
**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 June 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 June 3, 2021, 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/ Charlie Harrison

Charlie Harrison
Company Secretary

Dated: June 4, 2021

INDEX TO EXHIBITS

Item

- 99.1 Press release of Mesoblast Ltd, dated June 3, 2021.
- 99.2 Investor presentation of Mesoblast Ltd, dated June 3, 2021.

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

Melbourne, Australia; June 3 and New York, USA; June 2, 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 period ended March 31, 2021.

“We are pleased with the recent clinical outcomes regarding our lead product candidate remestemcel-L and continue to progress our regulatory discussions with the aim of achieving approval. Our focus and top priority remains on successfully bringing remestemcel-L to children with the devastating complication of steroid-refractory acute graft versus host disease and adults fighting COVID-19 acute respiratory distress syndrome,” said Silviu Itescu, Chief Executive of Mesoblast.

Operational Highlights

Remestemcel-L in the treatment of steroid-refractory acute graft versus host disease (SR-aGVHD) in children:

- Mesoblast continues to be in discussion with the United States Food & Drug Administration (FDA) through a well-established regulatory process that may include a resubmission with a six month review with the aim of achieving approval of remestemcel-L in the treatment of steroid-refractory acute graft versus host disease (SR-aGVHD) in children
- As part of this process, Mesoblast recently met with the FDA’s Center for Biologics Evaluation and Research (CBER). Following CBER’s recommendation after this meeting, Mesoblast as a next step will discuss with CBER’s review team at the Office of Tissue and Advanced Therapies (OTAT) our approach to address certain outstanding chemistry, manufacturing and controls (CMC) items, including potency assay validation

Remestemcel-L in the treatment of COVID-19 ARDS in adults:

- Results from the randomized controlled trial of remestemcel-L in ventilator-dependent COVID-19 patients with moderate/severe acute respiratory distress syndrome (ARDS) indicated that in the pre-specified population under 65 years old (n=123), those who received remestemcel-L had a significantly reduced mortality through to 60 days. The trial had been halted after the third interim analysis and 222 enrolled patients since the 30-day primary endpoint would not be attained.
- In patients under 65 years, the benefit was further increased when remestemcel-L was used with dexamethasone as part of standard of care
- The trial also indicated that the mortality reduction by remestemcel-L in those under 65 years was accompanied by increased days alive off mechanical ventilation and reduced days in hospital

Rexlemestrocel-L in the treatment of chronic low back pain:

- Results from the trial of rexlemestrocel-L (MPC-06-ID) in 404 patients with chronic low back pain (CLBP) due to degenerative disc disease (DDD) indicated that a single injection of rexlemestrocel-L + hyaluronic acid (HA) carrier may provide at least two years of pain reduction, with opioid sparing activity in patients using opioids at baseline
- Significant and durable reductions in CLBP through 24 months were seen across the entire evaluable study population, and greatest pain reduction was observed in the pre-specified population with CLBP of shorter duration than the study median of 68 months
- The results indicate that treatment benefit may be greatest when inflammation is high and before irreversible fibrosis has occurred in the intervertebral disc



Financial Highlights

- Sales of TEMCELL® HS Inj.¹ in Japan for the treatment of aGVHD continue to recover from the effects of the temporary shutdown in production during mid-2020 which was undertaken in order to increase capacity to meet growing demand for the product
- Revenues from TEMCELL® royalties for the quarter ended March 31, 2021 were US\$1.9 million compared to US\$2.0 million in the quarter ended March 31, 2020
- Successful completion of US\$110 million private placement, with cash balance of US\$158.3 million at March 31, 2021
- Private placement was led by US investor group SurgCenter Development, one of the largest private operators of ambulatory surgical centres in the US specializing in spine, orthopaedic and total joint replacement
- Mesoblast entered into a contractual amendment with Hercules to extend the interest-only period of its debt facility through to at least October 2021

Key initiatives and Upcoming Milestones for the Next Two Quarters

Remestemcel-L

- In the treatment of steroid-refractory acute graft versus host disease (SR-GVHD) in children, Mesoblast plans to discuss with CBER's review team at the OTAT our approach to address certain outstanding CMC items, including potency assay validation
- In the regulatory pathway for remestemcel-L in patients with COVID-19 ARDS, Mesoblast intends to meet with FDA to discuss potential next steps based on the observed reduction in mortality in patients under 65 years in the recent trial
- The license and collaboration agreement between Mesoblast and Novartis for the development, manufacture, and commercialization of remestemcel-L, with an initial focus on the development of the treatment of ARDS, remains subject to certain closing conditions, including time during this period to analyze the results from the COVID-19 ARDS trial

Rexlemestrocel-L

- Mesoblast intends to meet with FDA to discuss a potential pathway for approval of rexlemestrocel-L in patients with chronic discogenic lower back pain based on the observed durable reduction in pain and opioid sparing activity in the CLBP Phase 3 trial
- Mesoblast intends to meet with FDA to discuss potential next steps in the regulatory pathway for rexlemestrocel-L in patients with chronic heart failure based on the observed reduction in mortality and morbidity in the chronic heart failure Phase 3 trial

Remestemcel-L

Steroid-Refractory Acute Graft Versus Host Disease

Mesoblast continues to be in discussion with the United States Food & Drug Administration (FDA) through a well-established regulatory process that may include a resubmission with a six month review with the aim of achieving approval of remestemcel-L in the treatment of steroid-refractory acute graft versus host disease (SR-aGVHD) in children.

As part of this process, Mesoblast recently met with the FDA's Center for Biologics Evaluation and Research (CBER). Following CBER's recommendation after this meeting, Mesoblast as a next step will discuss with CBER's review team at the Office of Tissue and Advanced Therapies (OTAT) our approach to address certain outstanding chemistry, manufacturing and controls (CMC) items, including potency assay validation.

Acute Respiratory Distress Syndrome due to COVID-19

Mesoblast recently announced top-line 60-day outcomes from the randomized, placebo-controlled trial of remestemcel-L in 222 ventilator-dependent COVID-19 patients with moderate/severe ARDS which had been halted after the third interim analysis since the 30-day primary endpoint would not be



attained. Remestemcel-L reduced mortality through day 60 by 46% in the pre-specified group below age 65, but not in patients 65 or older. Remestemcel-L reduced mortality by 75% and increased days alive off mechanical ventilation in patients under age 65 when combined with dexamethasone, in comparison with controls on dexamethasone.

Reduction in mortality in mechanically ventilated patients under 65 years old remains a critical unmet need since as many as 72% of currently hospitalized patients across the US with COVID-19 are in this age category.² This is similar to other causes of viral ARDS such as influenza where 70-80% of patients in intensive care units are under 65.^{3,4} The trial enrolled 222 mechanically ventilated COVID-19 patients with moderate/severe ARDS across the US, of whom 217 were randomized 1:1 and received either standard of care alone or standard of care plus 2 intravenous infusions of remestemcel-L at a dose of 2 million cells/kg 3-5 days apart. This was the same remestemcel-L dosing regimen used in the earlier compassionate use program where 11 of the 12 patients were younger than 65 and 75% successfully came off ventilatory support.

Key findings in the trial were:

- Remestemcel-L showed a positive but non-significant trend in overall mortality reduction through day 60 across the entire population of treated patients (n=217), Hazard Ratio (HR) 0.86, 95% CI (0.589, 1.246)^{5,6}; in those over age 65, there was no significant reduction in mortality (HR 1.05)
- In the pre-specified population of patients under age 65 (n=123), remestemcel-L significantly reduced mortality by 46% through day 60, 26% vs 42%, Hazard Ratio (HR) 0.54, 95% CI (0.286, 1.005), p=0.048^{5,6}
- Remestemcel-L had similar treatment effects on mortality in those under 65 years, with either moderate ARDS (HR 0.56)^{6,7} or severe ARDS (HR 0.56)^{6,7}
- Standard of care changed during the course of the trial to incorporate dexamethasone, with only 2% of the first 50 patients enrolled receiving dexamethasone compared with 84% of the subsequent 172 patients; this allowed for additional exploratory analyses of remestemcel-L treatment effects in patients who received dexamethasone as part of their standard of care
- Remestemcel-L reduced mortality through day 60 by 75% compared to controls in patients under 65 who received dexamethasone as part of their standard of care, 14% vs 45%, HR 0.25, 95% CI (0.085, 0.727), p=0.006^{5,6}
- Remestemcel-L increased days alive off ventilator within 60 days and reduced time to discharge from initial hospitalization compared to controls in patients under 65 who received dexamethasone as part of their standard of care, p=0.01 and p=0.005, respectively^{5,8}

Inflammatory Bowel Disease – Crohn’s Disease and Ulcerative Colitis

A randomized, controlled study of remestemcel-L delivered by an endoscope directly to the areas of inflammation and tissue injury in up to 48 patients with medically refractory Crohn’s disease and ulcerative colitis commenced at Cleveland Clinic in October 2020. The investigator-initiated study is the first in humans using local cell delivery in the gut and will enable Mesoblast to compare clinical outcomes using this delivery method with results from an ongoing randomized, placebo-controlled trial in patients with biologic-refractory Crohn’s disease where remestemcel-L was administered intravenously.

Relexemestrocil-L

Revascor for Chronic Heart Failure

The results from the landmark DREAM-HF randomized controlled trial in 537 treated patients with chronic heart failure with reduced left ventricular ejection fraction (HFrEF) who received relexemestrocil-L (REVASCOR®) or control sham, demonstrated that a single dose of relexemestrocil-L resulted in substantial and durable reductions in heart attacks, strokes, and cardiac deaths. The trial’s primary endpoint of reduction in volume overload related hospitalizations was not achieved. The results of this trial identify New York Heart Association (NYHA) class II HFrEF patients as the optimal



target population for greatest rexlemestrocel-L treatment effect, and therefore a focus for developing rexlemestrocel-L in the largest market in heart failure.

Based on the observed reduction in mortality and morbidity in this trial, Mesoblast intends to meet with the FDA to discuss potential next steps in the regulatory pathway.

MPC-06-ID for Chronic Low Back Pain due to Degenerative Disc Disease

The results from the randomized controlled trial of its allogeneic mesenchymal precursor cell (MPC) therapy rexlemestrocel-L in 404 enrolled patients with chronic low back pain (CLBP) due to degenerative disc disease (DDD) refractory to conventional treatments indicate that a single injection of rexlemestrocel-L + hyaluronic acid (HA) carrier may provide a safe, durable, and effective opioid-sparing therapy for patients with chronic inflammatory back pain due to degenerative disc disease, and that greatest benefits are seen when administered earlier in the disease process before irreversible fibrosis of the intervertebral disc has occurred.

There is a significant need for a safe, efficacious, and durable opioid-sparing treatment in patients with chronic low back pain due to severely inflamed degenerative disc disease. Mesoblast intends to meet with FDA to discuss a potential pathway for approval of rexlemestrocel-L in patients with chronic discogenic lower back pain based on the observed durable reduction in pain and opioid sparing activity in the CLBP trial.

Financial Results for the Three Months Ended March 31, 2021 (third quarter FY2021)

- **Balance sheet** cash on hand of US\$158.3 million at March 31, 2021, following the successful completion of US\$110 million private placement. Private placement was led by US investor group SurgCenter Development, one of the largest private operators of ambulatory surgical centres in the US specializing in spine, orthopaedic and total joint replacement. Mesoblast entered into a contractual amendment with Hercules to extend the interest-only period of its debt facility through to at least October 2021
- **Royalty revenues** on sales of TEMCELL® HS Inj. in Japan were US\$1.9 million for the third quarter FY2021 compared to US\$2.0 million for the third quarter FY2020 as sales continue to recover from the effects of the temporary shutdown in production during mid-2020 which was undertaken in order to increase capacity to meet growing demand for the product
- **Research and Development** expenses decreased from US\$14.4 million in FY2020 to US\$12.4 million in FY2021, due to a reduction in third party clinical trial costs
- **Manufacturing** expenses were US\$7.3 million for third quarter FY2021, compared to US\$7.6 million for third quarter FY2020
- **Management and Administration** expenses increased from US\$5.7 million for third quarter FY2020 to US\$8.1 million for third quarter FY2021; this increase was predominantly due to one-off expenditure in legal and professional fees associated with regulatory and financing activities
- **Finance Costs** for borrowing arrangements with Hercules and NovaQuest were US\$3.2 million for third quarter FY2021, compared to US\$3.4 million for third quarter FY2020.

As a result of the above and other remeasurements on revaluation of assets and liabilities, the loss after tax for the third quarter FY2021 was US\$26.5 million compared to US\$15.3 million for third quarter FY2020. The net loss attributable to ordinary shareholders was 4.39 US cents per share for third quarter FY2021, compared with 2.84 US cents per share for third quarter FY2020.

Conference Call

There will be a webcast today, beginning at 8.30am AEST (Thursday, June 3); 6.30pm EDT (Wednesday, June 2, 2021). It can be accessed via: <https://webcast.boardroom.media/mesoblast-limited/20210602/NaN60b6e20c3acee00019e165bd>

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



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 2040 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 has completed Phase 3 trials of rexmestrocel-L for advanced chronic heart failure and chronic low back pain. 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. 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. The Coronavirus Disease 2019 (COVID-19)-Associated Hospitalization Surveillance Network (COVID-NET). Centers for Disease Control and Prevention
3. Martin-Loeches et al. Pandemic and post-pandemic Influenza A (H1N1) infection in critically ill patients *Critical Care* 2011, 15:R286
4. Bonmarin I et al. Intensive care unit surveillance of influenza infection in France: the 2009/10 pandemic and the three subsequent seasons. *Euro Surveill.* 2015;20(46)
5. All p-values are descriptive and not adjusted for multiplicity
6. Hazard Ratios calculated using Cox regression proportional hazards model without adjustment; p-value from Kaplan-Meier log rank statistics
7. Interaction term between remestemcel-L treatment and ARDS severity in Cox regression proportional hazards model was not significant (p=0.98), indicating that treatment effect is not confounded by disease severity
8. Wilcoxon rank sum test

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 maintain for intellectual property rights covering its product candidates and technology; estimates of Mesoblast's expenses, future revenues, capital requirements and its needs for additional financing; Mesoblast's financial performance; developments relating to Mesoblast's competitors and industry; and the pricing and reimbursement of Mesoblast's product candidates, if approved. You should read this press release together with our risk factors, in our most recently filed reports with the SEC or on our website. Uncertainties and risks that may cause Mesoblast's actual results, performance or achievements to be materially different from those which may be expressed or implied by such statements, and accordingly, you should not place undue reliance on these forward-looking statements. We do not undertake any obligations to publicly update or revise any forward-looking statements, whether as a result of new information, future developments or otherwise.

Release authorized by the Chief Executive.

For more information, please contact:

Corporate Communications / Investors

Paul Hughes
T: +61 3 9639 6036
E: investors@mesoblast.com

Media

Kristen Bothwell
T: +1 917 613 5434
E: kbothwell@rubenstein.com



Consolidated Income Statement

(in U.S. dollars, in thousands, except per share amount)	Three Months Ended March 31,		Nine Months Ended March 31,	
	2021	2020	2021	2020
Revenue	1,915	12,201	5,461	31,455
Research & development	(12,441)	(14,379)	(45,957)	(40,922)
Manufacturing commercialization	(7,332)	(7,612)	(25,706)	(15,456)
Management and administration	(8,087)	(5,730)	(23,633)	(17,960)
Fair value remeasurement of contingent consideration	1,534	2,158	18,103	1,276
Other operating income and expenses	1,025	(442)	1,420	(67)
Finance costs	(3,227)	(3,414)	(7,193)	(9,814)
Loss before income tax	(26,613)	(17,218)	(77,505)	(51,488)
Income tax (expense)/benefit	98	1,955	754	6,158
Loss attributable to the owners of Mesoblast Limited	(26,515)	(15,263)	(76,751)	(45,330)
Losses per share from continuing operations attributable to the ordinary equity holders of the Group:	Cents	Cents	Cents	Cents
Basic - losses per share	(4.39)	(2.84)	(12.99)	(8.66)
Diluted - losses per share	(4.39)	(2.84)	(12.99)	(8.66)

Consolidated Statement of Comprehensive Income

(in U.S. dollars, in thousands)	Three Months Ended March 31,		Nine Months Ended March 31,	
	2021	2020	2021	2020
Loss for the period	(26,515)	(15,263)	(76,751)	(45,330)
Other comprehensive (loss)/income				
<i>Items that may be reclassified to profit and loss</i>				
Financial assets at fair value through other comprehensive income	81	94	109	(551)
Exchange differences on translation of foreign operations	(2,712)	(361)	(1,400)	(405)
Other comprehensive (loss) for the period, net of tax	(2,631)	(267)	(1,291)	(956)
Total comprehensive losses attributable to the owners of Mesoblast Limited	(29,146)	(15,530)	(78,042)	(46,286)

Consolidated Balance Sheet

(in U.S. dollars, in thousands)	As of March 31, 2021	As of June 30, 2020
Assets		
Current Assets		
Cash & cash equivalents	158,263	129,328
Trade & other receivables	2,947	1,574
Prepayments	8,556	5,646
Total Current Assets	169,766	136,548
Non-Current Assets		
Property, plant and equipment	2,989	2,293
Right-of-use assets	7,247	7,978
Financial assets at fair value through other comprehensive income	1,981	1,871
Other non-current assets	3,203	3,311
Intangible assets	580,939	581,601
Total Non-Current Assets	596,359	597,054
Total Assets	766,125	733,602
Liabilities		
Current Liabilities		
Trade and other payables	24,275	24,972
Provisions	18,757	29,197
Borrowings	52,673	32,455
Lease liabilities	2,841	3,519
Total Current Liabilities	98,546	90,143
Non-Current Liabilities		
Deferred tax liability	—	730
Provisions	17,823	27,563
Borrowings	39,847	57,023
Lease liabilities	6,479	6,317
Deferred consideration	2,500	2,500
Total Non-Current Liabilities	66,649	94,133
Total Liabilities	165,195	184,276
Net Assets	600,930	549,326
Equity		
Issued Capital	1,162,188	1,051,450
Reserves	64,251	46,634
(Accumulated losses)/retained earnings	(625,509)	(548,758)
Total Equity	600,930	549,326

Consolidated Statement of Cash Flows

(in U.S. dollars, in thousands)	Nine Months Ended March 31,	
	2021	2020
Cash flows from operating activities		
Commercialization revenue received	4,162	5,579
Upfront and milestone payments received	—	17,500
Government grants and tax incentives received	56	1,499
Payments to suppliers and employees (inclusive of goods and services tax)	(86,029)	(57,722)
Interest received	17	533
Interest and other costs of finance paid	(4,122)	(4,165)
Income taxes paid	(35)	(7)
Net cash (outflows) in operating activities	(85,951)	(36,783)
Cash flows from investing activities		
Investment in fixed assets	(1,424)	(1,305)
Payments for licenses	—	(100)
Net cash (outflows) in investing activities	(1,424)	(1,405)
Cash flows from financing activities		
Payments of transaction costs from borrowings	(13)	—
Proceeds from issue of shares	105,584	51,559
Proceeds from issue of warrants	12,969	—
Payments for share issue costs	(1,547)	(2,211)
Payments for lease liabilities	(2,100)	(1,219)
Net cash inflows by financing activities	114,893	48,129
Net increase in cash and cash equivalents	27,518	9,941
Cash and cash equivalents at beginning of period	129,328	50,426
FX gain/(losses) on the translation of foreign bank accounts	1,417	(290)
Cash and cash equivalents at end of period	158,263	60,077



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

JUNE 2021

ASX: MSB; Nasdaq: MESO



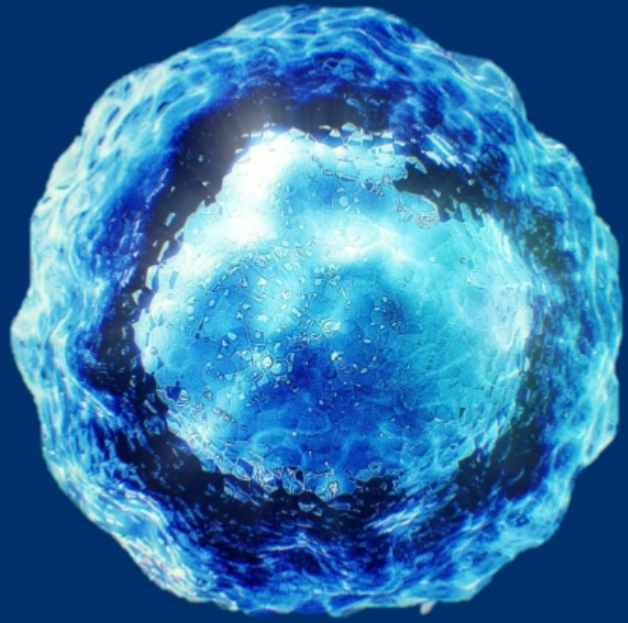


CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

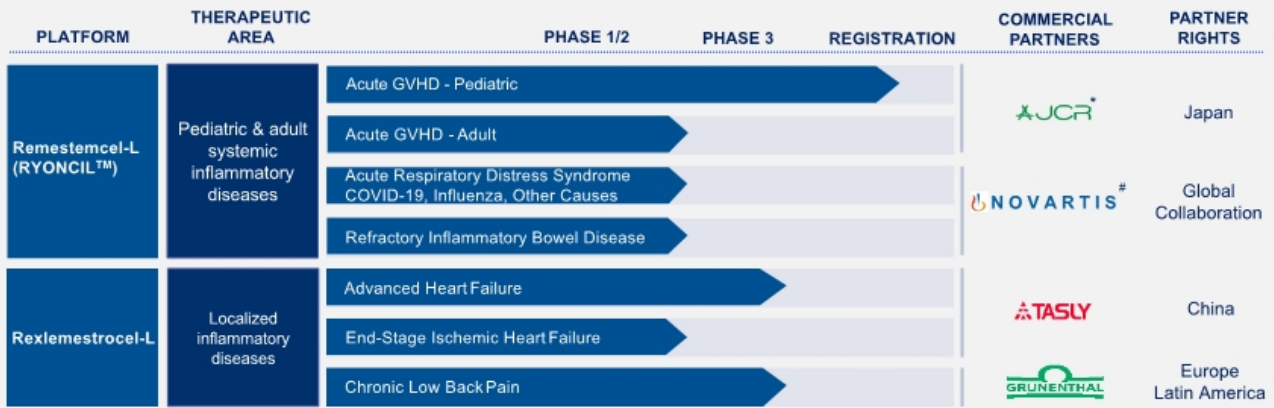
This presentation includes forward-looking statements that relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from any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



Pipeline



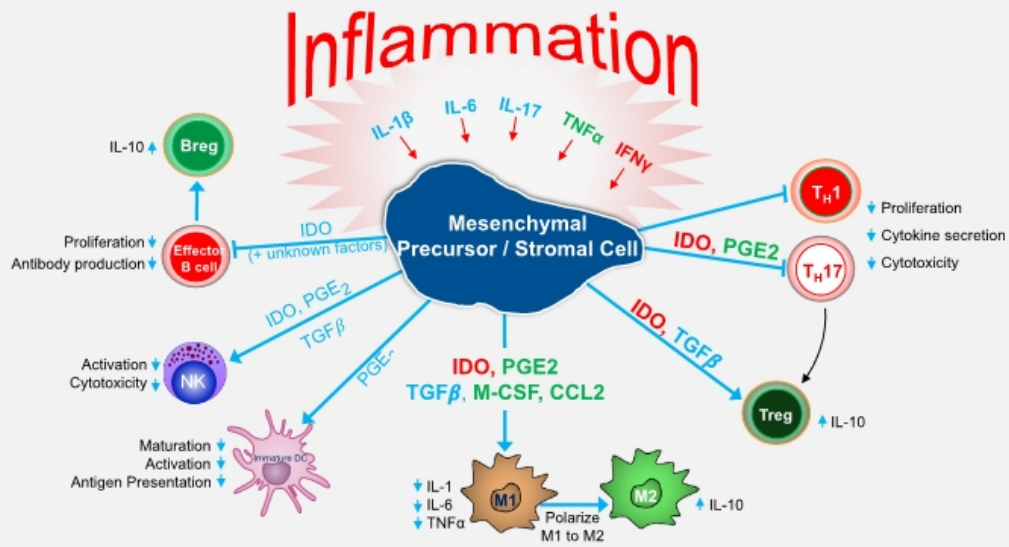
This chart is figurative and does not purport to show individual trial progress within a clinical program

* 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 1,100 patents and patent applications (82 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



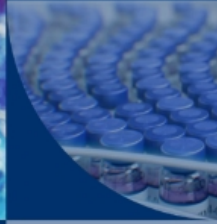
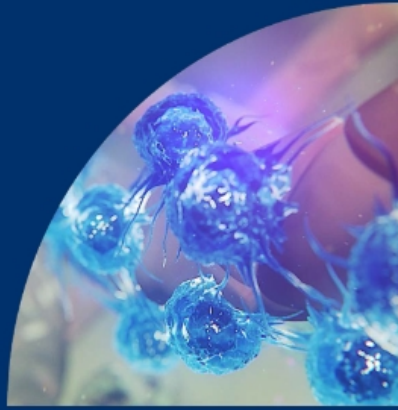
Commercial-scale Manufacturing Capabilities

- 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



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Financial Results



Strengthened Balance Sheet After Recent Capital Raise



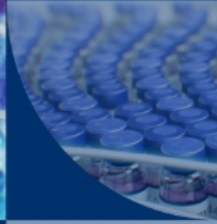
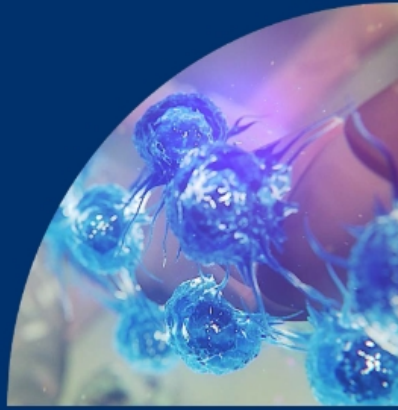
- Cash on hand as at March 31, 2021 is US\$158.3m
- Private placement completed in March 2021 was led by principals of SurgCenter Development, one of the largest private operators of ambulatory surgical centers in the US specializing in spine, orthopedic and total joint procedures
- Specific uses of proceeds include:
 - Operational and regulatory initiatives across multiple products as the company undertakes important late-stage meetings with FDA in the coming quarters
 - Building commercial supply of remestemcel-L ahead of potential approval for GVHD in children
 - Advancing optimized manufacturing of rexlemestrocet-L and remestemcel-L platforms for larger market opportunities

Ongoing Investment in R&D and Manufacturing

Profit and Loss for the three months ending (US\$m)	March 31, 2021	March 31, 2020
Commercialization revenue	2.0	2.1
Milestone revenue	-	10.0
Other revenue, including Interest	(0.1)	0.1
Total Revenue	1.9	12.2
Research and development	(12.4)	(14.4)
Manufacturing	(7.3)	(7.6)
Management & administration	(8.1)*	(5.7)
Contingent consideration	1.5	2.1
Other operating income & expenses	1.0	(0.4)
Finance costs	(3.2)	(3.4)
Loss before tax	(26.6)	(17.2)
Income tax benefit	0.1	1.9
Loss after tax	(26.5)	(15.3)

Figures are rounded

*Increase was predominantly due to one-off expenditure in legal and professional fees associated with financing and FDA regulatory activities

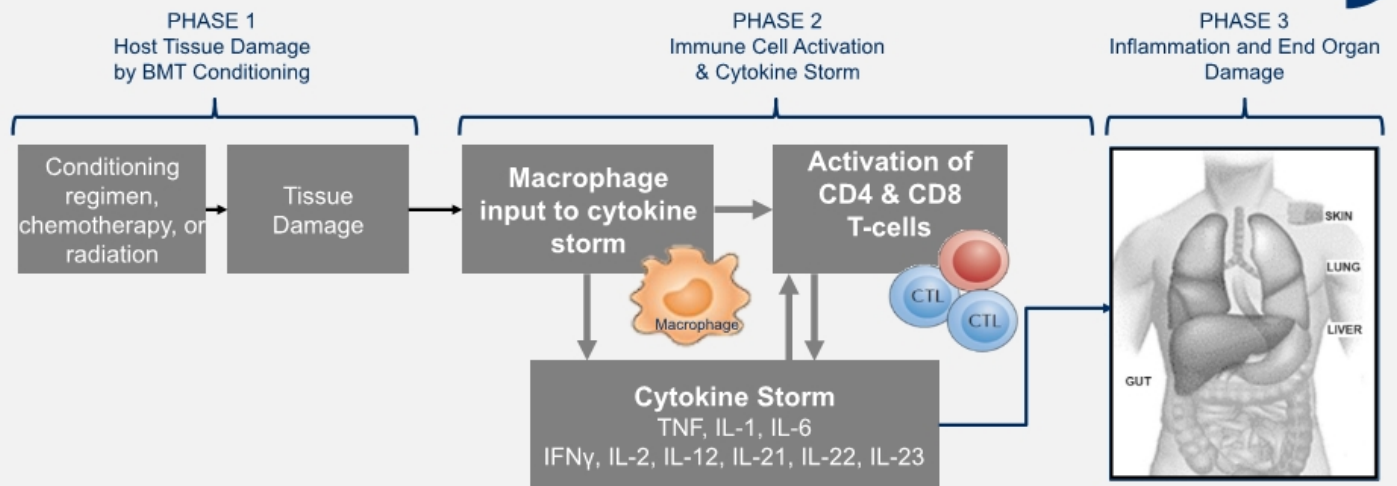


Remestemcel-L
- Acute Graft versus Host Disease
- Acute Respiratory Distress Syndrome

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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 US¹
- Despite prophylaxis, ~50% will develop aGVHD²
- 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:

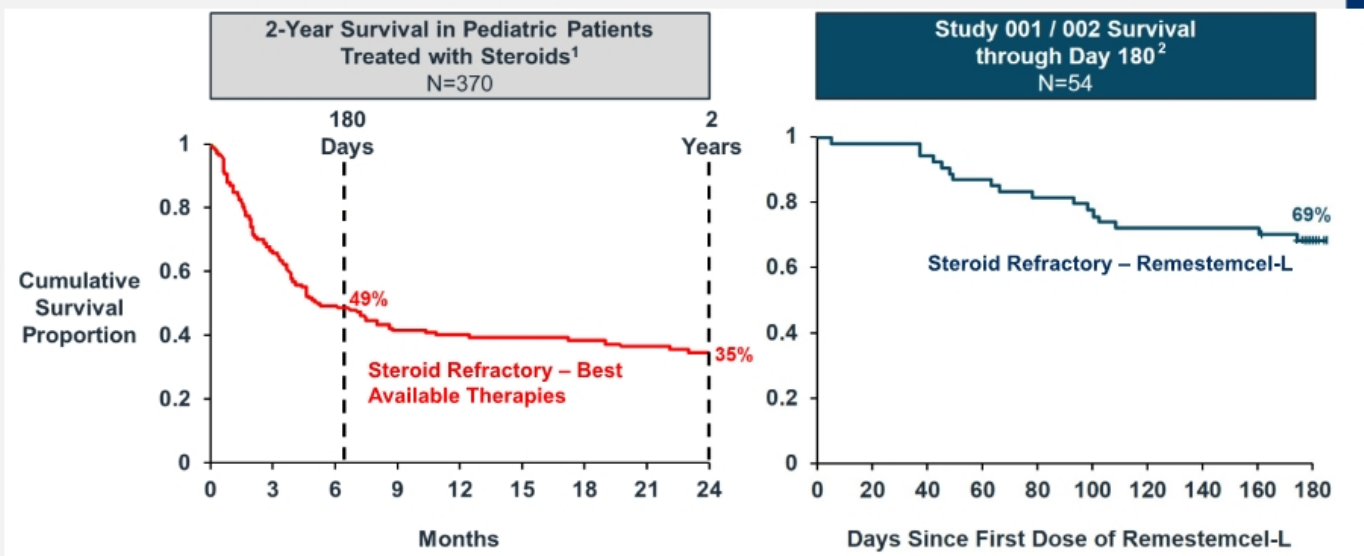
- Remestemcel-L was used as first-line therapy in a randomized controlled Phase 3 trial of 260 patients, with SR-aGVHD, including 27 children
- Remestemcel-L was used as salvage therapy in an expanded access program in 241 children with SR-aGVHD, 80% of whom had Grade C/D disease, and failed institutional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

	MAGIC ¹ N=30 ²	Protocol 280 (pediatric)		EAP 275	Study 001
		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

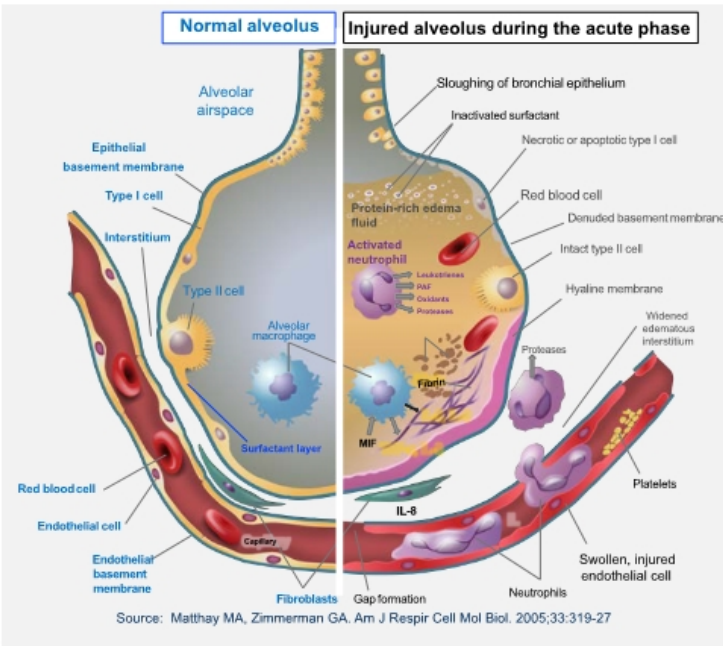
Remestemcel-L: Regulatory & Commercial Update for SR-aGVHD



- On August 13, 2020, results from 309 children with SR-aGVHD treated with remestemcel-L were presented to the Oncologic Drugs Advisory Committee (ODAC) of the United States Food and Drug Administration (FDA)
- The ODAC panel voted 9:1 that the available data support the efficacy of remestemcel-L in pediatric patients with SR-aGVHD*
- Despite the overwhelming ODAC vote, on September 30, the FDA provided Mesoblast with a Complete Response Letter (CRL)
- Mesoblast continues to be in discussion with the FDA through a well-established regulatory process that may include a resubmission with a six month review with the aim of achieving approval of remestemcel-L in the treatment of SR-aGVHD in children
- As part of this process, Mesoblast recently met with the FDA's Center for Biologics Evaluation and Research (CBER). Following CBER's recommendation after this meeting, Mesoblast as a next step will discuss with CBER's review team at the Office of Tissue and Advanced Therapies (OTAT) our approach to address certain outstanding chemistry, manufacturing and controls (CMC) items, including potency assay validation

* This vote includes a change to the original vote by one of the ODAC panel members after electronic voting closed

ARDS due to COVID-19, Influenza & Bacterial Infection – Major Unmet Need



Acute respiratory distress syndrome (ARDS)

- A major area of unmet medical need
- Multiple triggers including viral/bacterial infections such as coronavirus or influenza
- Typically requires extended ICU hospitalization and intervention by ventilation
- ~40-80% mortality in viral induced ARDS (influenza & COVID-19, respectively)¹⁻⁴

Pathophysiology

- Activation of alveolar M1 macrophages results in cytokine storm
- Influx of neutrophils results in proteolytic destruction
- Aberrant secretion of fluid by alveolar cells
- Interstitial edema, cell death and influx of inflammatory cells

1. Matthay MA, et al. Acute Respiratory Distress Syndrome. Nature 2019 5:18. doi: 10.1038/s41572-019-0069-0; 2. Bellani G, Laffey JG, Pham T, et al. Epidemiology and patterns of care, and mortality for patients with acute respiratory distress syndrome in intensive care units in 50 countries. JAMA 2016;315:768-800; 3. Petrilli CM et al. Factors associated with hospitalization and critical illness among 4,103 patients with Covid-19 disease in New York City. MedRxiv 2020; 4. Gibson PG, et al. COVID-19 ARDS: clinical features and differences to 'usual' pre-COVID ARDS. Med J Aust. 24 April 2020



Emergency IND in Ventilator-Dependent COVID-19 ARDS

- 11 patients (10/11 were < 65 years) with moderate or severe ARDS on ventilators, received two infusions of remestemcel-L 2 million cells/kg within five days at Mt. Sinai Hospital in New York City
- 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

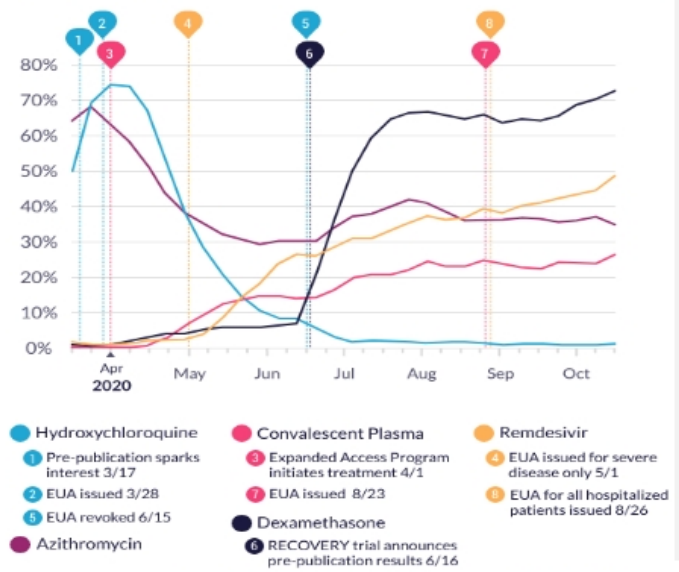
- Multi-center, randomized, controlled, blinded study to assess safety and efficacy of remestemcel-L versus placebo in ventilator-dependent patients with moderate/severe ARDS due to COVID-19
- Up to 300 patients randomized 1:1 to receive placebo or two infusions of remestemcel-L within 3-5 days
- 222 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

Dynamic Changes in the Treatment Regimes and Population Enrolled During the Trial

- Recent experience suggests that mortality benefits in ARDS patients are most likely to be seen when using anti-inflammatory therapy early and prior to mechanical ventilation¹
- During the conduct of the trial overall mortality in hospitalized COVID-19 patients dropped from 25.6% to 7.6%² due to widespread use of corticosteroids, antivirals and better supportive care
- Mortality benefits in hospitalized COVID-19 patients seen predominantly in younger patients (<65 years old)
- As a result of widespread use of anti-inflammatory agents and high flow nasal oxygen prior to mechanical ventilation, ventilated COVID-19 ARDS patients enrolled midway through the trial were significantly older and more refractory to all therapies

COVID-19 Patients, First COVID Hospitalization (n=39,115)

Primary Treatments



Source: Noel A. et al. Epic Health Research Network. Nov 2020

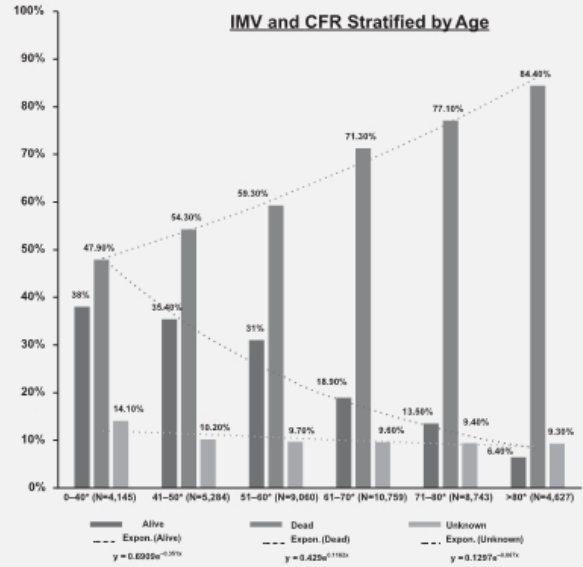
¹ Gordon AC, et al. Interleukin-6 Receptor Antagonists in Critically Ill Patients with Covid-19 – Preliminary report. doi.org/10.1101/2021.01.07.21249390
² Horwitz LJ, et al. Trends in COVID-19 Risk-Adjusted Mortality Rates. Jml Hosp Med. Oct 2020

Meta-Analysis of Case Fatality Rates (CFR) for COVID-19 Patients on Invasive Mechanical Ventilation (IMV): Mortality Significantly Increases with Age



Age	Alive n (% 95% CI)	Dead n (% 95% CI)	Unknown n (% 95% CI)
≤40* (N=4,145)	1,575 (38.0, 36.5–39.5)	1,985 (47.9, 46.4–49.4)	585 (14.1, 13.1–15.2)
41–50* (N=5,284)	1,872 (35.4, 34.1–36.7)	2,870 (54.3, 53.0–55.7)	542 (10.2, 9.5–11.1)
51–60* (N=9,060)	2,809 (31.0, 30.1–32.0)	5,373 (59.3, 58.3–60.3)	878 (9.7, 9.1–10.3)
61–70* (N=10,759)	2,033 (18.9, 18.2–19.6)	7,676 (71.3, 70.5–72.2)	1,050 (9.6, 9.2–10.3)
71–80* (N=8,743)	1,180 (13.5, 12.8–14.2)	6,740 (77.1, 76.2–78.0)	823 (9.4, 8.8–10.0)
>80* (N=4,627)	295 (6.4, 5.7–7.1)	3,903 (84.4, 83.3–85.4)	429 (9.3, 8.5–10.1)

Reported case fatality rates for patients receiving invasive mechanical ventilation stratified by age, reported in six studies. *Age stratification for ICNARC was 16–39, 40–49, 50–59, 60–69, 70–79, and >80. CFR = case fatality rate; CI = confidence interval; Expon. = exponential; ICNARC = Intensive Care National Audit and Research Centre; IMV = invasive mechanical ventilation.



Source: Am J Respir Crit Care Med Vol 203, Issue 1, pp 54–66, Jan 1, 2021. Sixty-nine studies were included, describing 57,420 adult patients with COVID-19 who received IMV. Fifty-four of 69 studies stated whether hospital outcomes were available but provided a definitive hospital outcome on only 13,120 (22.8%) of the total IMV patient population.

Viral ARDS ICU Admissions Are Predominantly Comprised Of Patients < 65 Years of Age

Severe Influenza Admissions To ICU In Spain During and Post Pandemic Period

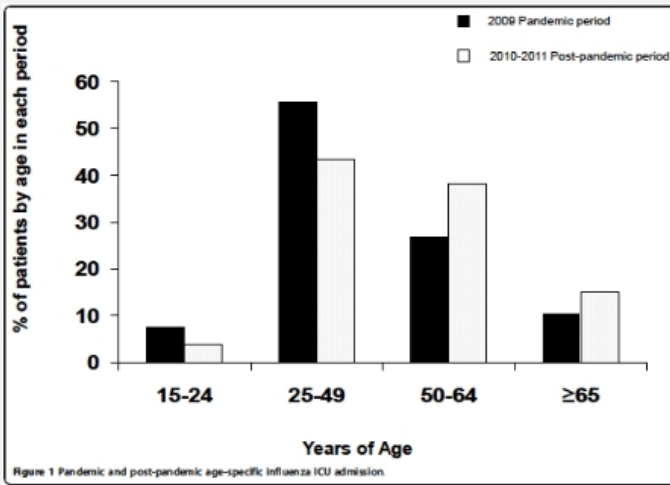
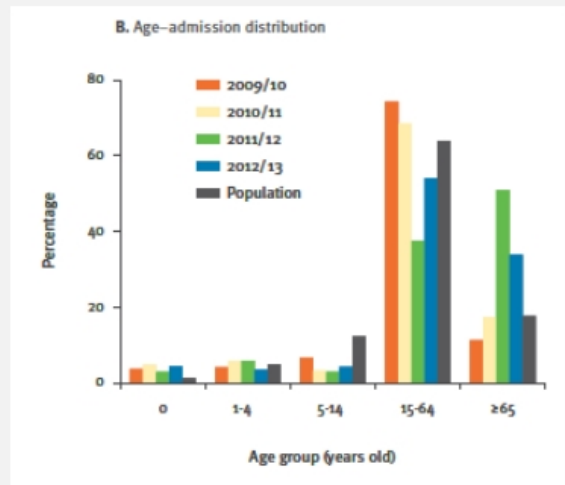


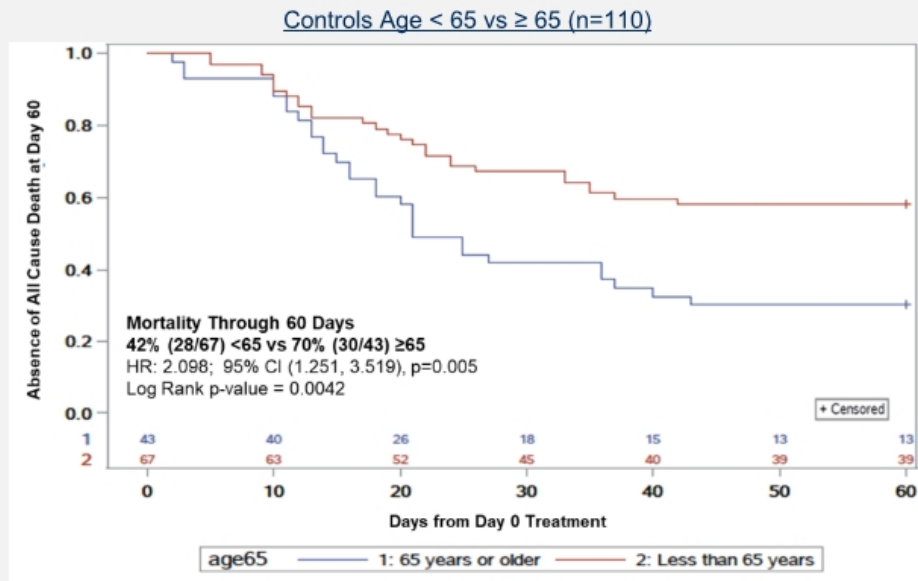
Figure 1 Pandemic and post-pandemic age-specific Influenza ICU admission.

Severe Influenza Admissions To ICU In France Over Time²



1. Martin-Loeches et al. Pandemic and post-pandemic Influenza A (H1N1) infection in critically ill patients *Critical Care* 2011, 15:R286
2. Bonmarin I et al. Intensive care unit surveillance of influenza infection in France: the 2009/10 pandemic and the three subsequent seasons *Euro Surveill.* 2015;20(46)

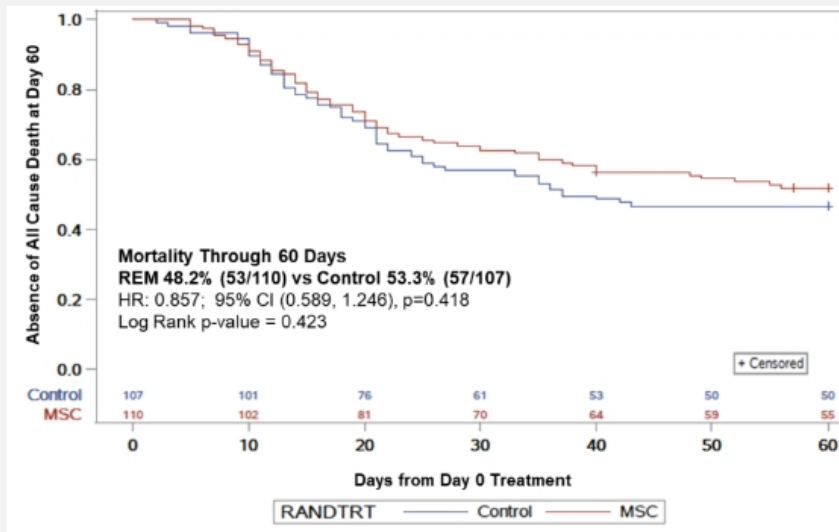
Greater Mortality through Day 60 in Control Patients Older than 65, Consistent with other Trials



Remestemcel-L vs Controls with COVID-19 ARDS: Mortality through 60 Days in Treated Patients



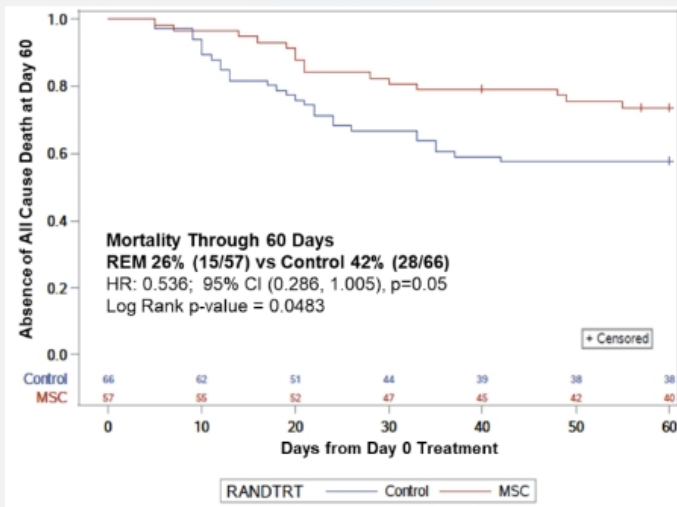
All Modified Intent to Treat Patients (n=217), REM vs Control



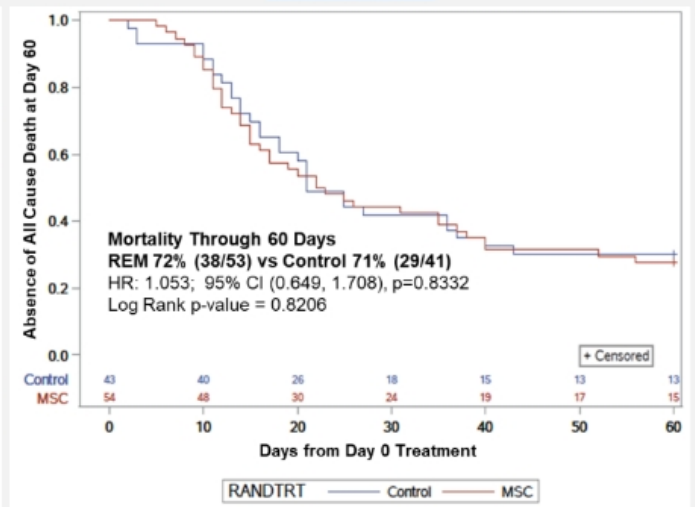
Remestemcel-L vs Controls: Pre-Specified Mortality Analysis through 60 Days < or ≥ 65 Years Old



Modified Intent to Treat Patients < 65 years old (n=123)
REM vs Control

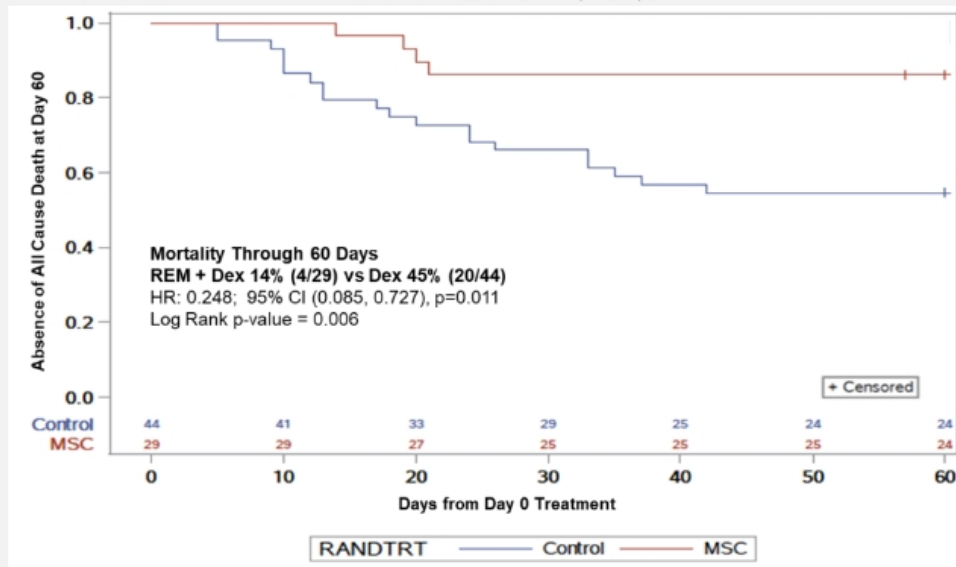


Modified Intent to Treat Patients ≥ 65 years old (n=94)
REM vs Control



Remestemcel-L plus Dexamethasone Synergistic in Reducing Mortality in Exploratory Population < 65 years old

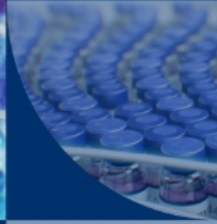
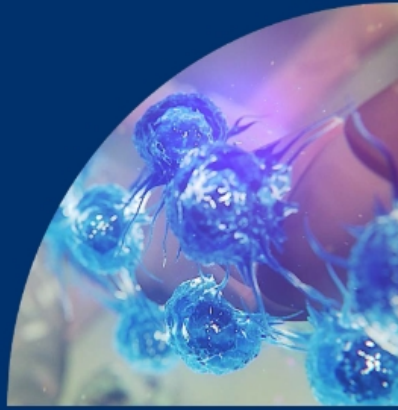
All Treated Patients < 65 years old
on Dexamethasone (n=73)



Conclusions and Next Steps for Remestemcel-L in ARDS Due to COVID-19



- Remestemcel-L did not significantly reduce overall mortality
- Remestemcel-L reduced mortality and increased ventilator-free days through 60 Days in pre-specified patient population < 65 years old
- Addition of remestemcel-L to dexamethasone was synergistic in reducing mortality and increasing days alive off ventilator through 60 Days in exploratory analysis of patients < 65
- Plan to meet with U.S. Food and Drug Administration (FDA) to discuss potential next steps
- Confirmatory Phase 3 trial in COVID-19 ARDS patients < 65 years of age with dexamethasone, explore additional remestemcel-L dosing regimens for patients with ARDS ≥ 65 years of age



Rexlemestrocel-L in Cardiac Disease:
DREAM HF Phase 3 Trial



ASX
Nasdaq



Chronic Heart Failure: Rising Incidence & High Mortality

- Cardiovascular disease (CVD) remains the leading cause of death in the United States¹
- Heart failure affects 6.5 million patients in the US and 26 million patients globally. As populations age, the prevalence is increasing²
- Chronic heart failure is a progressive disease with a high mortality that approaches 50% at 5 years^{2,3}, and at least 75% after an initial hospitalization⁴
- Patients with heart failure are also at high risk of recurrent major adverse cardiac events involving large vessels (heart attacks / strokes)

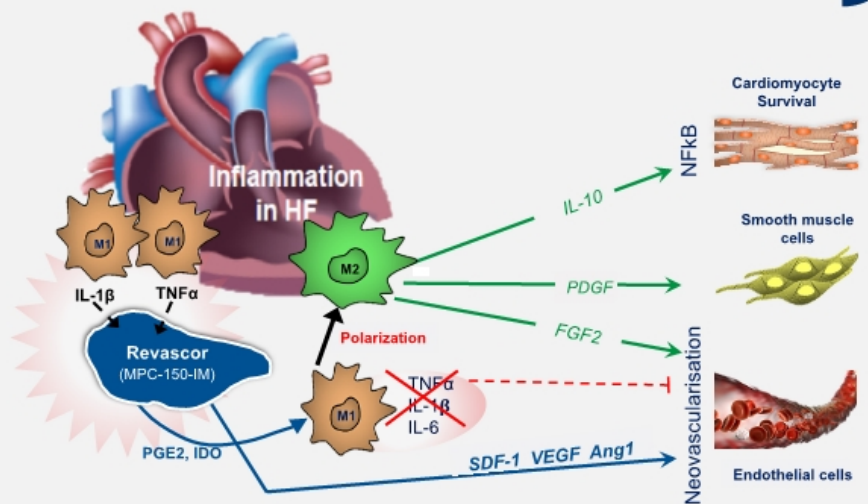
New therapies for chronic heart failure reduce recurrent hospitalizations due to cardiac decompensation, however they do not materially improve cardiac mortality or major ischemic events (heart attacks/strokes)

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

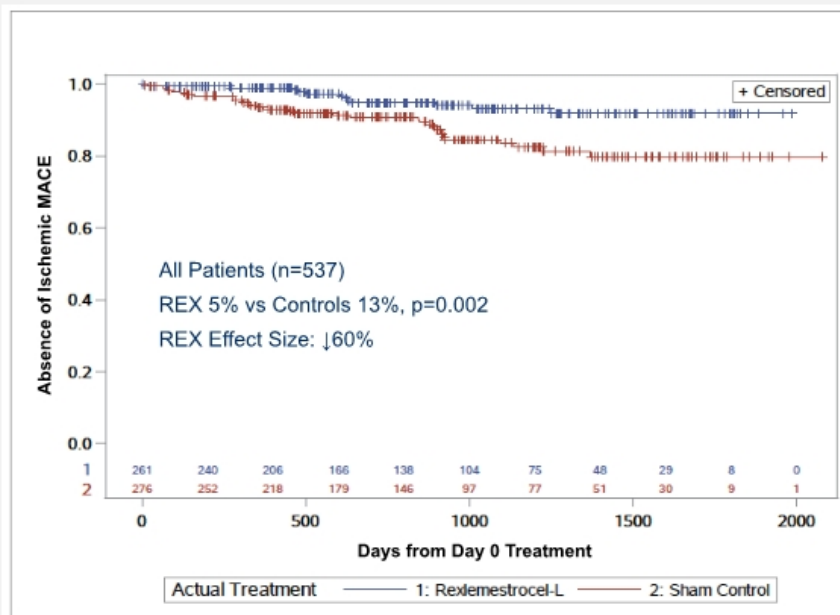
Mesenchymal precursor cells (MPC) key mechanisms of action thought to beneficially impact the heart and the systemic vasculature:

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

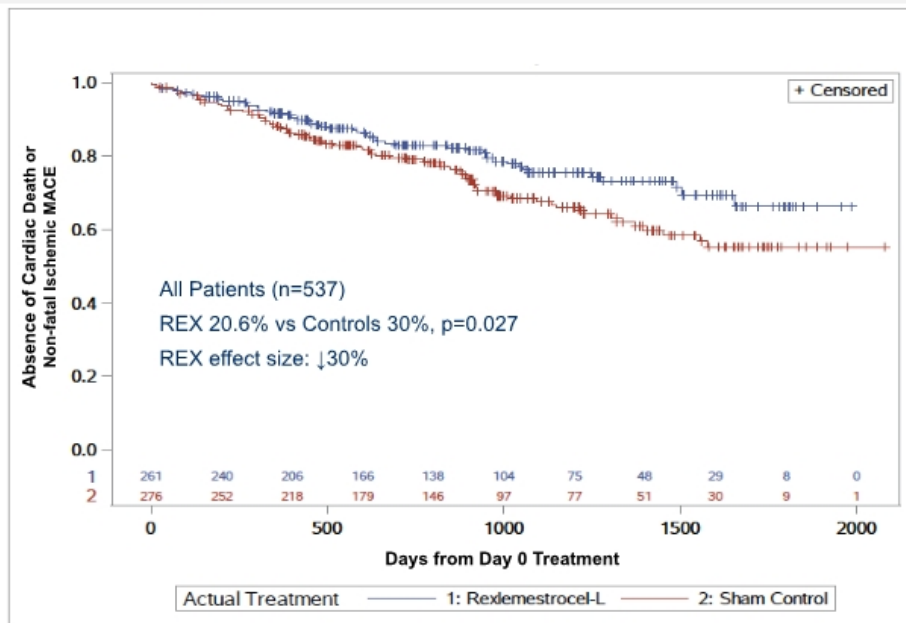


Borow KM, Yaroshinsky A, Greenberg B, Perin E. Phase 3 DREAM-HF Trial of Mesenchymal Precursor Cells in Chronic Heart Failure: A Review of Biological Plausibility and Implementation of Flexible Clinical Trial Design. *Circ Res.* 2019;125:265-281

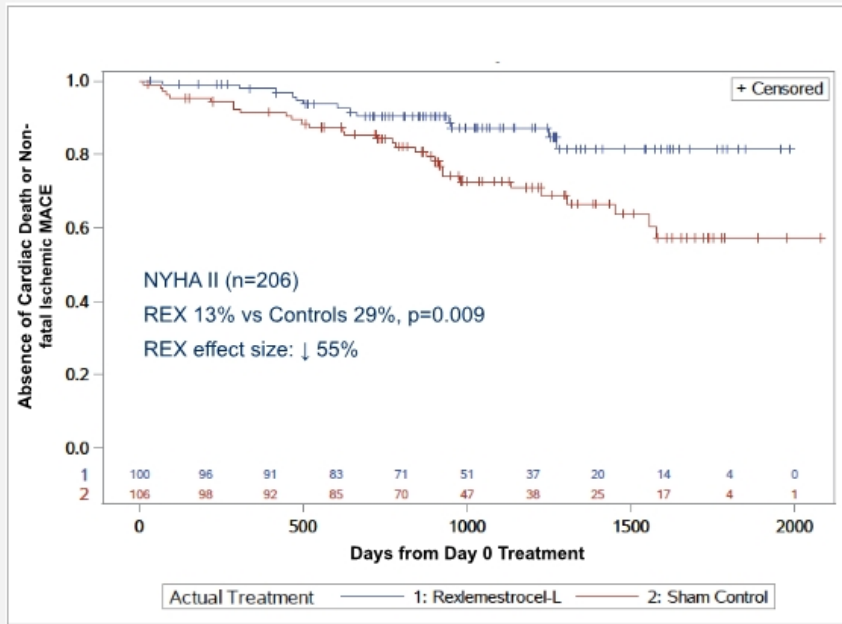
Ischemic MACE: Rexlemestrocel-L Significantly Reduced Incidence of MI & Stroke by 60% Relative to Controls (n=537 Patients)



3P-MACE: Rilexestrocel-L Significantly Reduced Composite of Cardiac Death, MI or Stroke Compared to Controls Across All 537 Patients

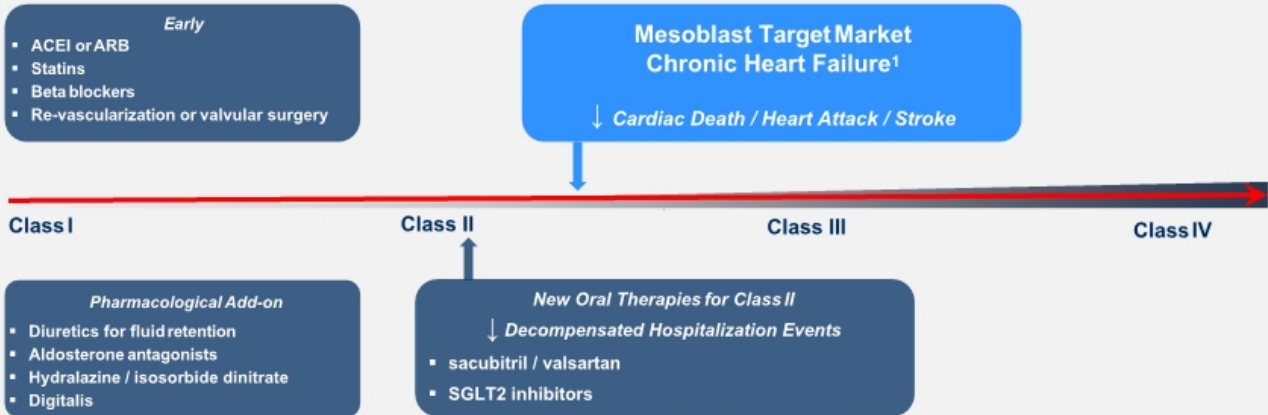


3P-MACE: Rylemestrocel-L Significantly Reduced Composite of Cardiac Death, MI or Stroke by 55% in 206 NYHA Class II Patients

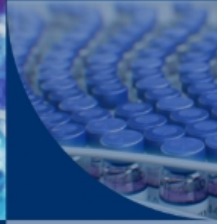
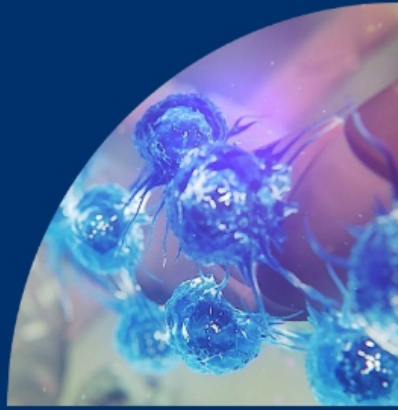


Treatment Algorithm in Progressive Heart Failure

Progressive Vascular (Endothelial) Dysfunction and Heart Failure



1. GlobalData-PharmaPoint Heart Failure (2016); McMurray et al., 2012; Yancy et al., 2013, 2016 ACC/AHA/HFSA Focused Update on New Pharmacological Therapy for Heart Failure: An Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure.



Rexlemestrocel-L in Chronic Low
Back Pain: Phase 3 Trial

ASX
NASDAQ



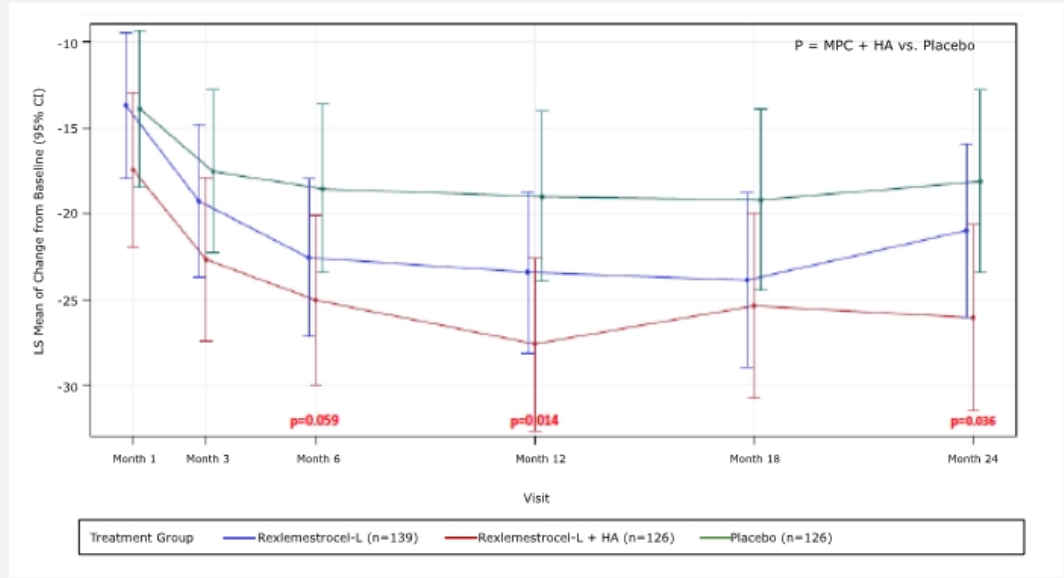
Single Injection of Rexlemestrocel-L + HA in Phase 3 Trial Results in at Least 2 Years of Pain Reduction with Opioid Sparing Activity in Patients with CLBP



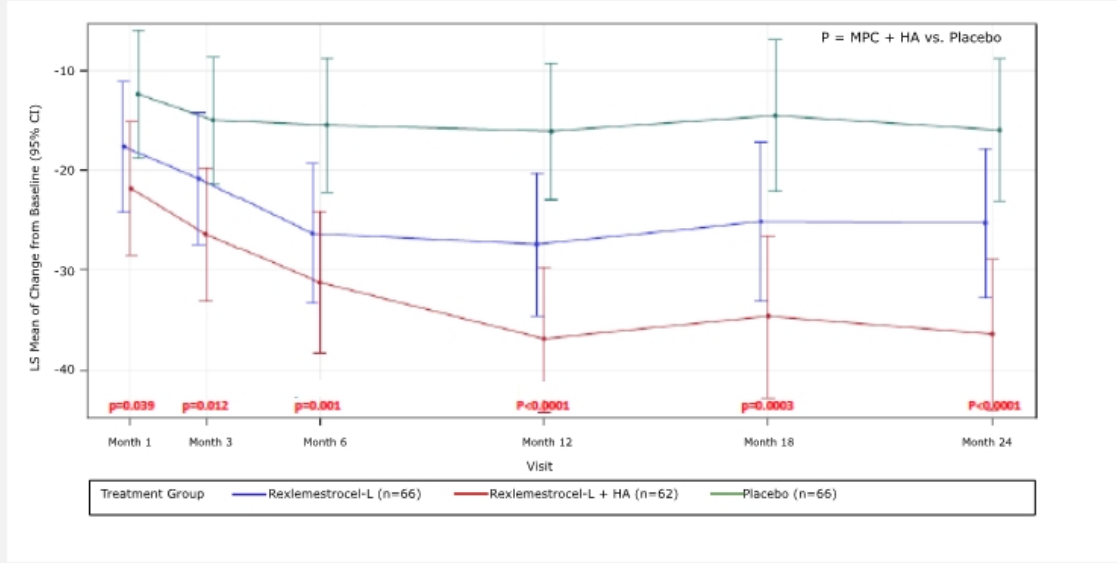
- Achievement of significant and durable reductions in CLBP through 24 months across the entire evaluable study population (n=391) compared with saline controls
- Greatest pain reduction observed in the pre-specified population with CLBP of shorter duration than the study median of 68 months (n=194), significantly greater reduction at all time points (1, 3, 6, 12, 18 and 24 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 24 months there was a 40% reduction in opioid use

Rexlemestrocel-L may provide a safe, durable, and effective opioid-sparing therapy for patients with chronic inflammatory back pain due to degenerative disc disease, and that greatest benefits are seen when administered earlier in the disease process

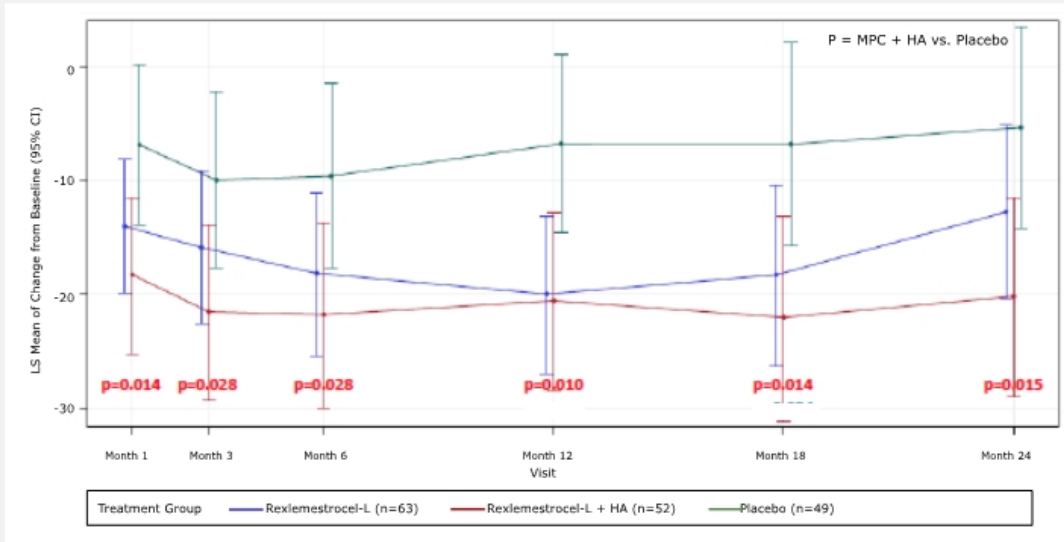
LS Mean VAS Low Back Pain Change from Baseline VAS of 60.4 - Entire Study (n=391)



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



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



Key initiatives and Upcoming Milestones for the Next Two Quarters

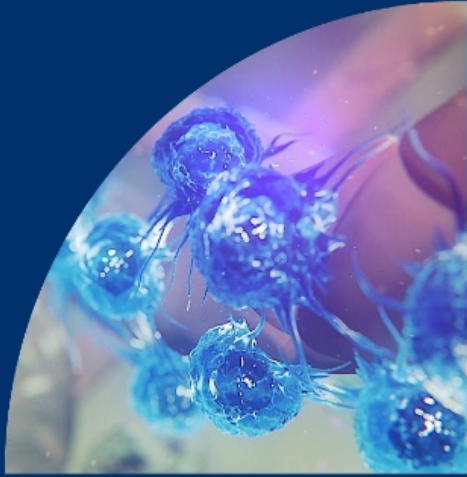


Remestemcel-L

- In the treatment of SR-GVHD in children, Mesoblast plans to discuss with CBER's review team at the OTAT our approach to address certain outstanding CMC items, including potency assay validation
- In the regulatory pathway for remestemcel-L in patients with COVID-19 ARDS, Mesoblast intends to meet with FDA to discuss potential next steps based on the observed reduction in mortality in patients under 65 years in the recent trial
- The license and collaboration agreement between Mesoblast and Novartis for the development, manufacture, and commercialization of remestemcel-L, with an initial focus on the development of the treatment of ARDS, remains subject to certain closing conditions, including time during this period to analyze the results from the COVID-19 ARDS trial

Rexlemestrocel-L

- Mesoblast intends to meet with FDA and EMA to discuss a potential pathway for approval of rexlemestrocel-L in patients with chronic discogenic lower back pain based on the Phase 3 trial results
- Mesoblast intends to meet with FDA to discuss potential next steps in the regulatory pathway for rexlemestrocel-L in patients with chronic heart failure based on the observed reduction in mortality and morbidity in the chronic heart failure Phase 3 trial



mesoblast
the regenerative medicine company



ASX
NASDAQ

