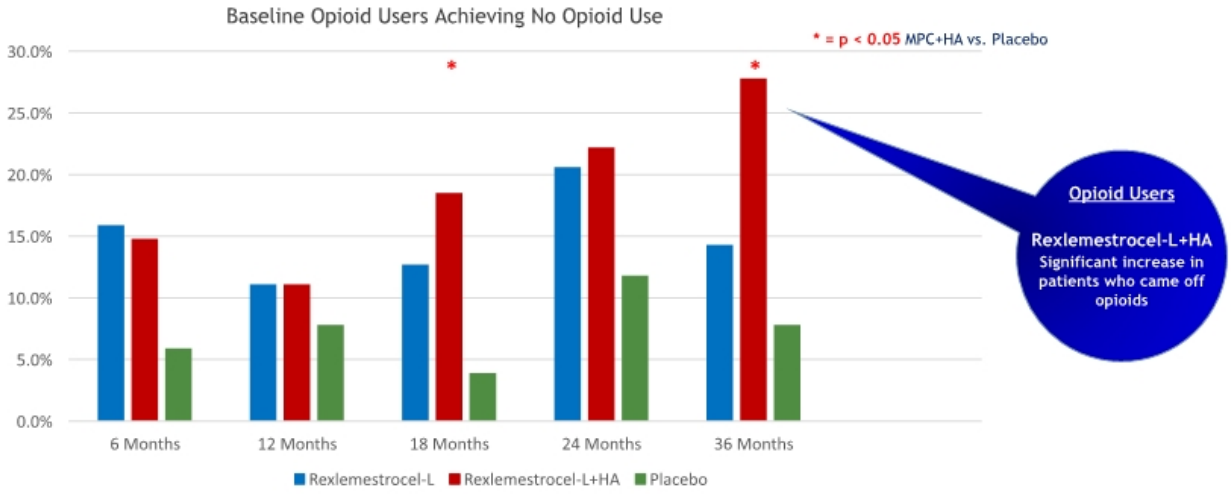
Phase 3 Trial: Outcome

Rexlemestrocel-L + HA Increased the Proportion of Patients with Baseline Opioid Use Who Were Not Taking an Opioid at 36 Months



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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)

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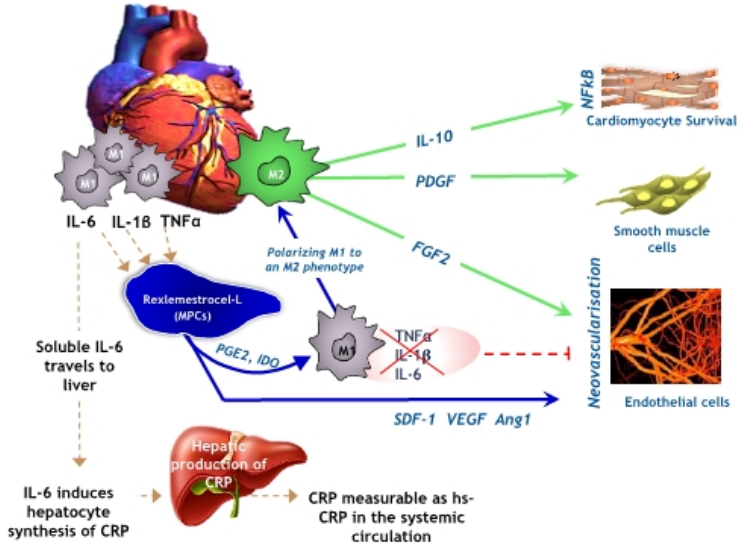
Rexlemestrocel-L: Proposed Mechanism of Action

Intra-Cardiac Administration in Treatment of both Heart Failure & Large Vessel Atherosclerosis

Mesenchymal precursor cells (MPC) beneficially act the heart and the systemic vasculature:

1. Reduce cardiac / systemic inflammation
2. Reversal of endothelial dysfunction
3. Induce microvascular networks within viable heart muscle
4. Reduce heart muscle death

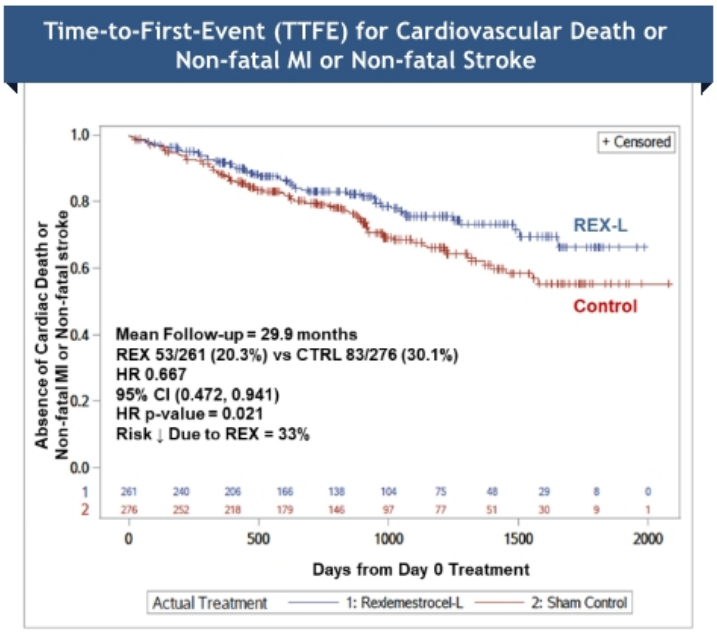


M1=pro-inflammatory macrophage; IL-6=interleukin 6 (pro-inflammatory cytokine); IL-1ß=interleukin-1 beta (pro-inflammatory cytokine); TNFα=Tumour Necrosis Factor alpha (pro-inflammatory cytokine); IL-1-=interleukin 10 (anti-inflammatory cytokine); M2=anti-inflammatory macrophage

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

DREAM-HF Phase 3 Trial in HFrEF

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



MACE=Major Adverse Cardiovascular Event; TTFE=Time To First Event; MI=Myocardial Infarction (Heart Attack)

Kaplan-Meier log rank statistics

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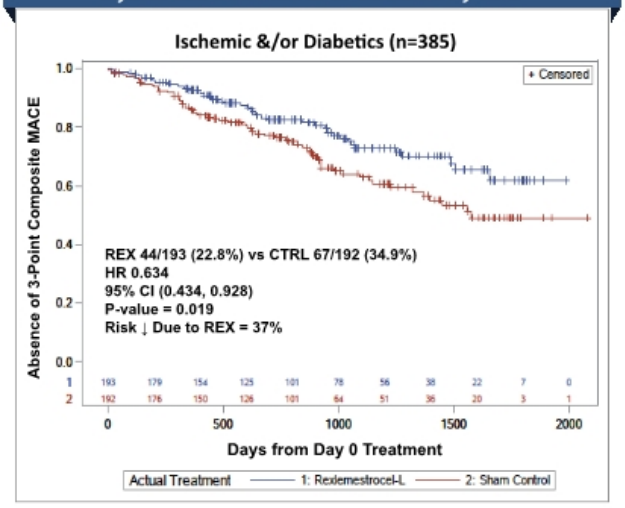
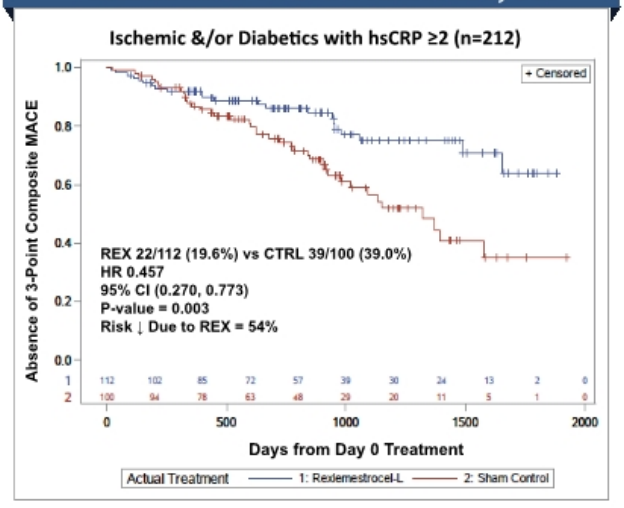
DREAM-HF Phase 3 Trial in HFrEF

3-Point Composite MACE, High-Risk Patients (Myocardial Ischemia &/or Diabetes), 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

MACE=Major Adverse Cardiovascular Event; TTFE=Time To First Event; IMM=Irreversible Morbidity or Mortality; hs-CRP=High-Sensitivity C-Reactive Protein (a measure of systemic inflammation)

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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 non-fatal MI, or non-fatal stroke, or cardiovascular death

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

Rexlemestrocel-L: Conclusions & Key Next Steps in 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


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Thank You