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 November 2021

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 November 22, 2021, Mesoblast Limited filed with the Australian Securities Exchange a new release announcement, which is attached hereto as Exhibit 99.1, and is incorporated herein by reference.

On November 22, 2021, Mesoblast Limited filed with the Australian Securities Exchange a new issue announcement and application for quotation of additional securities and agreement (Appendix 3B), which is attached hereto as Exhibit 99.2, and is incorporated herein by reference.

On November 24, 2021, Mesoblast Limited filed with the Australian Securities Exchange a new release announcement and investor presentation, which are attached hereto as Exhibit 99.3 and Exhibit 99.4, 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: November 25, 2021

INDEX TO EXHIBITS

Item

99.1	Press release of Mesoblast Ltd, dated November 22, 2021.
99.2	Appendix 3B of Mesoblast Ltd, dated November 22, 2021
99.3	Press release of Mesoblast Ltd, dated November 24, 2021.
99.4	Investor presentation of Mesoblast Ltd, dated November 24, 2021.

asx announcement

mesoblast
the regenerative medicine company

MESOBLAST AND OAKTREE CAPITAL ENTER INTO REFINANCING AND EXPANSION OF SENIOR DEBT FACILITY

Melbourne, Australia; November 22, and New York, USA; November 21, 2021: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today announced that it has successfully refinanced its existing senior debt facility with a new US$90 million five year facility provided by funds managed by Oaktree Capital Management, L.P. ("Oaktree").

Mesoblast drew the first tranche of US$60 million on closing, with proceeds being used to repay the outstanding balance of the existing senior debt facility with Hercules Capital, Inc. Up to an additional US$30 million may be drawn on or before December 31, 2022, subject to certain milestones. The facility has a three-year interest only period, at a rate of 9.75% per annum, after which time 40% of the principal amortizes over two years and a final payment due November 2026. Oaktree will also receive warrants to purchase 1,769,669 American Depositary Shares (ADSs)[1] at US$7.26 per ADS, a 15% premium to the 30-day VWAP. The warrants may be exercised within 7 years of issuance.

"We are pleased to have leading global investment management firm Oaktree as our new financing partner as we focus on bringing our first product to the US market. Oaktree has a demonstrated partnership approach to innovative companies, making it an excellent fit to support Mesoblast's commercial growth strategy over the next five years," said Silviu Itescu, Chief Executive of Mesoblast.

Aman Kumar, Co-Portfolio Manager of Life Sciences Lending at Oaktree said, "We are delighted to partner with Mesoblast at this point in its development. We recognize the quality of the portfolio and the significant near-term milestones that could help the company successfully commercialize its first product in the US."

Cantor Fitzgerald & Co. acted as exclusive arranger and financial advisor to Mesoblast in this transaction.

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

1 The warrants will be issued under a prospectus to be lodged with ASIC under which the warrants will be offered to Oaktree. The agreement to issue the warrants is subject to approval of Mesoblast shareholders if required at the time of issue for the purposes of the 15% placement limit in Listing Rule 7.1.

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About Oaktree
Oaktree is a leader among global investment managers specializing in alternative investments,
with $158 billion in assets under management as of September 30, 2021. The firm emphasizes an opportunistic, value-oriented and risk-controlled approach to investments in credit, private equity, real assets and listed equities. The firm has over 1,000 employees and offices in 19 cities worldwide. For additional information, please visit Oaktree's website at http://www.oaktreecapital.com/

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: Mesoblast's ability to meet the necessary conditions and milestones to draw down on the facility; 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, 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:

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Proposed issue of securities

Announcement Summary

Entity name

MESOBLAST LIMITED

Announcement Type

New announcement

Date of this announcement

22/11/2021

The Proposed issue is:

☑ A placement or other type of issue

Total number of +securities proposed to be issued for a placement or other type of issue

ASX +security code	+Security description	Maximum Number of +securities to be issued
New class-code to be confirmed	ADS warrants	1,769,669

Proposed +issue date

31/12/2021

Refer to next page for full details of the announcement

Part 1 - Entity and announcement details

1.1 Name of +Entity

MESOBLAST LIMITED

We (the entity named above) give ASX the following information about a proposed issue of +securities and, if ASX agrees to +quote any of the +securities (including any rights) on a +deferred settlement basis, we agree to the matters set out in Appendix 3B of the ASX Listing Rules.
If the +securities are being offered under a +disclosure document or +PDS and are intended to be quoted on ASX, we also apply for quotation of all of the +securities that may be issued under the +disclosure document or +PDS on the terms set out in Appendix 2A of the ASX Listing Rules (on the understanding that once the final number of +securities issued under the +disclosure document or +PDS is known, in accordance with Listing Rule 3.10.3C, we will complete and lodge with ASX an Appendix 2A online form notifying ASX of their issue and applying for their quotation).

1.2 Registered Number Type

ACN

Registration Number

109431870

1.3 ASX issuer code

MSB

1.4 The announcement is

☑ New announcement

1.5 Date of this announcement

22/11/2021

1.6 The Proposed issue is:

☑ A placement or other type of issue

Part 7 - Details of proposed placement or other issue

Part 7A - Conditions

7A.1 Do any external approvals need to be obtained or other conditions satisfied before the placement or other type of issue can proceed on an unconditional basis?

☑ Yes

7A.1a Conditions

Approval/Condition	Date for determination	Is the date estimated or actual?	** Approval received/condition met?
+Security holder approval	29/11/2021	☑ Actual	

Comments

Mesoblast is seeking to refresh its 15% placement limit for the purposes of ASX Listing Rule 7.4 at its upcoming Annual General Meeting - please see Notice of Annual General Meeting lodged 29 October 2021.

Part 7B - Issue details

Is the proposed security a 'New class' (+securities in a class that is not yet quoted or recorded by ASX) or an 'Existing class' (additional securities in a class that is already quoted or recorded by ASX)?

☑ New class

Will the proposed issue of this +security include an offer of attaching +securities?

☑ No

Details of +securities proposed to be issued

ISIN Code (if Issuer is a foreign company and +securities are non CDIs)

Have you received confirmation from ASX that the terms of the proposed +securities are appropriate and equitable under listing rule 6.1?

☑ No

Will the entity be seeking quotation of the 'new' class of +securities on ASX?

☑ No

ASX +security code

New class-code to be confirmed

+Security description

ADS warrants

+Security type

Options

Number of +securities proposed to be issued

1,769,669

Offer price details

Are the +securities proposed to be issued being issued for a cash consideration?

☑ No

Please describe the consideration being provided for the +securities

In connection with refinancing of existing senior debt facility with a new US$90 million five year facility provided by funds managed by Oaktree Capital Management, L.P.

Please provide an estimate of the AUD equivalent of the consideration being provided for the +securities

Will all the +securities issued in this class rank equally in all respects from their issue date?

☑ Yes

Options details

+Security currency	Exercise price	Expiry date
USD - US Dollar	USD 7.2600	31/12/2028

Details of the type of +security that will be issued if the option is exercised

Other

Description

Mesoblast American Depositary Share. Please see Preliminary Final Report including Appendix 4E lodged 31 August 2021 for more information on Mesoblast American Depositary Shares

Please provide a URL link for a document lodged with ASX setting out the material terms of the +securities proposed to be issued or provide the information by separate announcement.

See announcement lodged 22 November 2021

Part 7C - Timetable

7C.1 Proposed +issue date

31/12/2021

Part 7D - Listing Rule requirements

7D.1 Has the entity obtained, or is it obtaining, +security holder approval for the entire issue under listing rule 7.1?

☑ Yes

7D.1a Date of meeting or proposed meeting to approve the issue under listing rule 7.1

29/11/2021

7D.2 Is a party referred to in listing rule 10.11 participating in the proposed issue?

☑ No

7D.3 Will any of the +securities to be issued be +restricted securities for the purposes of the listing rules?

☑ No

7D.4 Will any of the +securities to be issued be subject to +voluntary escrow?

☑ No

Part 7E - Fees and expenses

7E.1 Will there be a lead manager or broker to the proposed issue?

☑ No

7E.2 Is the proposed issue to be underwritten?

☑ No

7E.4 Details of any other material fees or costs to be incurred by the entity in connection with the proposed issue

Part 7F - Further Information

7F.01 The purpose(s) for which the entity is issuing the securities

See announcement dated 22 November 2021

7F.1 Will the entity be changing its dividend/distribution policy if the proposed issue proceeds?

☑ No

7F.2 Any other information the entity wishes to provide about the proposed issue

asx announcement

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the regenerative medicine company

OPERATIONAL HIGHLIGHTS AND FINANCIAL RESULTS FOR THE PERIOD ENDED SEPTEMBER 30, 2021

Melbourne, Australia; November 24 and New York, USA; November 23, 2021: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today reported operational highlights and financial results for the first quarter ended September 30, 2021.

"We are pleased to have entered into a strategic financing partnership with leading global investment management firm Oaktree Capital as we focus on bringing our first product to the US market and in line with our commercial growth strategy over the next five years," said Silviu Itescu, Chief Executive of Mesoblast"

Financial & Operational Highlights

- Successfully entered into a refinancing and expansion of our senior debt facility with Oaktree Capital Management. The new US$90 million, 5-year secured facility has a 3-year interest only period after which time 40% of the principal amortizes over two years and a final payment due no later than November 2026.
- Cash on hand at the end of the quarter was US$116.0 million
- Revenues from TEMCELL® HS Inj.[1] royalties in Japan were US$2.4 million, an increase of 22% on the previous quarter, and of 90% on the comparative quarter last year
- Net cash operating usage was US$19.6 million for the quarter, a reduction of US$8.6 million on the comparative quarter
- Loss after tax improved US$1.9 million on the comparative quarter
- Results published in the latest issue of the peer-reviewed journal *Bone Marrow Transplantation*[2] showed that children with steroid-refractory acute graft versus host disease (SR-aGVHD) and biomarkers predictive for highest mortality had 64% survival when treated with remestemcel-L compared with only 10% survival when treated with other available therapies, including ruxolitinib or other biologics
- These data provide further support for the proposed anti-inflammatory mechanism of action of remestemcel-L and its immunomodulatory activity in patients with SR-aGVHD, resulting in improved survival outcomes
- At the upcoming scheduled meeting with United States Food & Drug Administration's (FDA) Office of Tissue and Advanced Therapies (OTAT), Mesoblast will address the appropriateness of potency assays related to remestemcel-L's proposed anti-inflammatory mechanism of action as well as the outstanding chemistry, manufacturing and controls (CMC) items which could support a resubmission of the current Biologics License Application (BLA) for remestemcel-L in the treatment of SR-aGVHD in children
- Mesoblast 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 acute respiratory distress syndrome (ARDS) due to COVID-19. The FDA advised that an additional clinical study which showed statistically positive outcomes in conjunction with the recently completed 222 patient trial may be sufficient to provide a dataset in support of an EUA
- Results from the randomized, controlled Phase 3 trial of rexlemestrocel-L in 565 patients with New York Heart Association (NYHA) class II and class III chronic heart failure (CHF) with low ejection fraction (HFrEF) were presented as a late breaking presentation at the American Heart

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Association (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 cardiovascular mortality, heart attacks or strokes
- Mesoblast is in ongoing discussions with the FDA on the potential pathways to US regulatory approval for its rexlemestrocel-L product candidate in heart failure patients at high risk of cardiovascular mortality, heart attacks or strokes

DETAILED CLINICAL ACTIVITIES DURING FOR THE PERIOD

Remestemcel-L

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

Results published in the peer-reviewed journal Bone Marrow Transplantation[2] showed that children with SR-aGVHD and biomarkers predictive for highest mortality had 64% survival when treated with remestemcel-L compared with only 10% survival when treated with other available therapies.

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 outcomes differed according to treatment with remestemcel-L vs other therapies in children at highest risk of death, namely those with baseline MAGIC Algorithm Probability (MAP) biomarker levels ≥0.291, a level predictive of very high mortality and poor responses to therapy in SR-aGVHD. MAP combines the serum concentrations of two biomarkers, Reg3α and ST2, into a single value that predicts long-term outcomes and significant GI tract damage.

MAP levels ≥0.291 were present in 48% of remestemcel-L treated children (12/25) and 37% of the MAGIC cohort (10/27). 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 extend previous observations showing that children who achieved clinically meaningful responses and survival after treatment with remestemcel-L had significant reductions in the ST2 biomarker of inflammation, consistent with healing of the GI tract.[4]

These data provide further support for the proposed anti-inflammatory mechanism of action of remestemcel-L and its immunomodulatory activity in patients with SR-aGVHD, resulting in improved survival outcomes. At its upcoming scheduled meeting with FDA’s OTAT, Mesoblast will address the appropriateness of potency assays related to remestemcel-L’s proposed anti-inflammatory mechanism of action as well as the outstanding CMC items which could support a resubmission of the current BLA for remestemcel-L in the treatment of SR-aGVHD in children with a six month review.

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

Early this quarter, Mesoblast met with the FDA in regard to potential 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

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 information in BLA 125706 for pediatric SR-aGVHD.

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FDA indicated that potency assays must be established and agreed prior to commencement of the proposed Phase 3 clinical trial. FDA indicated that the potency assays currently in development appeared to be reasonable based on in vitro results provided in the briefing document, the in vitro activity of the product appears to be relatively well established, though the relationship between in vitro activity and the product's actual mechanism of action remains theoretical.

Mesoblast has entered into a license and collaboration agreement with Novartis for the development, manufacture, and commercialization of remestemcel-L, with an initial focus on the treatment of acute respiratory distress syndrome (ARDS) including that associated with COVID-19. The agreement remains subject to certain closing conditions, including time to analyze the results from the COVID-19 ARDS trial.

Mesoblast plans to move forward with an additional Phase 3 trial in COVID-19 ARDS with the next step being to agree with the FDA the final protocol and potency assay.

Rexlemestrocel-L

Chronic Heart Failure

Data from the randomized, controlled Phase 3 trial of rexlemestrocel-L in 565 patients with NYHA class II and class III 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 cardiovascular mortality, heart attacks or strokes

The presentation highlighted that a single dose of rexlemestrocel-L on top of standard care versus standard of care alone:

- Reduced the incidence of heart attacks or strokes across all 537 NYHA class II or class III treated patients
- Reduced the incidence of heart attacks or strokes by an even greater amount in 301 patients with high levels inflammation
- Reduced the incidence of cardiovascular death in NYHA class II patients with the greatest effect seen in patients with high levels of inflammation
- Did not further reduce the frequency of hospitalization for worsening HF symptoms as previously reported

Whereas most traditional treatments address the congestion or fluid overload associated with heart failure, rexlemestrocel-L addresses the inflammation that is at the centre of advanced chronic heart failure – widely regarded as the leading cause of death in the developed world.

The ability of rexlemestrocel-L to significantly impact cardiac death, heart attacks and strokes on top of maximal HFrEF therapy reflects the unique mechanisms-of-action of this allogeneic cellular therapy on reduction of inflammation and improved microvasculature. The unchecked intra-cardiac inflammation in HFrEF patients causes progressive loss of heart muscle, replacement with scar tissue, and death. Persistent inflammation in the blood circulation also results in accelerated atherosclerosis with plaque progression and instability resulting in plaque rupture and potential blockage of major arteries, resulting in high rates of heart attacks and strokes in chronic HFrEF patients.

Rexlemestrocel-L is believed to reduce inflammatory cytokine production by immune cells, generating improved local networks of blood vessels within the damaged heart and reducing risk of plaque rupture in major arteries. The observed relationship between systemic inflammation and degree of benefit from treatment with rexlemestrocel-L supports the importance of the anti-inflammatory

mechanism-of-action of rexlemestrocel-L in addressing the high-risk of mortality and morbidity in HFrEF patients.

DETAILED FINANCIAL HIGHLIGHTS FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2021 (FIRST QUARTER FY2022)

- **Cash on hand** at the end of the quarter was US$116.0 million
- **Net operating cash** usage was US$19.6 million for the quarter, a reduction of US$8.6 million on the comparative quarter.
- **Total Revenue** was US$3.6 million for the first quarter FY2022, an increase of US$2.3 million on the comparative quarter due to growth in royalties and US$1.2 million of milestone revenue given Takeda received approval to manufacture and market Alofisel® (darvadstrocel) in Japan for the treatment of complex perianal fistulas in patients with non-active or mildly active luminal Crohn's Disease.

  Within revenue, royalties from TEMCELL® HS Inj.[1] in Japan were US$2.4 million, an increase of 22% on the previous quarter, and of 90% on the comparative quarter last year.
- **Research & Development expenses** reduced by US$10.0 million (52%), down to US$9.3 million for the first quarter FY2022 from US$19.3 million for the first 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** reduced by US$4.4 million (37%) down to US$7.5 million for the first quarter FY2022 from US$11.9 million for the first quarter FY2021 due to a reduction in process development activities. 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$26.0 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** reduced by US$1.8 million (23%), down to US$5.9 million for the first quarter FY2022 from US$7.7 million for the first quarter FY2021 as employee compensation costs were reduced.
- **Remeasurement of Contingent Consideration** reduced to a gain of US$0.3 million for the first quarter FY2022 whereas a gain of US$15.1 million was recognized in the first quarter FY2021 reflecting a reduction in future third party payments.
- **Finance Costs** predominantly for borrowing arrangements with Hercules and NovaQuest were US$3.6 million for the first quarter FY2022, compared to US$2.9 million for the first quarter FY2021.

Loss after tax improved US$1.9 million, down to US$22.6 million for the first quarter FY2022 compared to US$24.5 million for the first quarter FY2021.The net loss attributable to ordinary shareholders was 3.49 US cents per share for the first quarter FY2022, compared with 4.21 US cents per share for the first quarter FY2021.

Conference Call

There will be a webcast today, beginning at 9.00am AEDT (Wednesday, November 24); 5.00pm EST (Tuesday, November 23). It can be accessed via: https://webcast.openbriefing.com/8205/

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

About Mesoblast

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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.

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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. Presented at the annual meeting of the American Society of Hematology (ASH) 2020

Forward-Looking Statements

This announcement 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, 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

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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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asx announcement

mesoblast
the regenerative medicine company

Consolidated Income Statement

(in U.S. dollars, in thousands, except per share amount)	Three Months Ended September 30, 2021	2020
Revenue	3,594	1,305
Research & development	(9,328)	(19,278)
Manufacturing commercialization	(7,537)	(11,924)
Management and administration	(5,878)	(7,680)
Fair value remeasurement of contingent consideration	280	15,107
Other operating income and expenses	(178)	99
Finance costs	(3,660)	(2,903)
Loss before income tax	**(22,707)**	**(25,274)**
Income tax (expense)/benefit	62	730
Loss attributable to the owners of Mesoblast Limited	**(22,645)**	**(24,544)**
Losses per share from continuing operations attributable to the ordinary equity holders of the Group:	**Cents**	**Cents**
Basic - losses per share	(3.49)	(4.21)
Diluted - losses per share	(3.49)	(4.21)

Consolidated Statement of Comprehensive Income

(in U.S. dollars, in thousands)	Three Months Ended September 30, 2021	2020
Loss for the period	**(22,645)**	**(24,544)**
Other comprehensive (loss)/income		
Items that may be reclassified to profit and loss		
Exchange differences on translation of foreign operations	(349)	408
Items that will not be reclassified to profit and loss		
Financial assets at fair value through other comprehensive income	154	81
Other comprehensive (loss)/income for the period, net of tax	**(195)**	**489**
Total comprehensive losses attributable to the owners of Mesoblast Limited	**(22,840)**	**(24,055)**

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Consolidated Balance Sheet

(in U.S. dollars, in thousands)	As of September 30, 2021	As of June 30, 2021
Assets		
Current Assets		
Cash & cash equivalents	115,956	136,881
Trade & other receivables	5,627	4,842
Prepayments	4,637	6,504
Total Current Assets	**126,220**	**148,227**
Non-Current Assets		
Property, plant and equipment	2,750	3,021
Right-of-use assets	8,485	9,119
Financial assets at fair value through other comprehensive income	2,234	2,080
Other non-current assets	1,952	1,724
Intangible assets	580,178	580,546
Total Non-Current Assets	**595,599**	**596,490**
Total Assets	**721,819**	**744,717**
Liabilities		
Current Liabilities		
Trade and other payables	16,263	19,598
Provisions	19,649	18,710
Borrowings	53,847	53,200
Lease liabilities	3,140	2,765
Total Current Liabilities	**92,899**	**94,273**
Non-Current Liabilities		
Deferred tax liability	—	—
Provisions	16,465	17,017
Borrowings	42,651	41,045
Lease liabilities	7,558	8,485
Deferred consideration	2,500	2,500
Total Non-Current Liabilities	**69,174**	**69,047**
Total Liabilities	**162,073**	**163,320**
Net Assets	**559,746**	**581,397**
Equity		
Issued Capital	1,163,492	1,163,153
Reserves	66,468	65,813
(Accumulated losses)/retained earnings	(670,214)	(647,569)
Total Equity	**559,746**	**581,397**

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Consolidated Statement of Cash Flows

(in U.S. dollars, in thousands)	Three Months Ended September 30, 2021	2020
Cash flows from operating activities		
Commercialization revenue received	1,995	682
Government grants and tax incentives received	24	17
Payments to suppliers and employees (inclusive of goods and services tax)	(20,223)	(27,484)
Interest received	4	13
Interest and other costs of finance paid	(1,407)	(1,389)
Income taxes paid	—	(6)
Net cash (outflows) in operating activities	**(19,606)**	**(28,167)**
Cash flows from investing activities		
Investment in fixed assets	(99)	(81)
Net cash (outflows) in investing activities	**(99)**	**(81)**
Cash flows from financing activities		
Payments of transaction costs from borrowings	(100)	—
Proceeds from issue of shares	147	8,134
Payments for share issue costs	(104)	(897)
Payments for lease liabilities	(686)	(695)
Net cash inflows by financing activities	**(743)**	**6,542**
Net decrease in cash and cash equivalents	(20,448)	(21,706)
Cash and cash equivalents at beginning of period	136,881	129,328
FX gain/(losses) on the translation of foreign bank accounts	(477)	501
Cash and cash equivalents at end of period	**115,956**	**108,123**

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Exhibit 99.4

mesoblast

Operational Highlights & Financial Results for the Period Ended September 30, 2021

NOVEMBER 2021

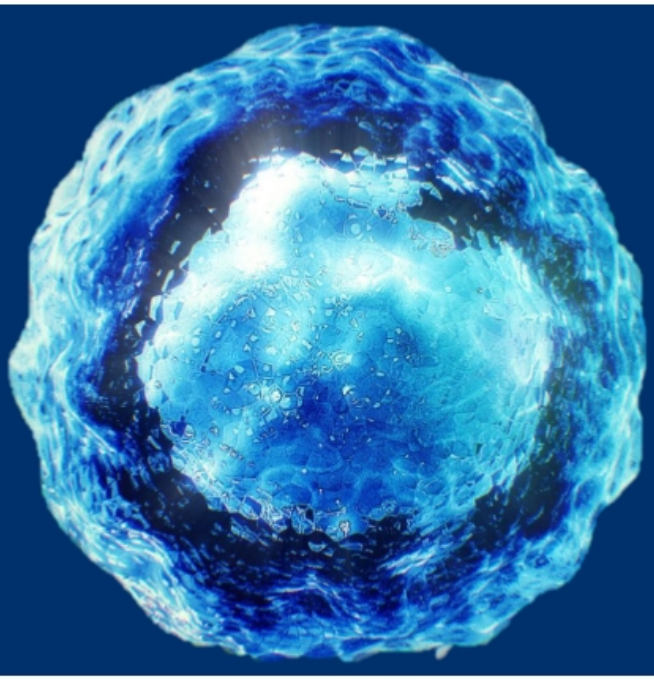
ASX: MSB; Nasdaq: MESO

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

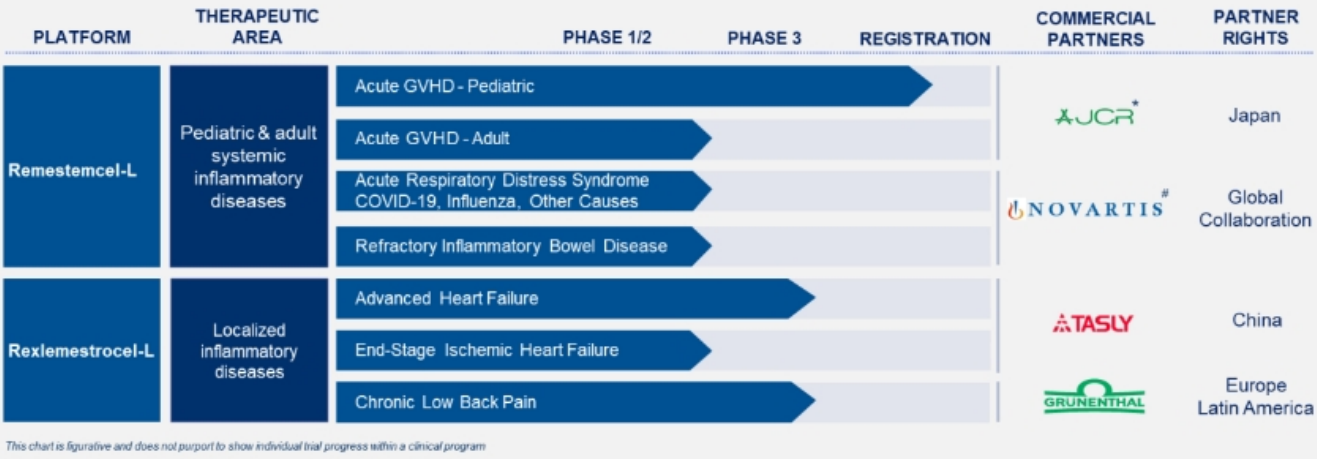
This presentation includes forward-looking statements that relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from any 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 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



Pipeline



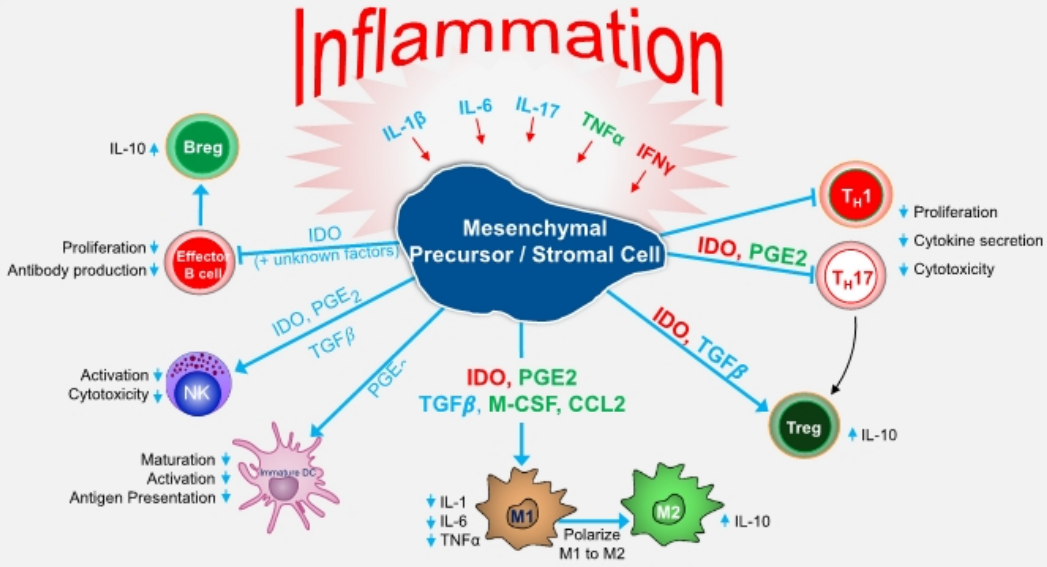
This chart is figurative and does not purport to show individual trial progress within a clinical program

* Mesoblast has the right to use data generated by JCR Pharmaceuticals Co Ltd in Japan to support its development and commercialization plans for remestemcel-L in the US and other major healthcare markets, including for GVHD and Hypoxic Ischemic Encephalopathy

The agreement remains subject to certain closing conditions, including time to analyze the results from the COVID-19 ARDS trial

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

Global IP Estate Provides Substantial Competitive Advantage

- Extensive patent portfolio with protection extending through 2040 in all major markets
- Over 1,000 patents and patent applications (~80 patent families) across all major jurisdictions
- Covers composition of matter, manufacturing, and therapeutic applications of mesenchymal lineage cells
- Provides strong global protection in areas of our core commercial focus against cell-based competitor products
- When outside our core commercial areas, may consider granting rights to third parties who require access to our patent portfolio to commercialize their products
- Mesoblast receives royalty income from its patent licensee TiGenix, S.A.U., a wholly owned subsidiary of Takeda, on its worldwide sales of its product Alofisel® for the treatment of complex perianal fistulas in adult patients with Crohn's disease, as well as milestone payments

Therapeutic Areas
Core commercial and non-core indications

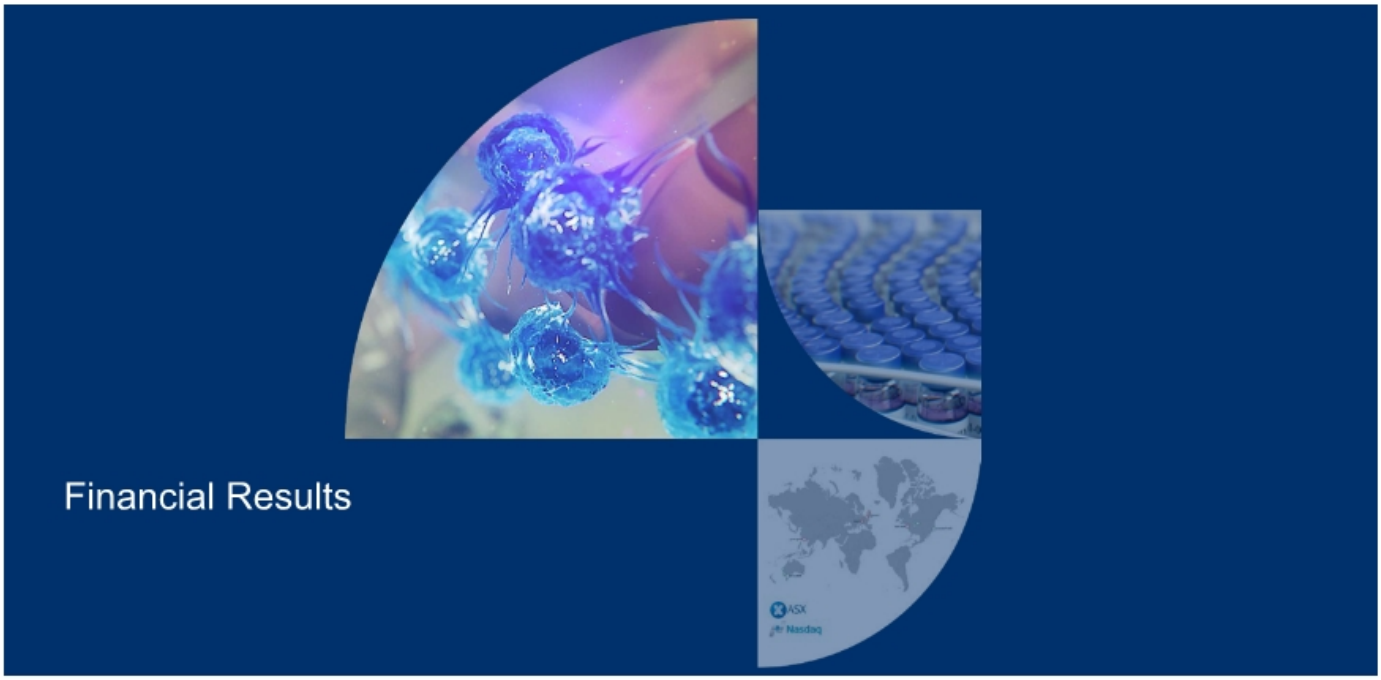
Sources
Allogeneic / Autologous (Bone Marrow, Adipose, Dental Pulp, Placental), Pluripotent (iPS)

Markets
Global coverage including U.S., Europe, China, and Japan

Commercial-scale Manufacturing Capabilities

- Scalable allogeneic “off-the-shelf” cellular platforms
- Manufacturing meets stringent criteria of international regulatory agencies
- Robust quality assurance processes ensure final product with batch-to-batch consistency and reproducibility
- Projected increase in capacity requirements for maturing pipeline
  - Proprietary xeno-free technologies will increase yields and output
  - Moving to 3D bioreactors will reduce labor and improve manufacturing efficiencies
  - These innovations will significantly reduce cost of goods

Manufacturing Remestemcel-L


Financial Results
ASX
Nasdaq

Financial Highlights

- Successfully entered into a refinancing and expansion of our senior debt facility with Oaktree Capital Management. The new US$90 million, 5-year secured facility has a 3-year interest only period after which time 40% of the principal amortizes over two years and a final payment due no later than November 2026
- Cash on hand at the end of the quarter was US$116.0 million
- Revenues from TEMCELL® HS Inj.[1] royalties in Japan were US$2.4 million, an increase of 22% on the previous quarter, and of 90% on the comparative quarter last year
- Net cash operating burn was US$19.6 million for the quarter, a reduction of US$8.6 million on the comparative quarter
- Loss after tax improved US$1.9 million on the comparative quarter

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

Increased Revenues and Reduced Expenditures Resulted in Improved Loss after Tax

P&L for the 3 months ended (US$m)	Sept 30, 2021	Sept 30, 2020
Commercialization revenue	2.4	1.3
Milestone revenue	1.2	-
Total Revenue	**3.6**	**1.3**
Research and development	(9.3)	(19.3)
Manufacturing	(7.5)	(11.9)
Management & administration	(5.9)	(7.7)
Contingent consideration	0.3	15.1
Other operating income & expenses	(0.2)	0.1
Finance costs	(3.7)	(2.9)
Loss before tax	**(22.7)**	**(25.3)**
Income tax benefit	-	0.7
Loss after tax	**(22.7)**	**(24.5)**

Figures are rounded

Revenue:
Royalties from TEMCELL® HS Inj.[1] in Japan increased to $2.4m, 22% on the previous quarter, and 90% on the comparative quarter last year.

Milestone revenue of US$1.2m as Takeda received approval to manufacture and market Alofisel® (darvadstrocel) in Japan for the treatment of complex perianal fistulas in patients with non-active or mildly active luminal Crohn's Disease.

Research & Development:
52% reduction of $10.0m in R&D 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.

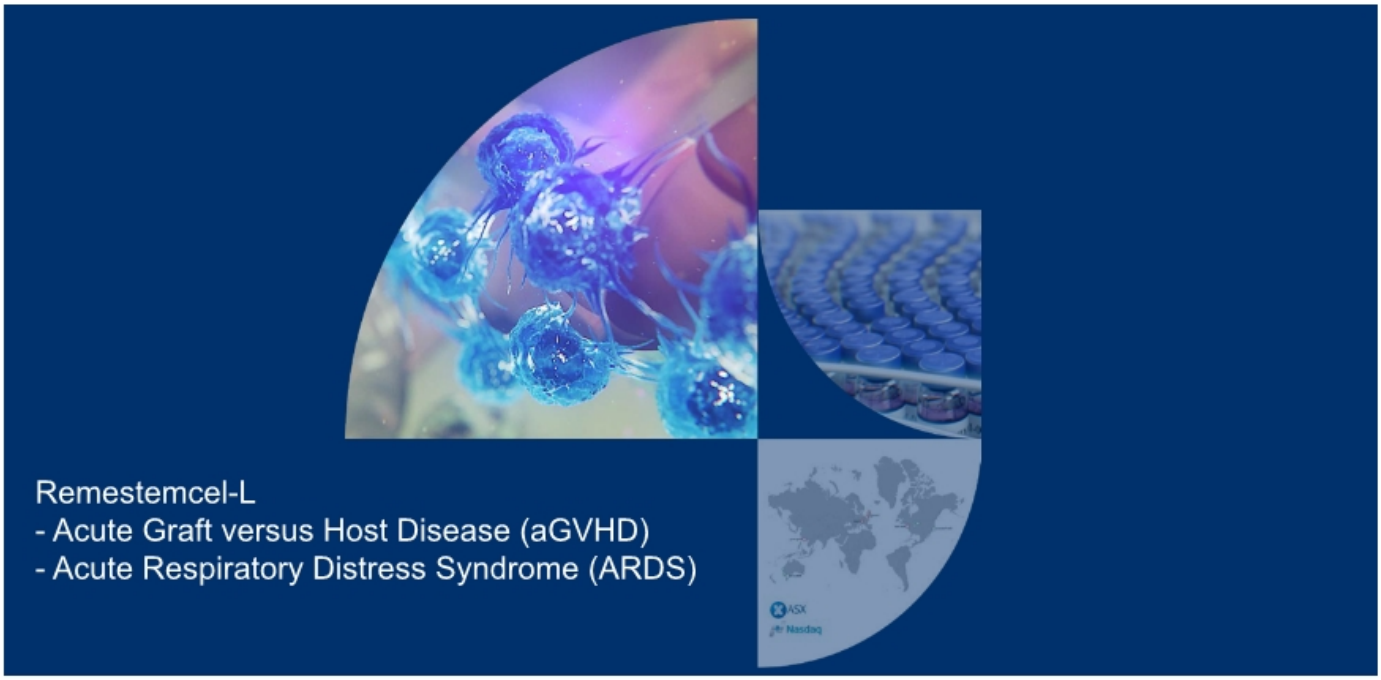
Manufacturing:
37% reduction of $4.4m in Manufacturing due to a reduction in process development activities. During the quarter we continued to build our pre-launch inventory levels of remestemcel-L to support the long-term commercial supply for SR-aGVHD and COVID ARDS.

We expect to recognize the existing US$26.0 million of remestemcel-L pre-launch inventory on the balance sheet if we receive FDA approval.

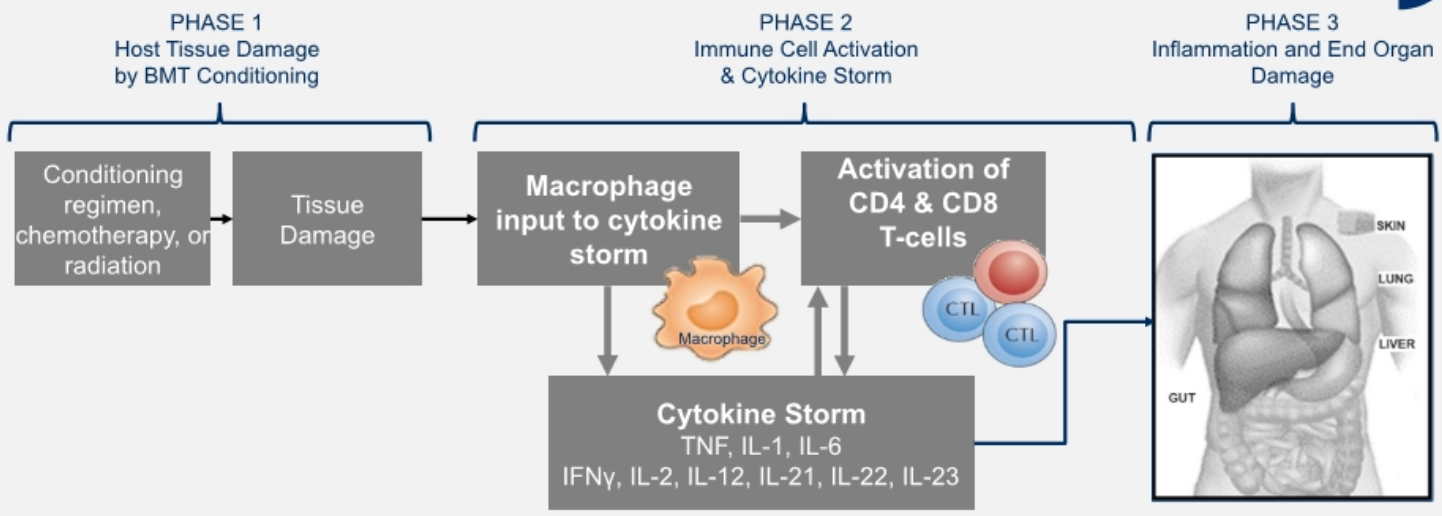
Management & Administration:
23% reduction of $1.8m compared to Q1 FY2021 as employee compensation costs were reduced.

Contingent Consideration:
$14.8m reduction. Q1 FY2021 included a $15.1m gain reflecting a reduction in future third party payments.

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


Remestemcel-L
- Acute Graft versus Host Disease (aGVHD)
- Acute Respiratory Distress Syndrome (ARDS)
ASX
Nasdaq

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



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

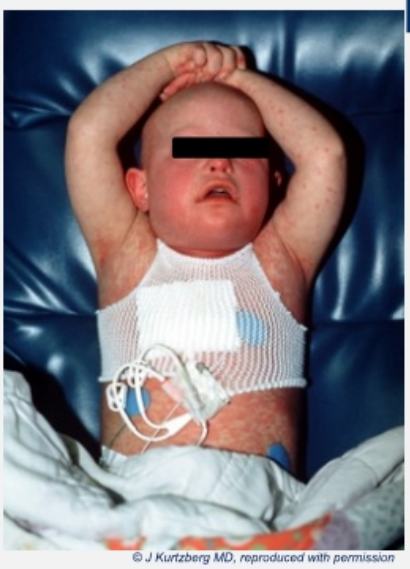
Children with Steroid-Refractory Acute GVHD at High Risk of Treatment Failure and Death

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:

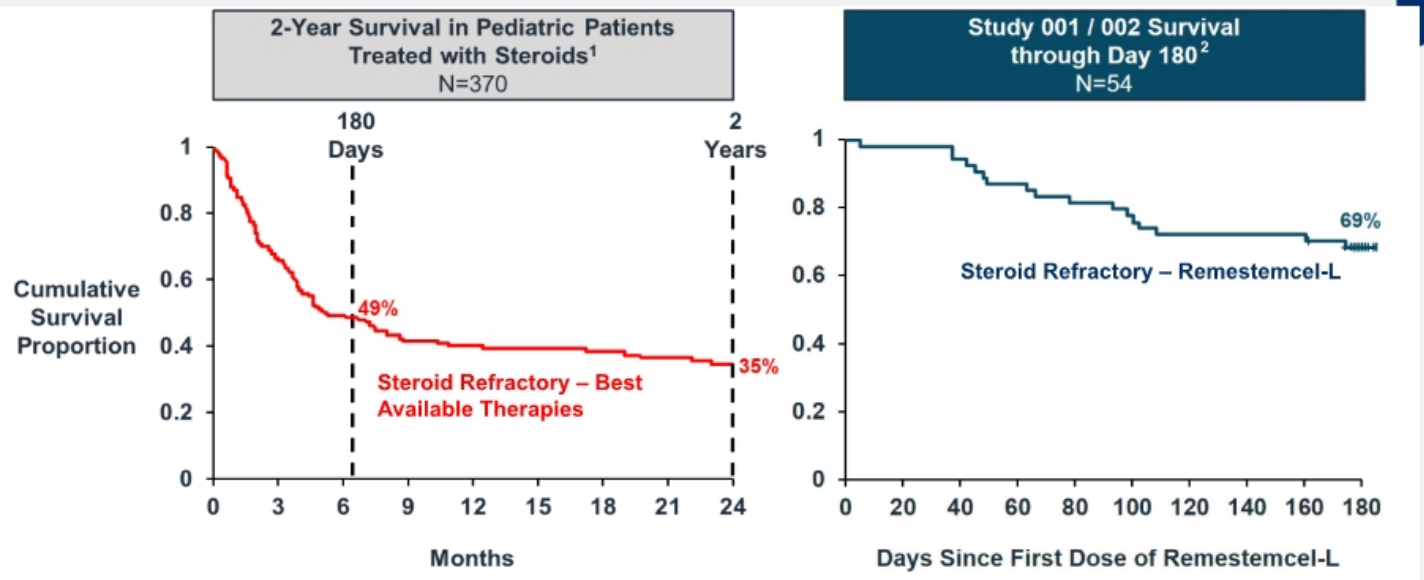
- Remestemcel-L was used as first-line therapy in a randomized controlled Phase 3 trial of 260 patients, with SR-aGVHD, including 27 children
- Remestemcel-L was used as salvage therapy in an expanded access program in 241 children with SR-aGVHD, 80% of whom had Grade C/D disease, and failed institutional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

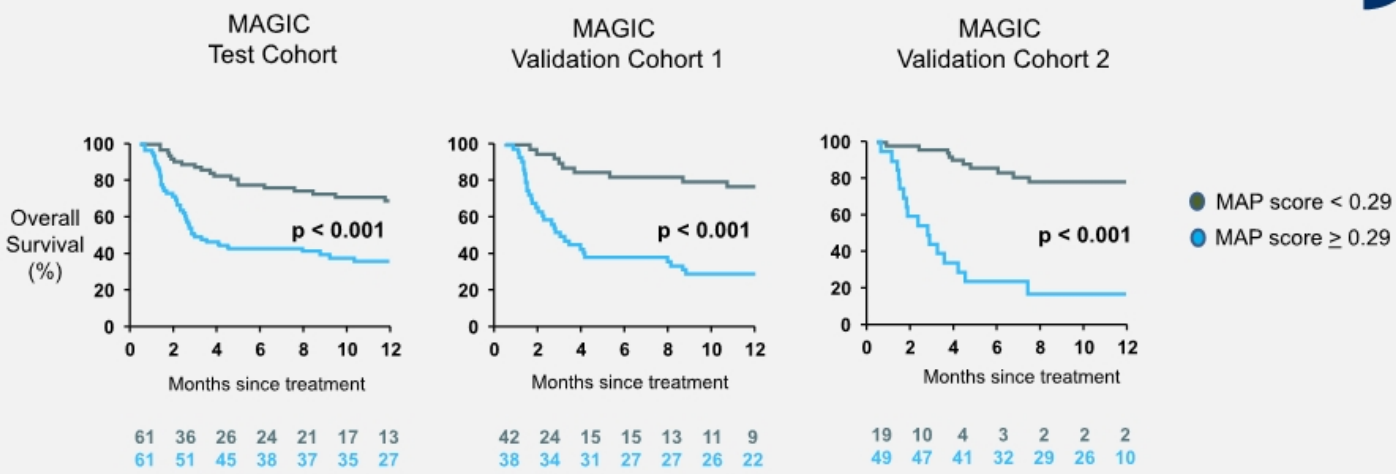
1. Mount Sinai Acute GVHD International Consortium (MAGIC) - a group of ten BMT centers throughout the US and Europe whose purpose is to conduct ground-breaking clinical trials in GVHD, including developing informative biorepositories that assist in developing treatments that can guide GVHD therapy.
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



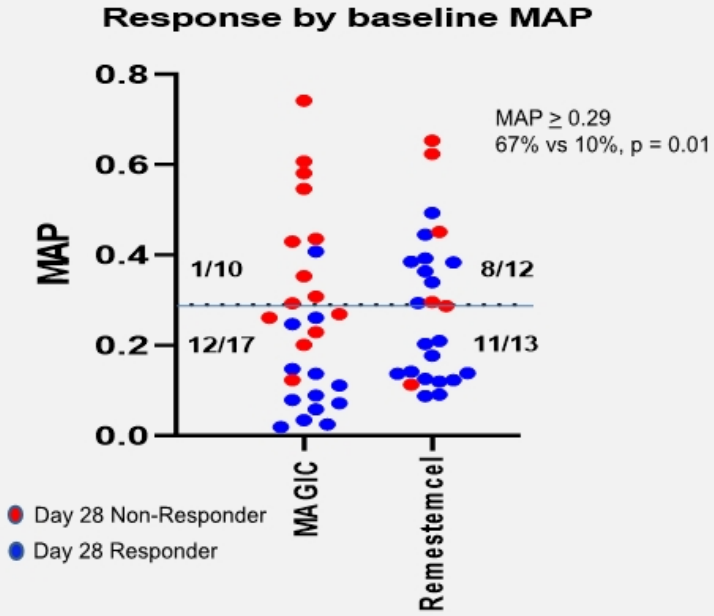
1. Adapted and redrawn from Figure 2 of MacMillan, M.L. et al. Pediatric acute GVHD: clinical phenotype and response to upfront steroids. Bone Marrow Transplant 55, 165–171 (2020); 2. Kurtzberg, J. et al. A Phase 3, Single-Arm, Prospective Study of Remestemcel-L, Ex Vivo Culture-Expanded Adult Human 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

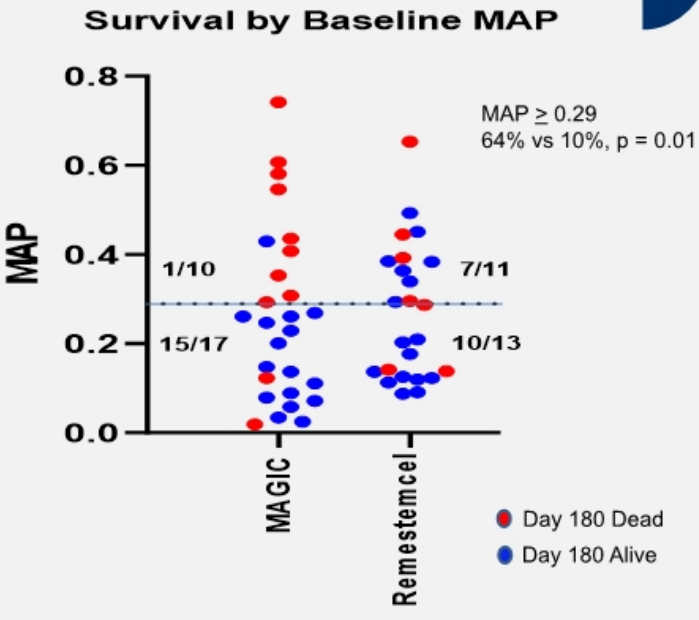
MAGIC Algorithm Probability Biomarker Score (MBS, MAP) > 0.29 is a Validated Threshold Identifying Acute GVHD Patients at High Risk of Non-Response to Treatment and Death



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 Results in 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

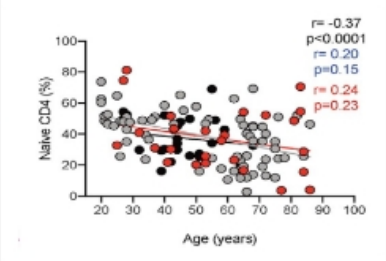
- These data provide further support for the proposed anti-inflammatory mechanism of action of remestemcel-L and its immunomodulatory activity in patients with SR-aGVHD, resulting in improved survival outcomes
- At the upcoming scheduled meeting with United States Food & Drug Administration's (FDA) Office of Tissue and Advanced Therapies (OTAT), Mesoblast will address the appropriateness of potency assays related to remestemcel-L's proposed anti-inflammatory mechanism of action as well as the outstanding chemistry, manufacturing and controls (CMC) items
- These discussions could support a resubmission of the current Biologics License Application (BLA) with a six month review with the aim of achieving approval for remestemcel-L in the treatment of SR-aGVHD in children

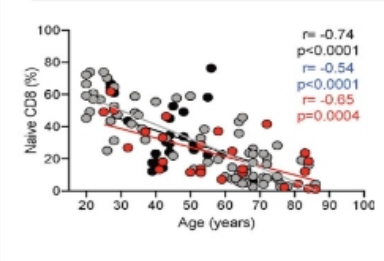
Overview – Remestemcel-L for ARDS due to COVID-19

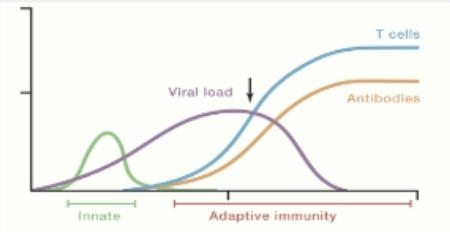
- COVID-19 is a respiratory virus with a high mortality due to a severe inflammatory condition of the lungs called acute respiratory disease syndrome (ARDS)
- ARDS is caused by cytokine storm in lungs of patients infected with COVID-19 and is the primary cause of death
- The extensive safety data of remestemcel-L and its anti-inflammatory effects in aGVHD makes a compelling rationale for evaluating remestemcel-L in COVID-19 ARDS
- Intravenous delivery of remestemcel-L results in selective migration to the lungs making inflammatory lung disease an ideal target for this therapy
- 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

Age > 65 years is Associated with Reduced Naïve T Cell Response to SARS-CoV-2, Delayed Viral Clearance and Greater Disease Severity

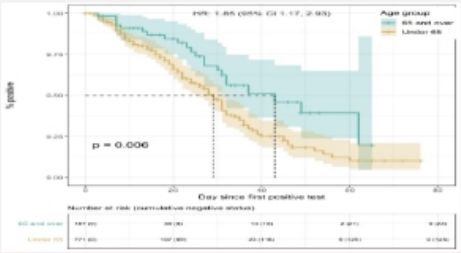
Naïve CD4 and CD8 T Cells reduced in age > 65





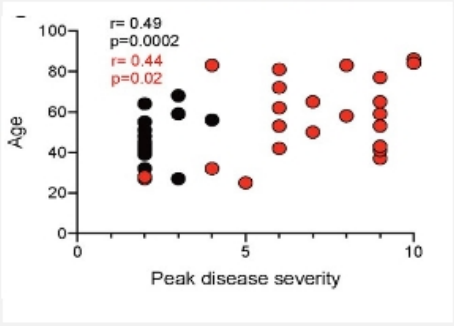


SARS-CoV-2-specific CD4 T cells and CD8 T cells limit disease severity



Median duration to negative status longer in subjects over 65 years (43 days) compared with under 65 years (29 days)

Age > 65 associated with greater COVID-19 peak disease severity



Rydyznski Moderbacher et al., Antigen-Specific Adaptive Immunity to SARS-CoV-2 in Acute COVID-19 and Associations with Age and Disease Severity. 2020, Cell 183, 996–1012; doi.org/10.1016/j.cell.2020.09.038
Stehlik P et al. Repeat testing for SARS-CoV-2: persistence of viral RNA is common, and clearance is slower in older people. Medical Journal of Australia 2021; doi:10.5694/mja2.51036

Clinical Experience with Remestemcel-L in COVID-19 ARDS

Emergency IND in Ventilator-Dependent COVID-19 ARDS

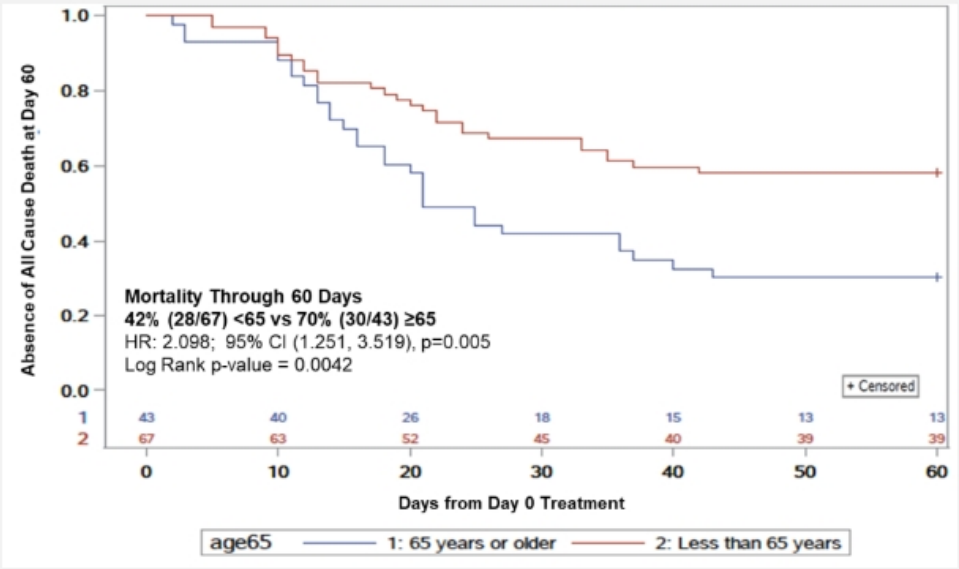
- **11 patients (10/11 were < 65 years)** with moderate/severe ARDS on ventilators at Mt. Sinai Hospital in New York
- Patients received two infusions of remestemcel-L 2 million cells/kg within five days
- Nine patients (82%) successfully came off ventilator and were discharged from the ICU
- Experience under the emergency IND informed the dosing regimen for the randomized controlled Phase 2b/3 trial, however no data on this dosing regimen in patients ≥ 65 years

Phase 3 Randomized Controlled Trial in COVID-19 ARDS

- Multi-center, randomized, controlled, blinded study to assess safety and efficacy of remestemcel-L versus placebo in ventilator-dependent patients with moderate/severe ARDS due to COVID-19
- Up to 300 patients randomized 1:1 to receive placebo or two infusions of remestemcel-L within 3-5 days
- 222 patients enrolled before the study was stopped by DSMB as unlikely to meet primary endpoint of 43% overall mortality reduction
- **The median age increased from 59 in the first half of the trial to 67 in the second half (p<0.0001)**
- Preliminary results based on 60-day patient follow-up post randomization
- Pre-specified analysis of results stratified by age < or ≥ 65: 125 patients < 65 years, 97 patients ≥ 65 years

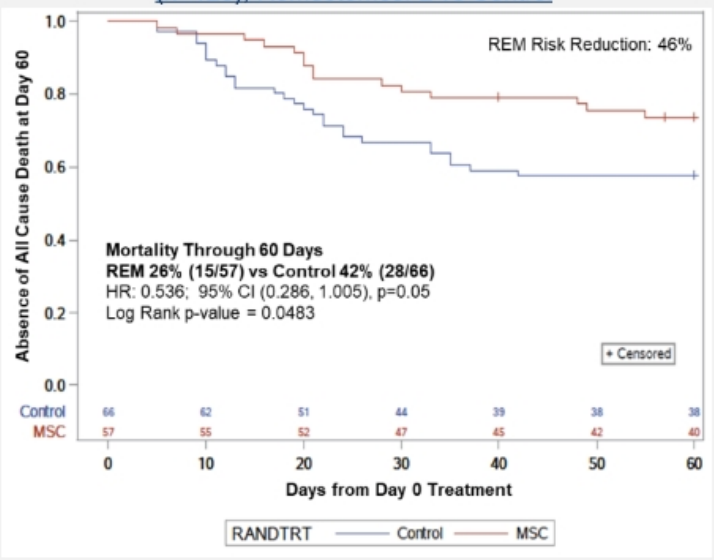
Greater Mortality through Day 60 in Control Patients Older than 65, Consistent with Other Trials

Controls Age < 65 vs ≥ 65 (n=110)

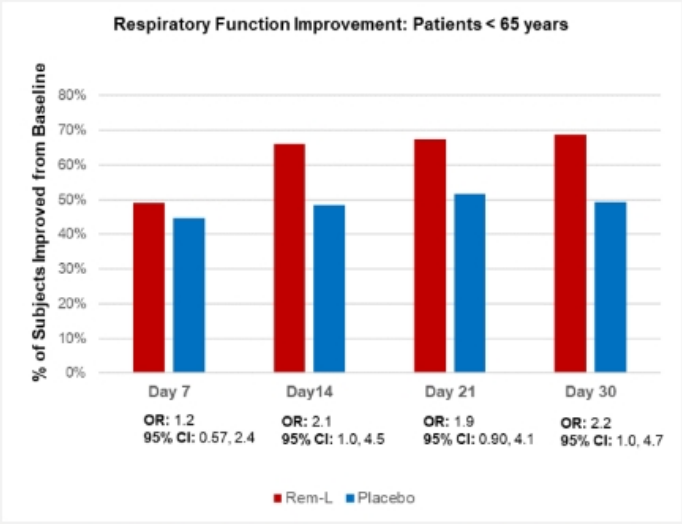


Greatest Mortality Reduction Improved ARDS Severity* Seen in Remestemcel-L Treated Patients < 65 years

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



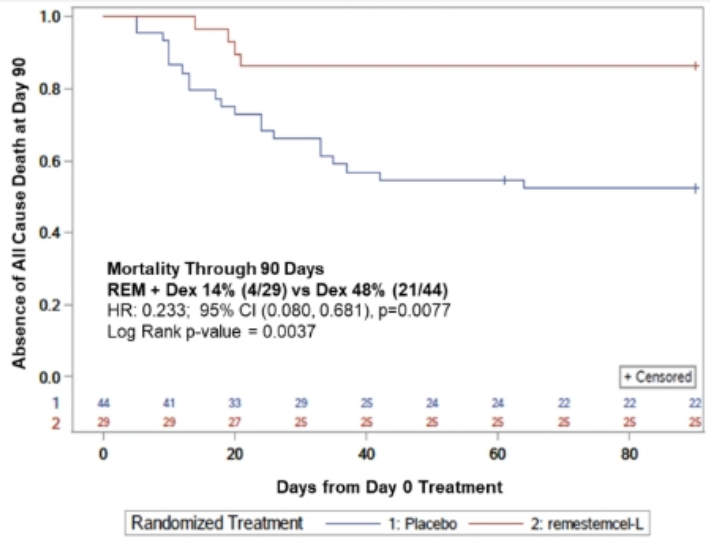
Treated Patients (mITT) **< 65 years old** (n=123) Remestemcel-L vs Control



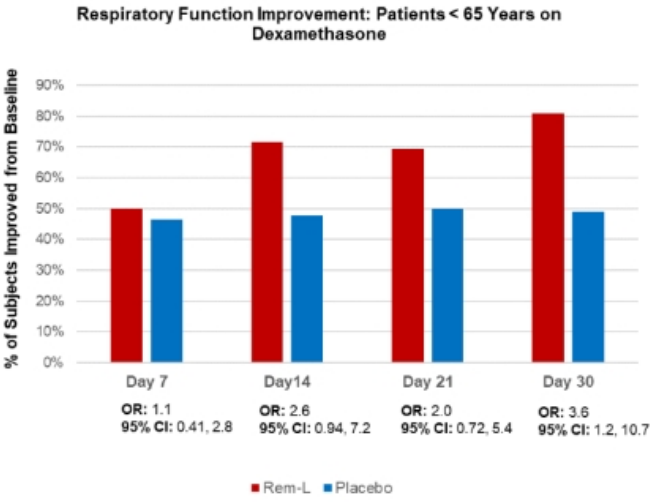
* Measured as resolution and/or improvement of ARDS as defined by the Berlin criteria at Days 7, 14, 21, and 30 post-randomizations

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



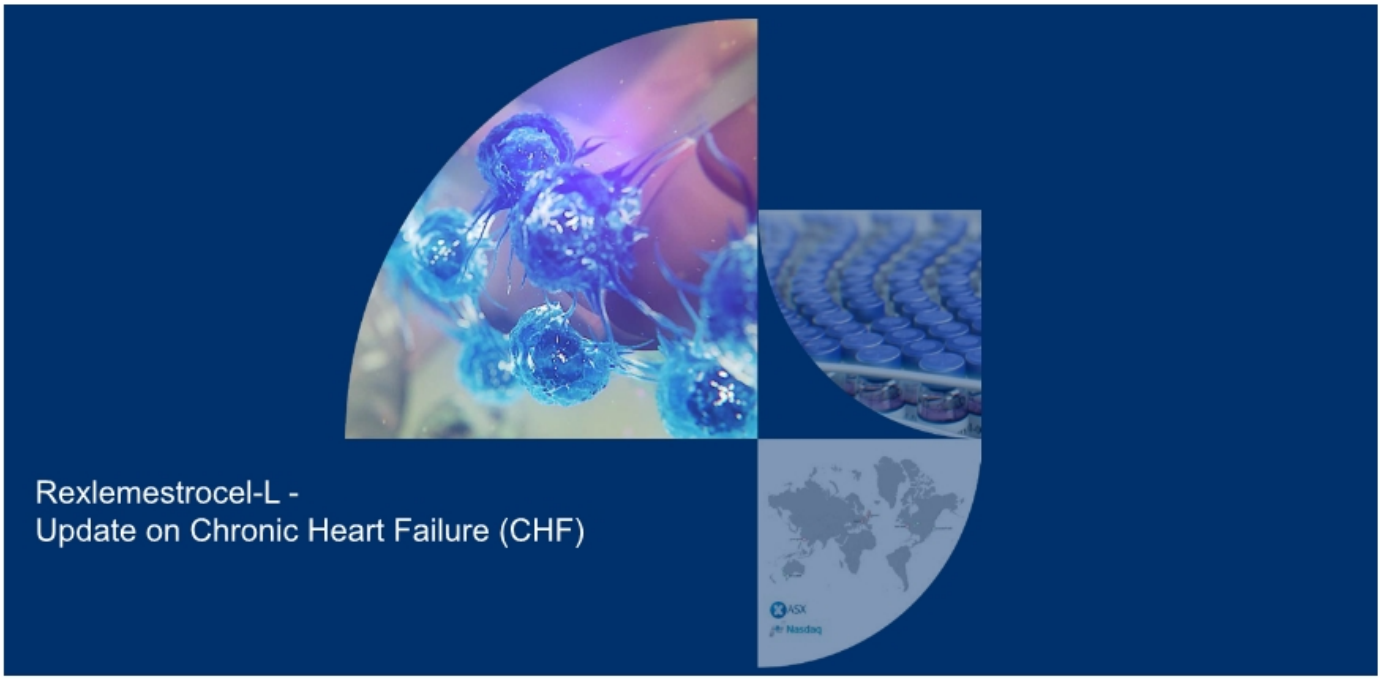
Treated Patients (mITT) < 65 years old on Dexamethasone (n=73)



* 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

- Mesoblast 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 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 EUA
- FDA indicated that potency assays must be established and agreed prior to commencement of the proposed Phase 3 clinical trial
- Mesoblast plans to move forward with an additional Phase 3 trial in COVID-19 ARDS with the next step being to agree with the FDA the final protocol and potency assay


Rexlemestrocel-L -
Update on Chronic Heart Failure (CHF)
ASX
Nasdaq

Chronic Heart Failure: Rising Incidence & High Mortality

- Cardiovascular disease remains the leading cause of death in the United States[1]
- Heart failure affects 6.5 million patients in the US and 26 million patients globally. As populations age, the prevalence is increasing[2]
- Chronic heart failure (CHF) is a progressive disease with a high mortality that approaches 50% at 5 years[2,3], and at least 75% after an initial hospitalization[4]
- Patients with heart failure are also at high risk of recurrent major adverse cardiac events involving large vessels (heart attacks / strokes)

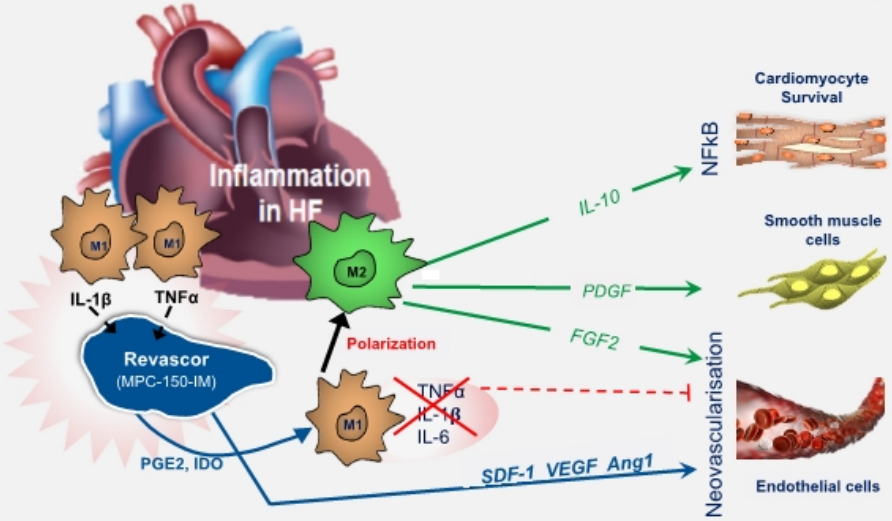
New therapies for chronic heart failure reduce recurrent hospitalizations due to cardiac decompensation, however they do not materially improve cardiac mortality or major ischemic events (heart attacks/strokes)

1. Muntner BEJ, et al. Heart Disease and Stroke Statistics-2019 Update: A Report From the American Heart Association. *Circulation.* Feb 19, 2019. 2. United States Food & Drug Administration. Treatment for Heart Failure: Endpoints for Drug Development. Draft Guidance. June 2019. 3. Taylor CJ, et al. Trends in survival after a diagnosis of heart failure in the United Kingdom 2000-2017: population-based cohort study. *BMJ.* 2019;364:l223. 4. Shah KS, et al. Heart Failure with Preserve, Borderline, and Reduced Ejection Fraction; 5-Year Outcomes. *JACC.* 2017;Nov12.

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



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

Late Breaking Presentation at American Heart Association Annual Meeting

- Data from the randomized, controlled Phase 3 trial of rexlemestrocel-L in 565 patients with NYHA class II and class III 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, gave the presentation titled *'Randomized Trial of Targeted Transendocardial Delivery of Mesenchymal Precursor Cells in High-Risk Chronic Heart Failure Patients with Reduced Ejection Fraction'*
- New data presented 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 cardiovascular mortality, heart attacks or strokes

DREAM HF: Overview of Phase 3 Trial

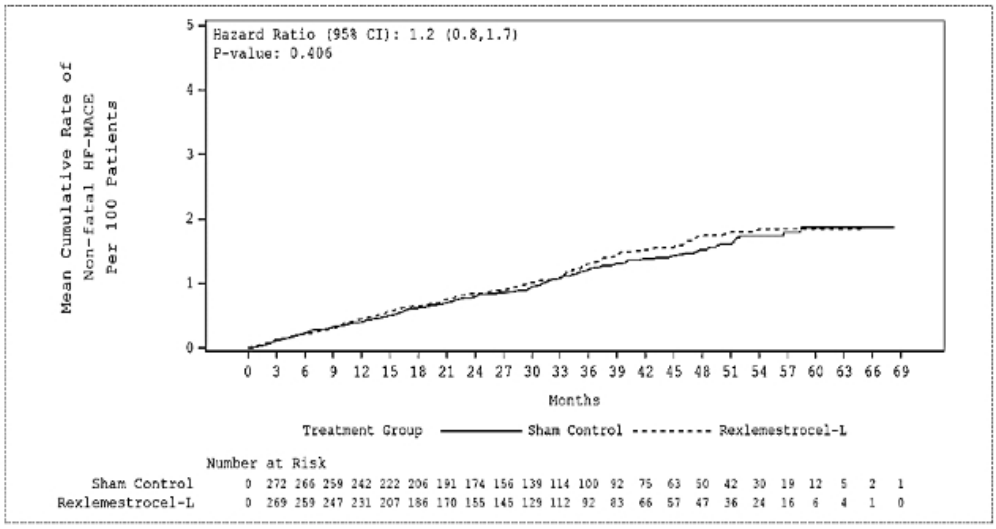
- Mesoblast's allogeneic cell therapy rexlemestrocel-L has a dual mechanism of action that involves immunomodulation and improvement in blood vessel integrity/function
- DREAM-HF Phase 3 trial was designed to evaluate whether rexlemestrocel-L could improve morbidity and mortality in advanced chronic heart failure patients
- Trial design: 1:1 randomized, controlled, double blinded; conducted over 55 sites across North America using 150 million cell dose vs control in 565 patients
- Primary endpoint: reduction in recurrent heart failure-related hospitalizations
- Secondary endpoints:
  - Reduction in ischemic cardiovascular events (heart attack / stroke)
  - Reduction in recurrent hospitalizations due to ischemic events (heart attack / stroke)
  - Reduction in death due to cardiac causes
- Composite of the pre-specified ischemic major adverse cardiac events (MACE: heart attack, stroke or cardiac death)

Rexlemestrocel-L Did Not Further Reduce Frequency of Hospitalization for Worsening HF Symptoms Over Maximal Standard of Care

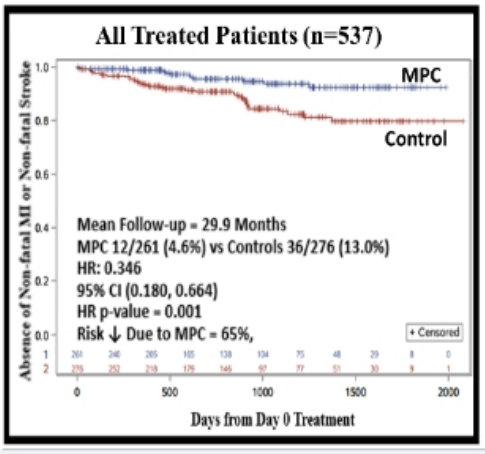
All Patients (n=537)

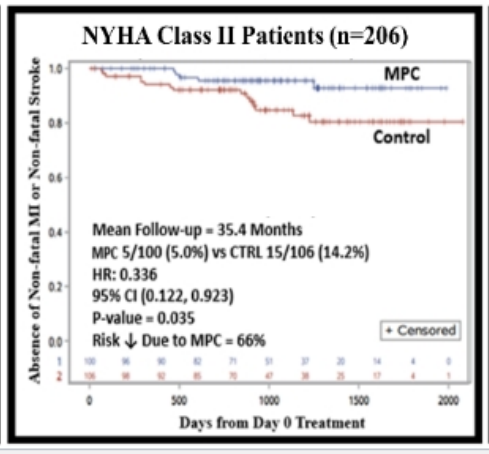
HR: 1.2

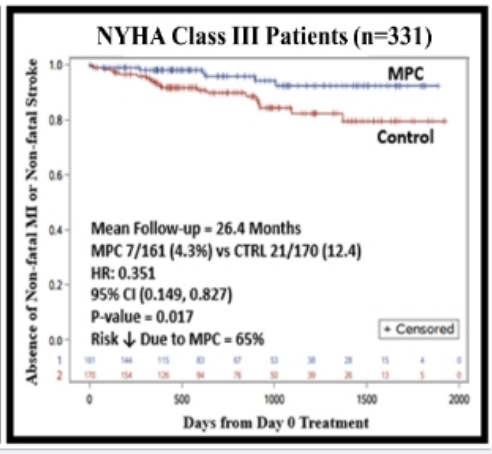
p=0.4



Rexlemestrocel-L Reduced Incidence of Non-fatal MI or Non-fatal Stroke Over Standard of Care Alone

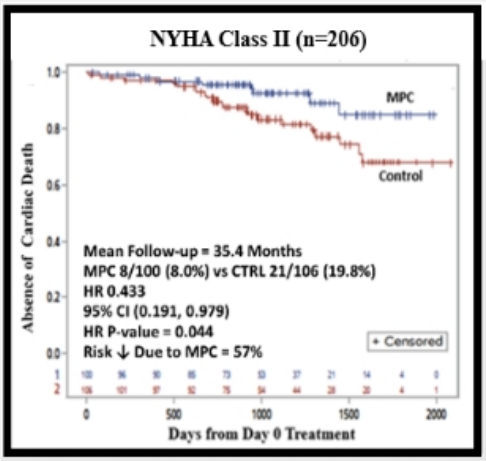


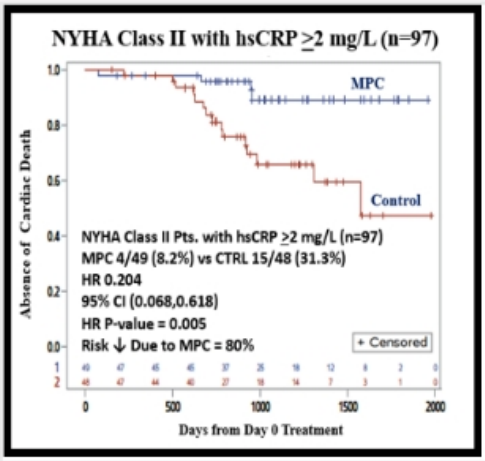


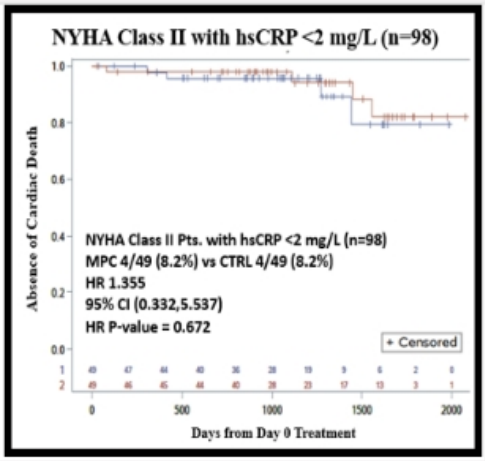


Rexlemestrocel-L Reduced Incidence of Cardiac Death, Particularly in Patients with Inflammation

Time-to-Cardiac Death in NYHA Class II Patients

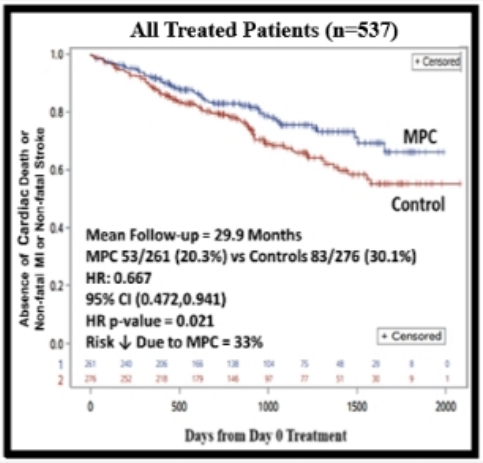


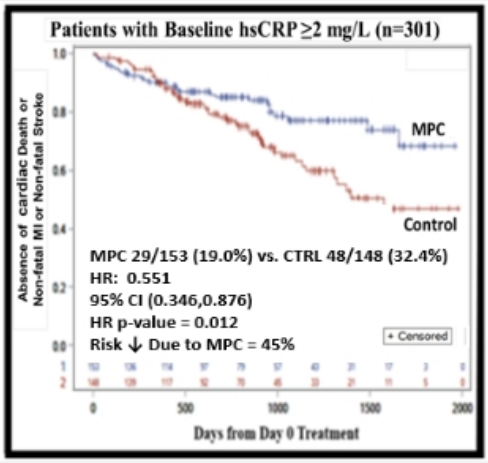


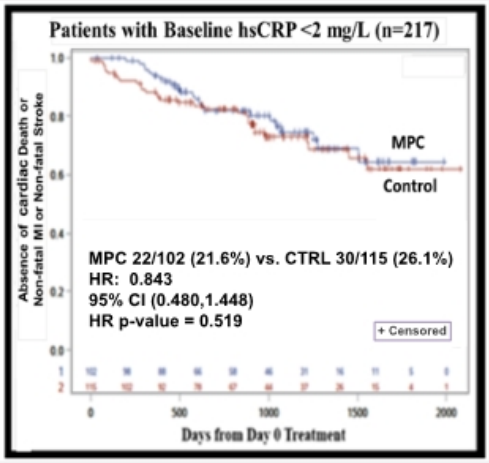


Rexlemestrocel-L Reduced Incidence of 3-Point MACE (Cardiac Death or MI or Stroke) in all 537 Treated Patients, and Especially in Those with Inflammation

Time-to-First-Event for Cardiac Death or Non-fatal MI or Non-fatal Stroke

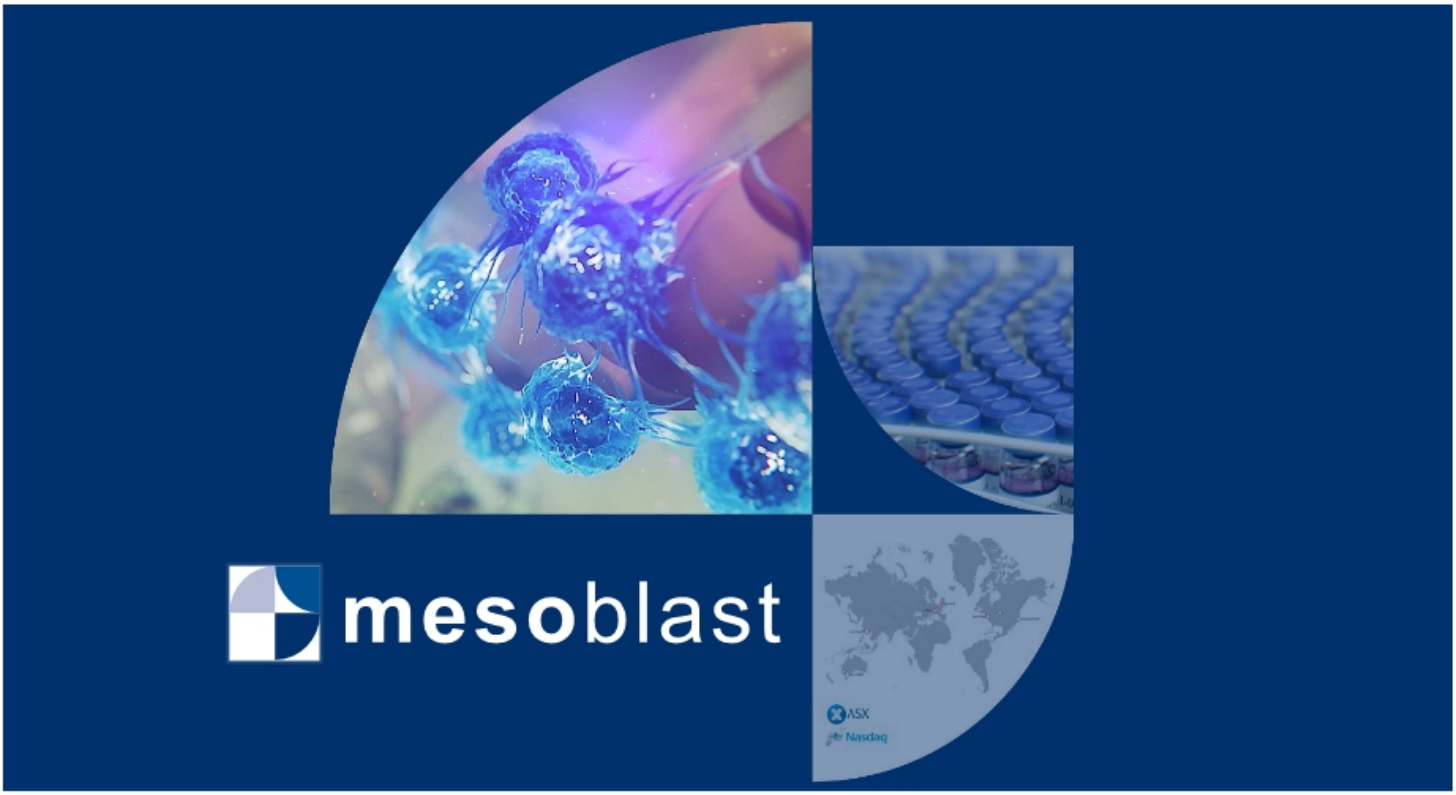






Conclusions

- Transendocardial delivery of 150 million allogeneic MPCs (rexlemestrocel-L) was safe and did not elicit any clinically meaningful immune-related responses
- Over a mean follow-up of 30 months, a single rexlemestrocel-L dose added to maximal standard of care significantly reduced:
  - Non-fatal MI or non-fatal stroke in NYHA class II & class III
  - Cardiac death in NYHA class II
  - Composite of cardiac death or non-fatal MI or non-fatal stroke in all 537 patients
  - Benefits of MPC therapy were most evident in 301 patients with baseline inflammation (plasma hsCRP ≥2 mg/L)
  - Rexlemestrocel-l did not further reduce frequency of hospitalization for worsening HF symptoms over maximal standard of care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