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 July 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 July 16, 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.

On July 16, 2021, Mesoblast Limited submitted a Change in Director's Interest Notice form to the Australian Securities Exchange, copy of which is attached to this report as Exhibit 99.3.

On July 19, 2021, Mesoblast Limited filed with the Australian Securities Exchange a new release announcement, which is attached hereto as Exhibit 99.4, and is incorporated herein by reference.

INDEX TO EXHIBITS

Item	
99.1	Press release of Mesoblast Ltd, dated July 16, 2021.
99.2	Investor presentation of Mesoblast Ltd, dated July 16, 2021.
99.3	Appendix 3Y of Mesoblast Ltd, dated July 16, 2021.
99.4	Press release of Mesoblast Ltd, dated July 19, 2021.

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: July 21, 2021

asx announcement

mesoblast
the regenerative medicine company

MESOBLAST PRESENTS RESPIRATORY FUNCTION RESULTS OF COVID-19 ARDS TRIAL AT PULMONARY DISEASE CONFERENCE

Melbourne, Australia; July 16 and New York, USA; July 15, 2021: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today presented clinical outcomes from the randomized controlled trial of remestemcel-L in ventilator-dependent COVID-19 patients with moderate/severe acute respiratory distress syndrome (ARDS). Results of respiratory function were highlighted at the biennial Stem Cells, Cell Therapies, and Bioengineering in Lung Biology and Diseases conference hosted by the University of Vermont, Burlington, VT, on July 15. The invited presentation was given by Mesoblast Chief Executive Officer, Dr Silviu Itescu, and materials have been lodged with the ASX.

The trial in mechanically ventilated COVID-19 patients with moderate/severe ARDS enrolled 222 patients across the United States, 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. As previously announced, while the trial did not meet its endpoint of 43% reduction in overall mortality, mortality was reduced through 60 days in the pre-specified subgroup analysis of 123 patients younger than 65, but not in those older than 65 where a more exuberant inflammatory response due to defective immune-mediated viral clearance mechanisms may require more prolonged or higher dosing of anti-inflammatory therapy. The mortality benefit in patients under 65 was even greater when remestemcel-L was used in addition to dexamethasone as standard of care.

Key secondary outcome results that were presented included:

- In patients under 65 years old, remestemcel-L improved respiratory function, as defined in pre-specified analyses by resolution or improvement in ARDS using the Berlin Criteria, at each of days 7, 14, 21, and 30 post-randomization, with Odds Ratio (OR) at Day 30 relative to controls of 2.2, 95% CI (1.0, 4.7)[1]
- In patients older than 65 years old, remestemcel-L improved respiratory function at day 7 relative to controls, but not at later time points, supporting the conclusion that more prolonged or higher dosing may be warranted in those over age 65 with COVID-19 ARDS
- Remestemcel-L improved respiratory function to an even greater extent in patients under 65 who received dexamethasone as part of their standard of care at each of days 7, 14, 21, and 30 post-randomization, with OR at Day 30 relative to controls on Dexamethasone alone of 3.6, 95% CI (1.2, 10.7)[1]
- Remestemcel-L also improved clinical outcomes based on a 7-point ordinal scale in patients under 65 who received dexamethasone as part of their standard of care at each of days 7, 14, 21, and 30 post-randomization, with OR at Day 30 relative to controls on Dexamethasone alone of 2.9, 95% CI (1.1, 7.7)[1]

Mesoblast 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 this COVID-19 ARDS trial.

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 rexlemestrocel-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

Footnotes

1. Treatment groups were compared using a mixed effect logistic regression model with patient as a random effect using all available data. Intermittent missing data assumed to be missing at random

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. All statements other than statements of historical fact, including our intention to discuss potential next steps with the FDA, are forward-looking statements, which are often indicated by terms such as "anticipate," "believe," "could," "estimate," "expect," "goal," "intend," "likely," "look forward to," "may," "plan," "potential," "predict," "project," "should," "will," "would" and similar expressions and variations thereof. 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. The risks, uncertainties and other factors that may impact our forward-looking statements include, but are not limited to: the timing, progress and results of Mesoblast's preclinical and clinical studies; Mesoblast's ability to advance product candidates into, enroll and successfully complete, clinical studies; the timing or likelihood of regulatory filings and approvals; whether the FDA agrees to a path forward; and the pricing and reimbursement of Mesoblast's product candidates, if approved; 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. 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. Unless required by law, we do not undertake any obligations to publicly update or revise any forward-looking statements, whether as a result of new information, future developments or otherwise.

Release authorized by the Chief Executive.

For more information, please contact:

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

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

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

Mesoblast Limited
ABN 68 109 431 870

www.mesoblast.com

Corporate Headquarters
Level 38
55 Collins Street
Melbourne 3000
Victoria Australia

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

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

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

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

T +65 6570 0635
F +65 6570 0176

Exhibit 99.2

mesoblast
the regenerative medicine company

Top-line Results for Remestemcel-L in COVID-19 ARDS

2021 Stem Cells, Cell Therapies, and Bioengineering in Lung Biology and Diseases

JULY 2021

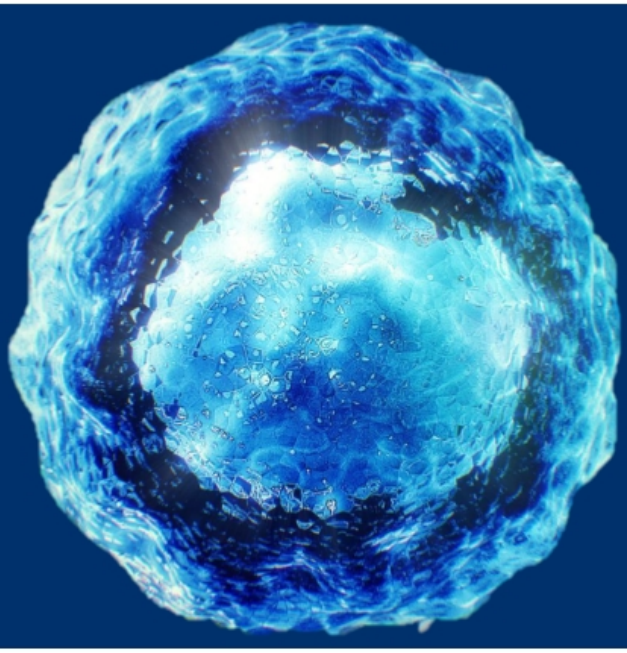
ASX: MSB; Nasdaq: MESO

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.

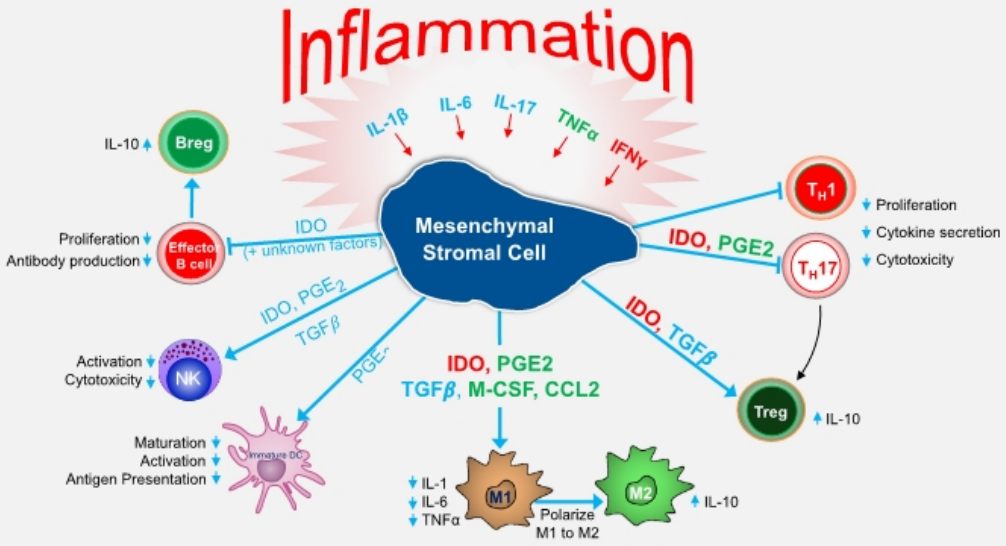
Our Mission

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



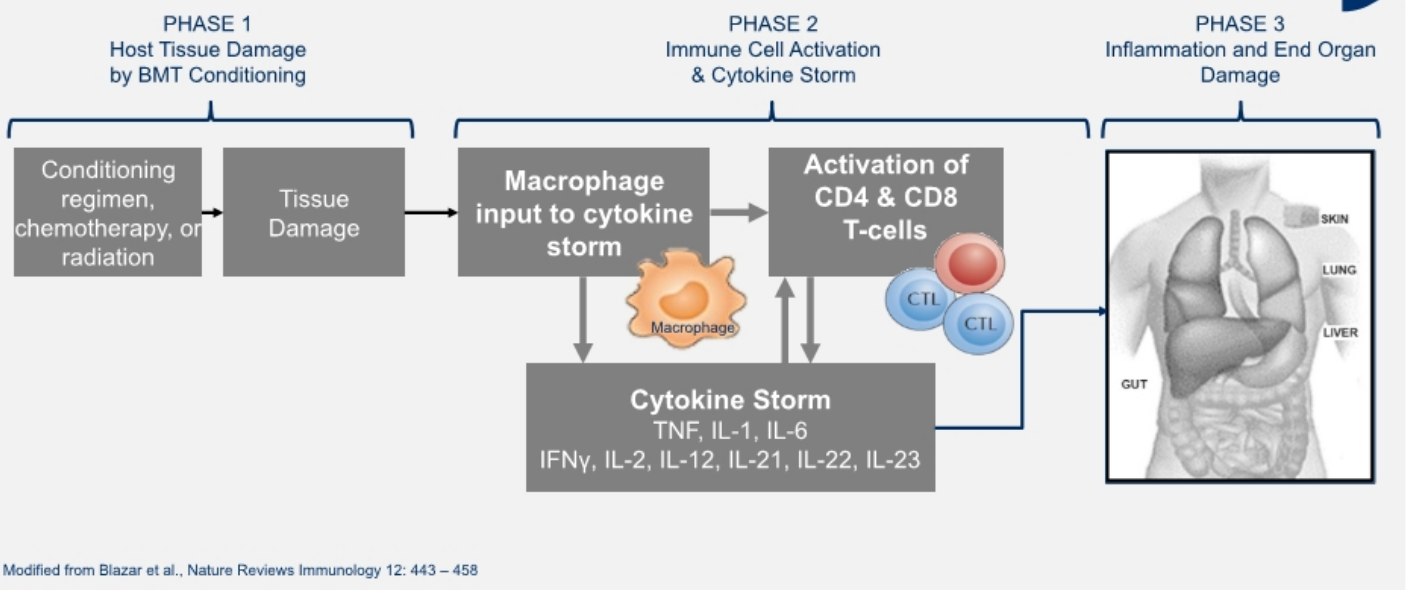
Platform Technology – Mechanism of Action (MOA)

Our mesenchymal 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

Acute Graft versus Host Disease (GVHD): A Prototypic Disease Driven by Cytokine Storm



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

Remestemcel-L in Steroid Refractory Acute GVHD: Clinical Evidence for a MOA Applicable to Various Inflammatory Conditions

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

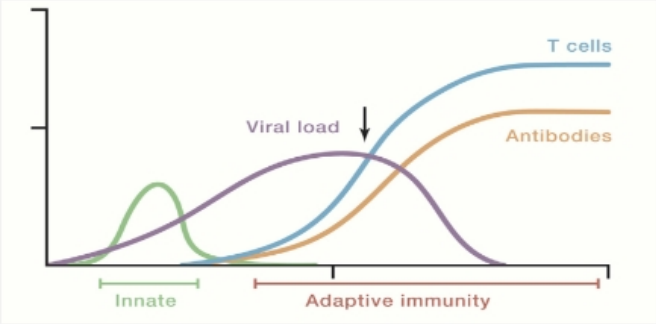
Cytokine Storm in COVID-19 ARDS Closely Resembles Secondary Hemophagocytic Lymphohistiocytosis (sHLH): A T Cell Driven Disease

- Secondary (or acquired) hemophagocytic lymphohistiocytosis (sHLH) is a life-threatening disease characterized by lymphocyte and macrophage hyperinflammation triggered by viral infections such as EBV, CMV, HHV)[1]
- Lung involvement including ARDS is common and of poor prognosis (>50% mortality)[2]
- Hematological manifestations involve severe anemia due to activated macrophages engulfing red blood cells.
- Excessive immune activation driven by cytotoxic T cells and macrophages resulting in cytokine storm and release of IFN-

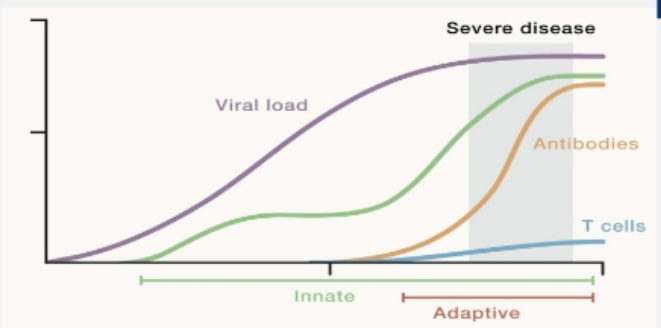
1. Bode et al. Recent advances in the diagnosis and treatment of hemophagocytic lymphohistiocytosis. *Arthritis Res Ther*. 2012 Jun 8;14(3):213
2. Seguin et al. Pulmonary Involvement in Patients With Hemophagocytic Lymphohistiocytosis. *Chest*. 2016 May;149(5):1294-301
3. Humblet-Baron et al. IFN-γ and CD25 drive distinct pathological features during hemophagocytic lymphohistiocytosis. *J Allergy Clin Immunol*. 2019 Jun; 143(6): 2215–2226.e7

Robust Adaptive *Naïve* T Cell Response in COVID-19 is Critical for Viral Clearance
Lack of Adequate T Cell Response Results in Increased Viral Load and Severe Disease

Average SARS2 infection



Severe SARS2 infection



- Analysis of SARS-CoV-2-specific adaptive immune responses during acute COVID-19 identifies coordination between SARS-CoV-2-specific CD4 T cells and CD8 T cells to limit disease severity
- Aged individuals often exhibit uncoordinated adaptive responses, potentially tied to scarcity of naive T cells highlighting immunologic risk factors linked to 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
Sette A and Crotty S. Adaptive immunity to SARS-CoV-2 and COVID19.https://doi.org/10.1016/j.cell.2021.01.007

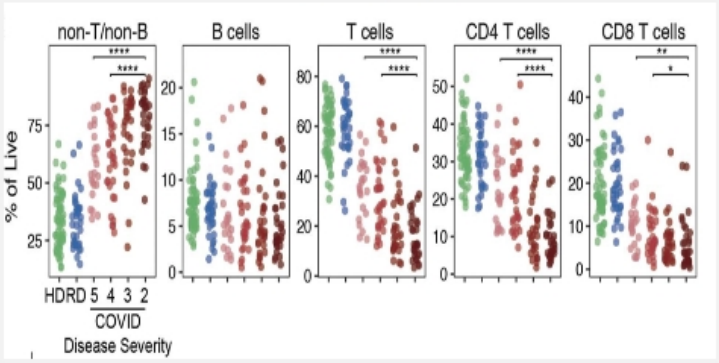
Severe COVID-19 Disease is Associated with Progressive **Depletion** of *Naïve* T Cells, and Aberrant **Activation** of *Non-Naïve* CD4 and CD8 T Cells

Death	COVID 1	Death
	COVID 2	Invasive mechanical ventilation
	COVID 3	Non-invasive ventilation
	COVID 4	Supplemental Oxygen
	COVID 5	No supplemental Oxygen; Requires medical care
	COVID 6	No supplemental Oxygen; No medical care
	COVID 7	Limitation in activities and/or requiring Oxygen
Mild	COVID 8	No limitation in activities

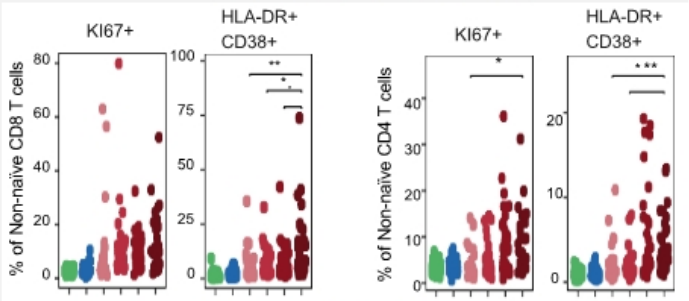
Hospitalization

Based off NIH Ordinal Scale

Naïve T Cells



Non-Naïve Activated T Cells



Frequencies of activated CD8 or CD4 T cells, shown as percent of non-naïve CD8 and CD4 T cells expressing KI67⁺ and HLA-DR⁺CD38⁺

D. Mathew et al., Deep immune profiling of COVID-19 patients reveals distinct immunotypes with therapeutic implications Science 369, eabc8511 (2020). DOI:10.1126/science.abc8511

Severity of COVID-19 Infection is Associated with Increased Activated T Cells Producing IFN-γ and GM-CSF

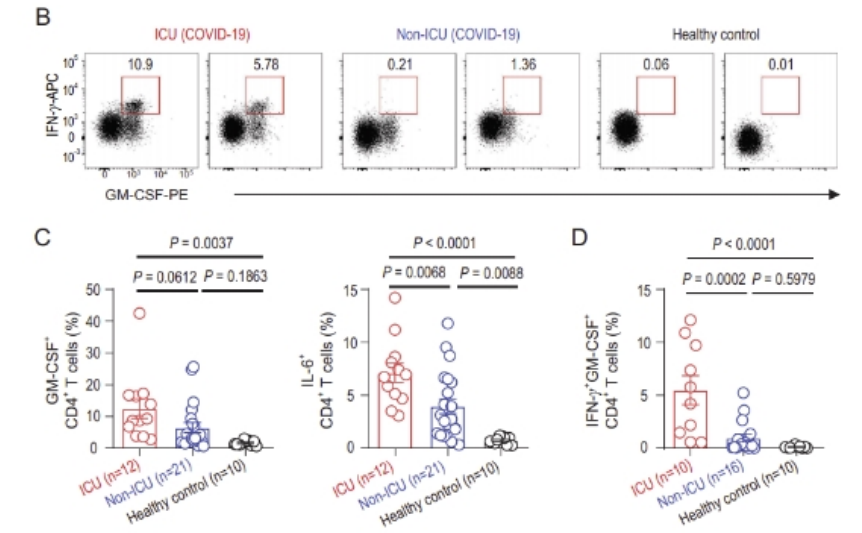


Figure: Pathogenic Th1 cells with high expression of GM-CSF in COVID-19 patients.

(B) Representative density plots showing an analysis of co-expression of GM-CSF and IFN-γ in gated CD45+CD3+CD4+ T-cells isolated from peripheral blood in healthy controls, ICU and non -ICU patients of COVID-19.

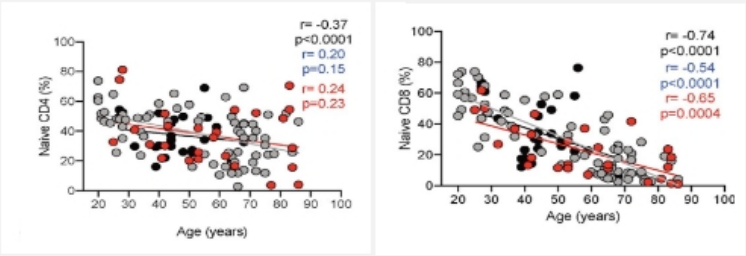
(C) Statistics calculated by the percentage of GM -CSF+ or IL-6+ cells from CD4+ T-cells.

(D) Statistics calculated by the percentage of GM-CSF+ and IFN-γ + co-expressing CD4+ T-cells. Data represent the mean ± SEM. One-way ANOVA. P < 0.05 was considered statistically significant.

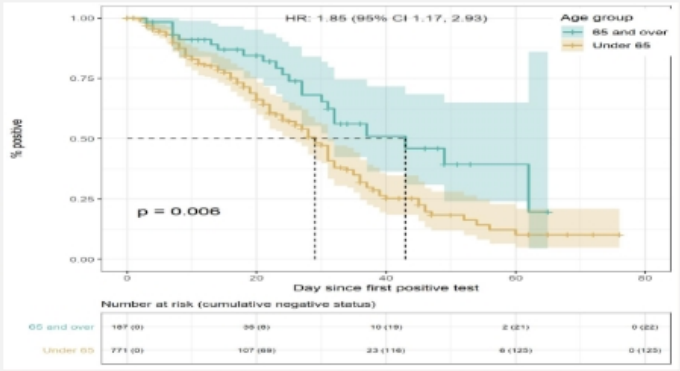
Zhou Y, et al. Pathogenic T cells and inflammatory monocytes incite inflammatory storm in severe COVID-19 patients. Natl Sci Rev. 2020;nwaa041

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

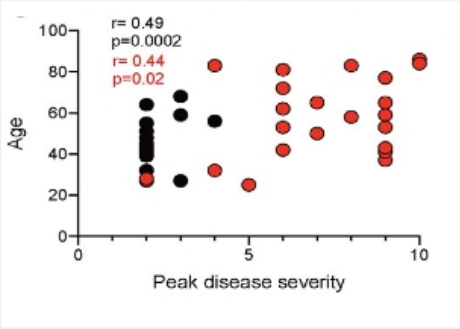
Naïve CD4 and CD8 T Cells reduced in age > 65



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

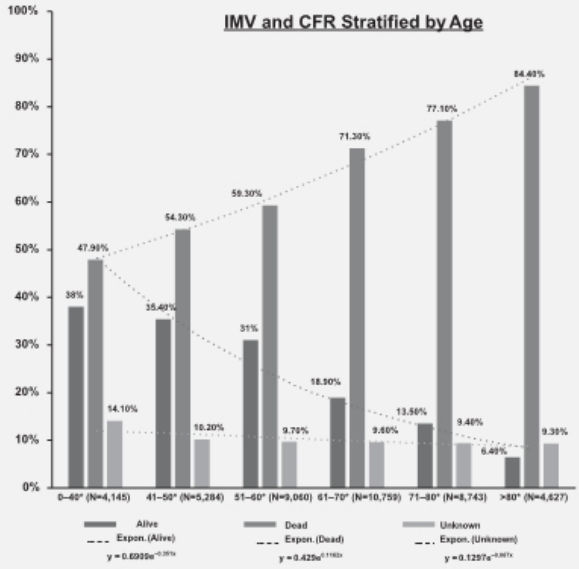


Rydyznski Moderbacher et al., Antigen-Specific Adaptive Immunity to SARS-CoV-2 in Acute COVID-19 and Associations with Age and Disease Severity. 2020, Cell 183, 996–1012; doi.org/10.1016/j.cell.2020.09.038
Stehlik P et al. Repeat testing for SARS-CoV-2: persistence of viral RNA is common, and clearance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

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.

Objectives of Immunomodulation with Remestemcel-L in COVID ARDS

MSCs have the potential to:

- Reduce activated *non-naïve* CD4 and CD8 T cells
- Reduce inflammatory cytokines produced by *non-naive* T cells to reduce macrophage and neutrophil influx, activation and cytokine storm
- Expand and enhance survival of *naïve* CD4 and CD8 T cells to accelerate viral clearance
- Improve pulmonary epithelial integrity

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 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

Baseline Summary Data: Intent to Treat Patients Pre-Specified Age < 65 & ≥ 65

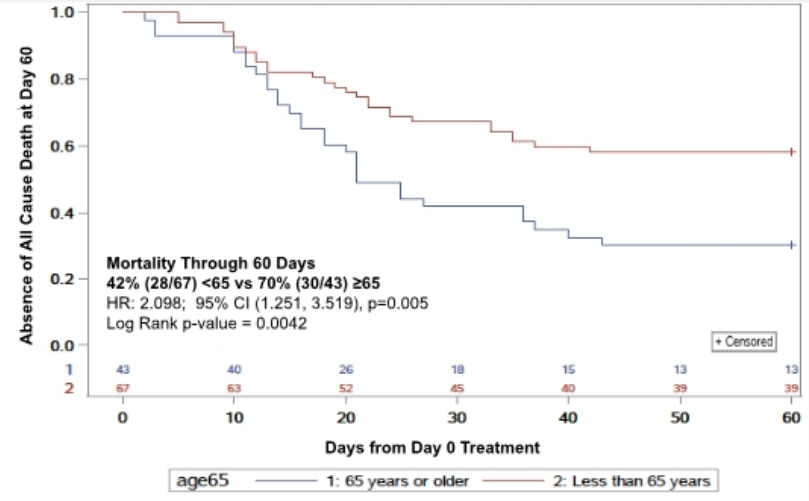
Category	ITT Patients < 65 years		ITT Patients ≥ 65 years	
	REM Mean n=58	Control Mean n=67	REM Mean n=54	Control Mean n=43
Sex (%) Male Female	 76% 24%	 70% 30%	 65% 35%	 65% 35%
Age (Yrs)	**52 (9.9)**	**51 (9.8)**	**72 (5.7)**	**73 (5.5)**
BMI (kg/m^2)	34.1 (7.7)	36.6 (8.2)	32 (7)	32(6)
CRP (mg/L)	29.8 (58.8)	19.5 (17.5)	17.2 (27.8)	26.4 (51.9)
PF Ratio **ARDS Severity (mild, moderate, severe)**	**163 (79)** **17.%, 48%, 24%** **(11% missing or no ARDS)**	**144 (85)** **9.%, 48%, 37%** **(6% missing or no ARDS)**	**132 (50)** **13.%, 57%, 28%** **(2% missing or no ARDS)**	**150 (54)** **14%, 67%, 14%** **(5% missing or no ARDS)**
SOFA Score	6.3 (2.4)	6.6 (1.8)	6.3 (2)	6.4 (1.9)
Any Steroids at Baseline Dexamethasone at Baseline	67% 50%	84% 67%	98% 78%	93% 67%
Remdesivir at Baseline	62%	63%	72%	74%
Anti-IL6 at Baseline	3%	4%	7%	5%

Baseline Summary Data: Increased Co-Morbid Conditions in Patients ≥ 65

All Patients - ITT	ITT Patients < 65 years		ITT Patients ≥ 65 years		< 65 vs ≥ 65
	REM Mean n=58	Control Mean n=67	REM Mean n=54	Control Mean n=43	Chi-Squared P-Value
Medical History					
COPD	2%	1%	13%	12%	0.0004
Asthma	10%	10%	6%	9%	
Pulmonary Fibrosis.	0%	0%	4%	0%	
CF	0%	0%	0%	0%	
MI last 12 months	0%	0%	2%	2%	
CHF	2%	6%	9%	0%	
Cancer	3%	4%	19%	19%	0.0002
Renal Disease	7%	7%	19%	19%	0.0047
Immunological Disorder	3%	3%	4%	2%	
Smoker	27%	27%	43%	37%	0.0464
Hepatic	7%	0%	0%	12%	
Diabetes	45%	36%	39%	42%	
Hypertension	50%	49%	67%	70%	0.0069
Neurological	5%	1%	13%	7%	0.0074

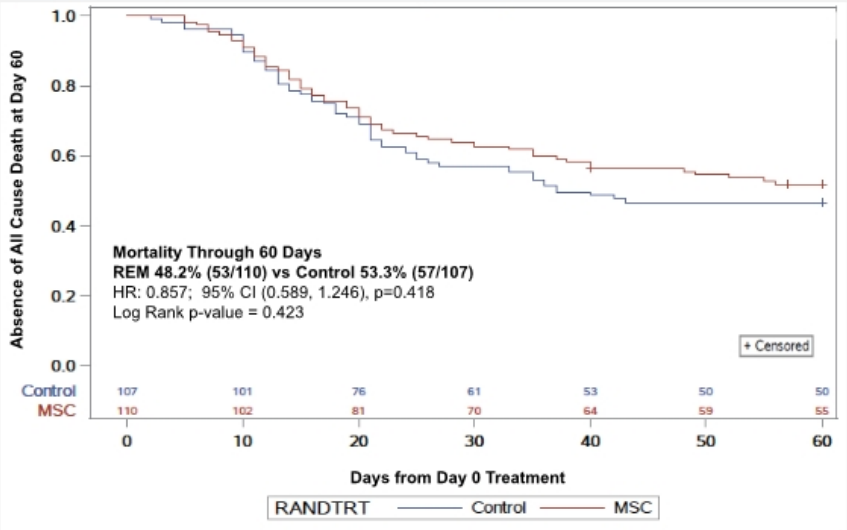
Greater Mortality through Day 60 in Control Patients Older than 65, Consistent with Other Trials

Controls Age < 65 vs ≥ 65 (n=110)



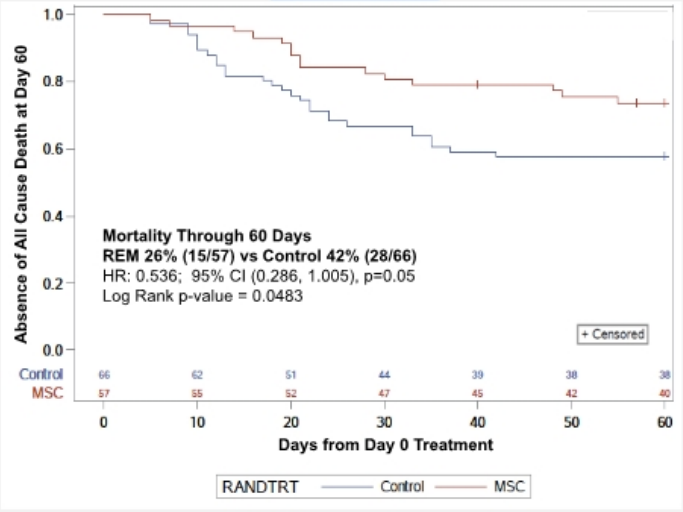
Remestemcel-L vs Controls with COVID-19 ARDS: Mortality through 60 Days in Treated Patients

All **Modified Intent to Treat** Patients (n=217), Remestemcel-L vs Control

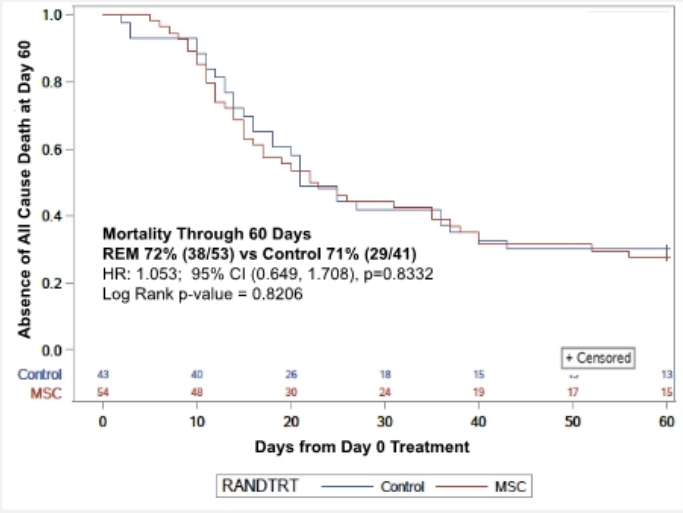


Remestemcel-L vs Controls:
Pre-Specified Mortality Analysis through 60 Days < or ≥ 65 Years Old

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

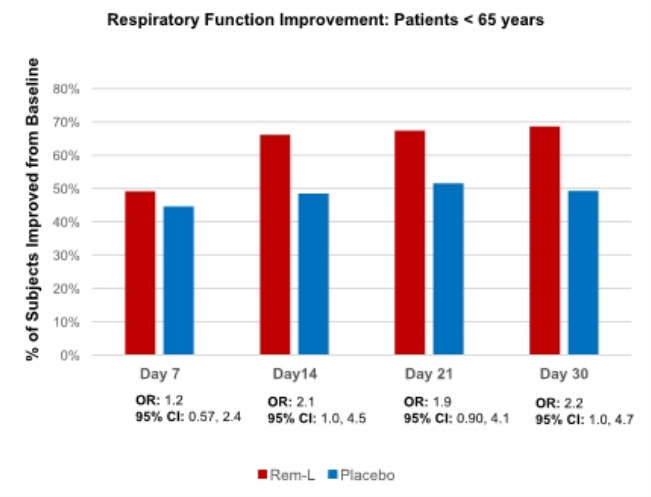


Modified Intent to Treat Patients **≥ 65 years old** (n=94)
REM vs Control

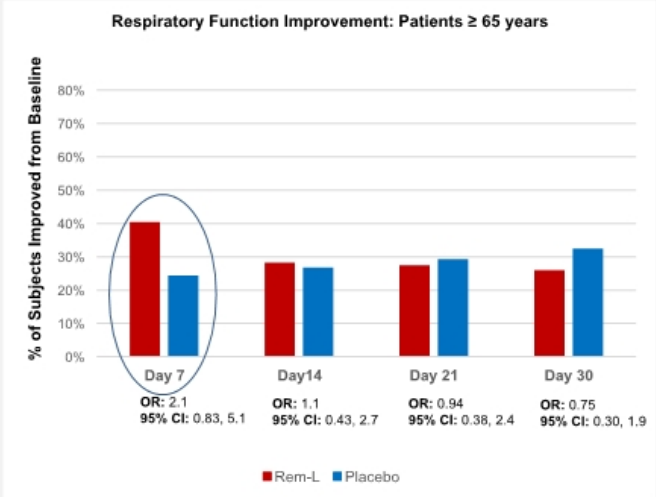


Remestemcel-L vs Controls: Analysis of Respiratory Function Improvement*

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

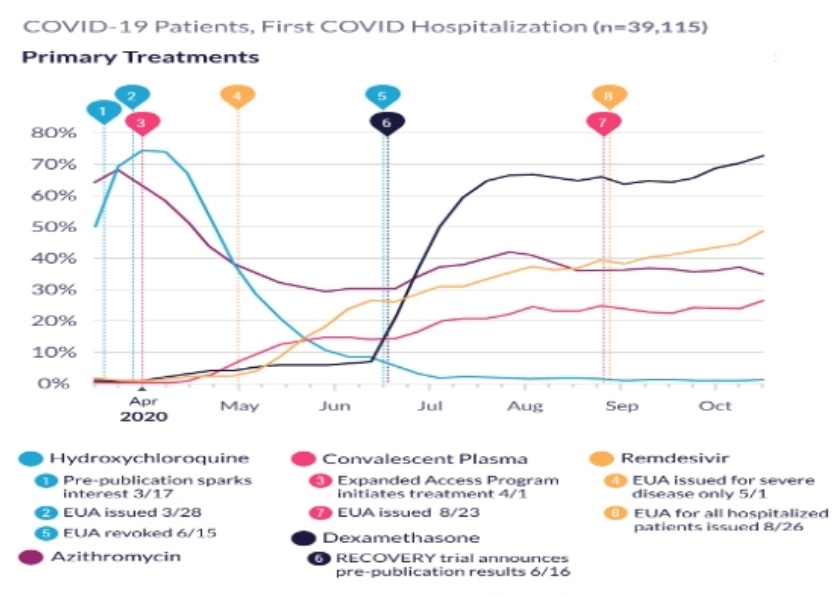


Treated Patients (mITT) **≥ 65 years old** (n=94)
Remestemcel-L vs Control



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

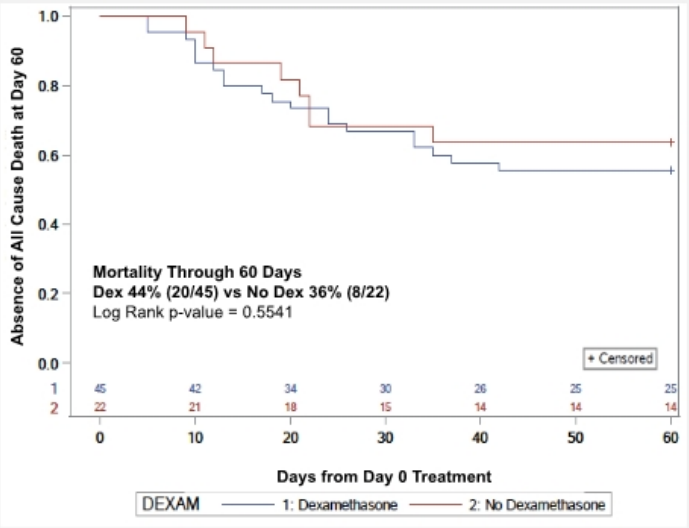
Dynamic Changes in the Treatment Regimes During the Trial



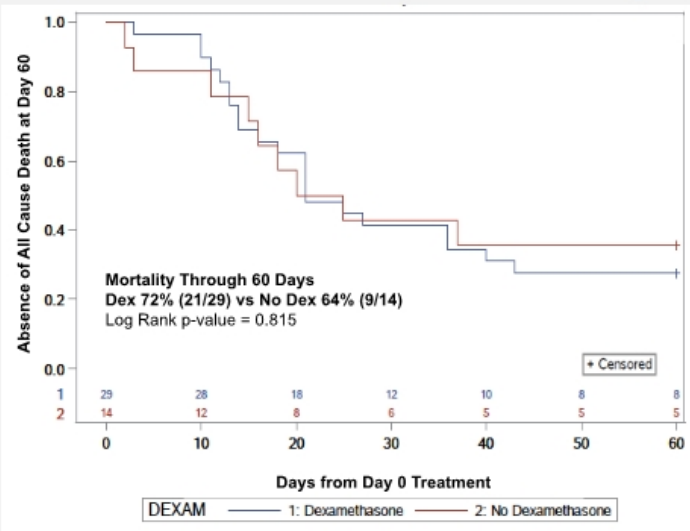
Source: Noel A. et al. Epic Health Research Network. Nov 2020

Dexamethasone did not Reduce Mortality in Controls on Invasive Mechanical Ventilation with Moderate/Severe COVID-19 ARDS

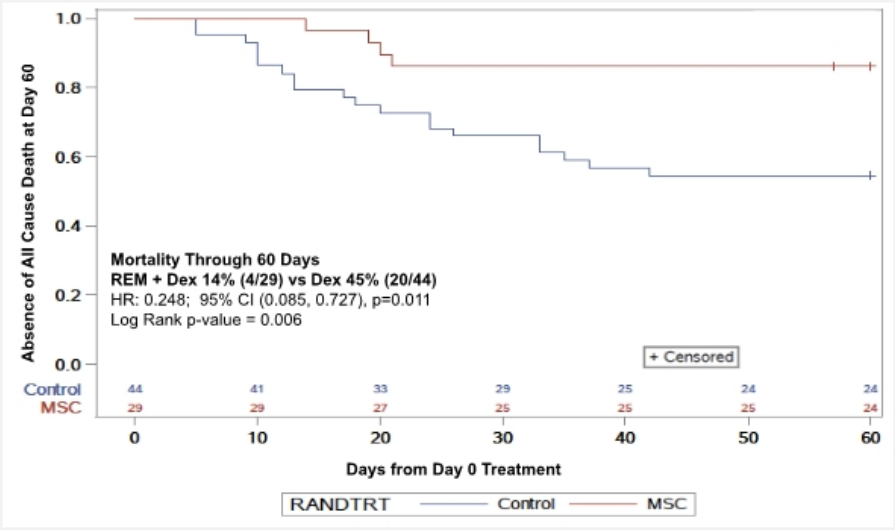
Controls < 65 years old +/- Dexamethasone (ITT n=67)



Controls ≥ 65 years old +/- Dexamethasone (ITT n=43)

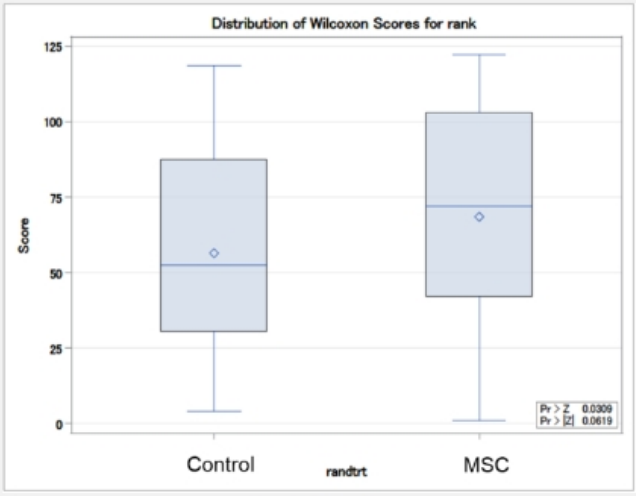


Remestemcel-L plus Dexamethasone:
Synergistic in Reducing Mortality in Exploratory Population < 65 years old



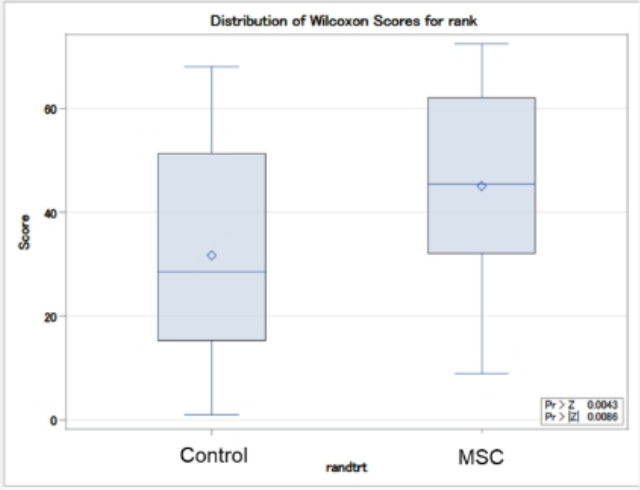
Remestemcel-L Increases Ventilator-Free Days Alive through 60 Days in Patients < 65 years old

All Treated Patients < 65 years old (n=123)



Ventilator-Free Days Alive Through Day 60

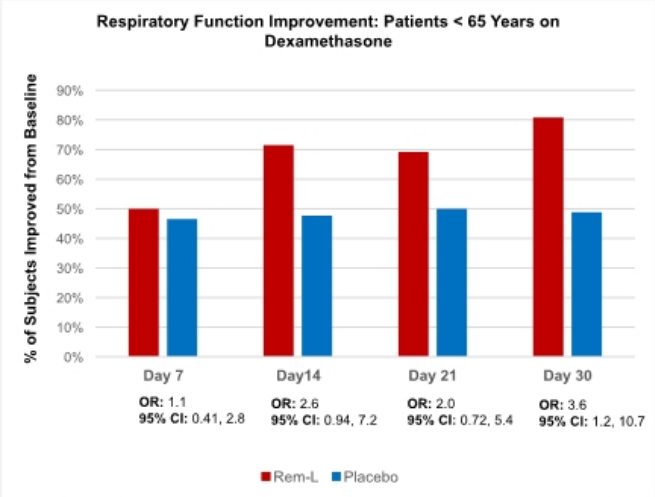
All Treated Patients < 65 years old on Dexamethasone (n=73)



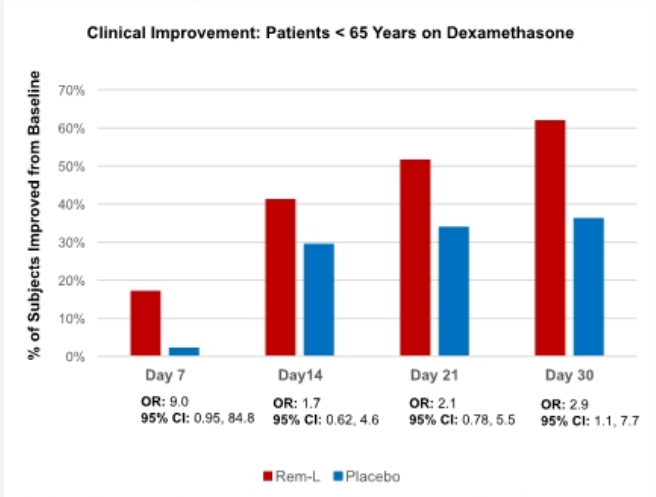
Ventilator-Free Days Alive Through Day 60

Remestemcel-L plus Dexamethasone: Analysis of Respiratory Function and Clinical Improvement* in Exploratory Population < 65 years old

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



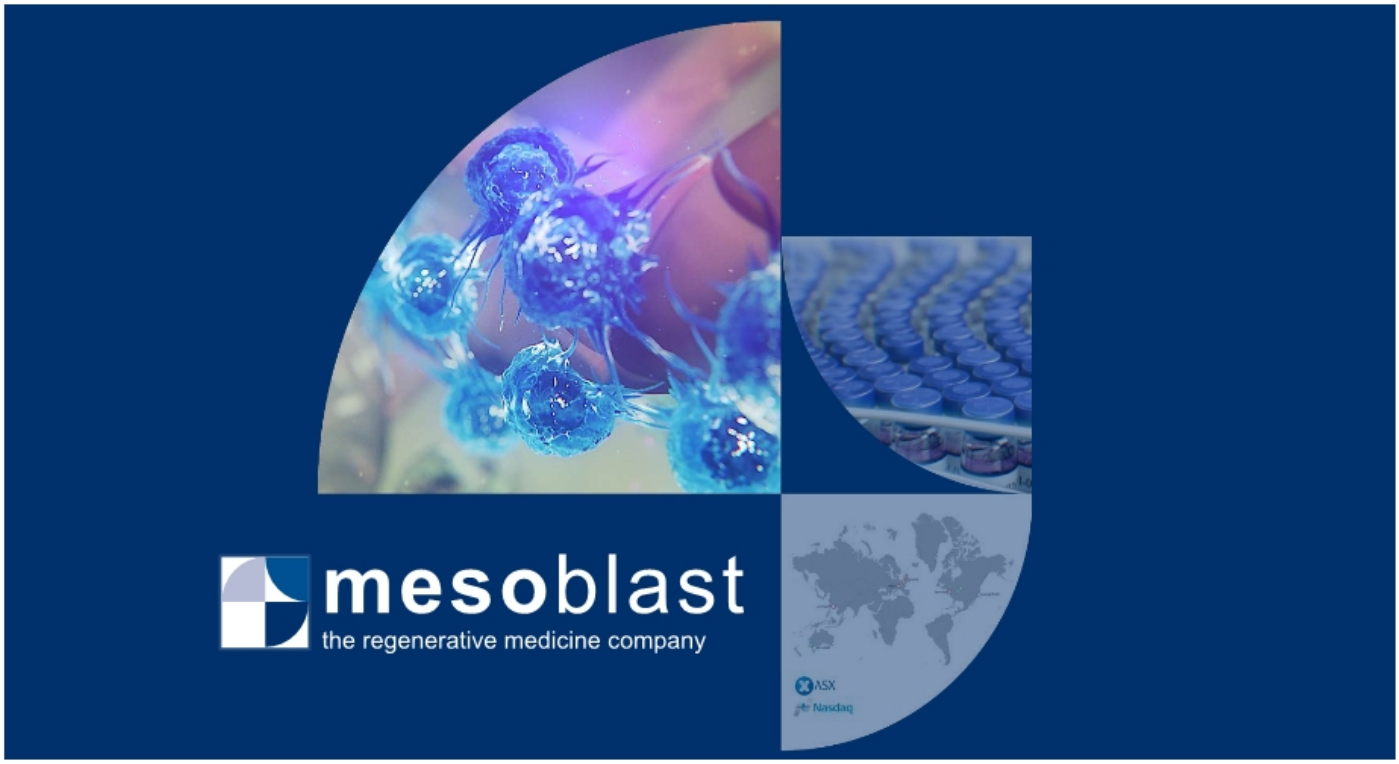
Treated Patients (mITT) **< 65 years old** on Dexamethasone (n=73)



* 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

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


mesoblast
the regenerative medicine company
ASX
Nasdaq

Rule 3.19A.2

Appendix 3Y

Change of Director's Interest Notice

Information or documents not available now must be given to ASX as soon as available. Information and documents given to ASX become ASX's property and may be made public.

Introduced 30/09/01 Amended 01/01/11

Name of entity	**Mesoblast Limited**
ABN	**68 109 431 870**

We (the entity) give ASX the following information under listing rule 3.19A.2 and as agent for the director for the purposes of section 205G of the Corporations Act.

Name of Director	**Silviu Itescu (Chief Executive Officer)**
Date of last notice	**24 June 2020**

Part 1 - Change of director's relevant interests in securities

In the case of a trust, this includes interests in the trust made available by the responsible entity of the trust

Note: In the case of a company, interests which come within paragraph (i) of the definition of "notifiable interest of a director" should be disclosed in this part.

Direct or indirect interest	Direct
Nature of indirect interest (including registered holder) Note: Provide details of the circumstances giving rise to the relevant interest.	Not applicable
Date of change	7 July 2021
No. of securities held prior to change	68,958,928 ordinary shares, held as follows: •Direct: 67,756,838 ordinary shares; and •Indirect: 1,202,090 ordinary shares 1,885,334 options
Class	Options
Number acquired	1,200,000 options issued with approval of shareholders at 2020 AGM
Number disposed	Not applicable
Value/Consideration Note: If consideration is non-cash, provide details and estimated valuation	Nil

+ See chapter 19 for defined terms.

No. of securities held after change	68,958,928 ordinary shares, held as follows: •Direct: 67,756,838 ordinary shares; and •Indirect: 1,202,090 ordinary shares 3,085,334 options
Nature of change Example: on-market trade, off-market trade, exercise of options, issue of securities under dividend reinvestment plan, participation in buy-back	Issue of options with approval by shareholders at the 2020 AGM

Part 2 – Change of director's interests in contracts

Note: In the case of a company, interests which come within paragraph (ii) of the definition of "notifiable interest of a director" should be disclosed in this part.

Detail of contract	Not Applicable
Nature of interest	Not Applicable
Name of registered holder (if issued securities)	Not Applicable
Date of change	Not Applicable
No. and class of securities to which interest related prior to change Note: Details are only required for a contract in relation to which the interest has changed	Not Applicable
Interest acquired	Not Applicable
Interest disposed	Not Applicable
Value/Consideration Note: If consideration is non-cash, provide details and an estimated valuation	Not Applicable
Interest after change	Not Applicable

Part 3 – +Closed period

Were the interests in the securities or contracts detailed above traded during a +closed period where prior written clearance was required?	No

+ See chapter 19 for defined terms.

If so, was prior written clearance provided to allow the trade to proceed during this period?	Not Applicable
If prior written clearance was provided, on what date was this provided?	Not Applicable

+ See chapter 19 for defined terms.

asx announcement

mesoblast
the regenerative medicine company

NINETY DAY SURVIVAL OUTCOMES IN COVID-19 ARDS TRIAL OF REMESTEMCEL-L PRESENTED AT ISCT MEETING ON ADVANCES IN CELL & GENE THERAPIES FOR LUNG DISEASES

Melbourne, Australia and New York, USA; July 19, 2021: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, presented 90-day survival outcomes from the 222-patient randomized controlled trial of remestemcel-L in ventilator-dependent COVID-19 patients with moderate/severe acute respiratory distress syndrome (ARDS) at an invited presentation on July 17 to the International Society for Cell & Gene Therapy (ISCT) Scientific Signatures Series on Cell and Gene Therapies in Lung Diseases and Critical Illnesses. The results showed that two doses of remestemcel-L at days 3-5 conferred durable survival benefit through at least 90 days in the pre-specified subgroup of patients under age 65.

Key presentation findings were:

- Remestemcel-L significantly reduced mortality by 48% at 90 days compared to controls in a pre-specified analysis of 123 treated patients under 65 years old, 26% vs 44%, Hazard Ratio (HR) 0.52, 95% CI (0.277, 0.964), p=0.038.[1,2] This compares favourably with the 46% mortality reduction reported at 60 days (p=0.048)[1,2] and indicates a durable treatment benefit in this patient population.
- Remestemcel-L was even more effective when evaluated in an exploratory analysis in patients on dexamethasone as part of their standard of care, with 90-day mortality being reduced by 77% compared to controls under 65 who received dexamethasone, 14% vs 48%, HR 0.23, 95% CI (0.080, 0.681), p=0.0037[1,2]
- These survival benefits were accompanied by significant improvements relative to controls in pre-specified secondary endpoints of ventilator-free days, respiratory function as assessed by ARDS severity, and overall clinical improvement on a 7-point ordinal scale.
- Despite a treatment-related improvement in respiratory function at day 7, there was no mortality reduction in the 97 treated patients over age 65, suggesting the need for more prolonged or higher dosing of anti-inflammatory therapy in these patients who may have a more exuberant inflammatory response associated with defective immune-mediated viral clearance mechanisms.

Recently published guidance to industry by the U.S. Food and Drug Administration (FDA)[3] has recommended demonstration of mortality benefit for at least 60 days in critically ill patients. Mesoblast will be meeting shortly with the FDA to discuss the durable mortality reduction seen in patients under 65 years old who received remestemcel-L in this randomized controlled trial, and the regulatory pathway for remestemcel-L in this patient population.

Mesoblast 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 this COVID-19 ARDS trial.

About the Trial of Remestemcel-L in Acute Respiratory Distress Syndrome (ARDS) due to COVID-19

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 12 patients were younger than 65 and 75% successfully came off ventilatory support.

The trial was halted in December 2020 after the Data Safety Monitoring Board (DSMB) performed a third interim analysis on the trial's first 180 patients, noting that the trial was not likely to meet the 30-day mortality reduction endpoint at the planned 300 patient enrolment. The trial was powered to achieve a primary endpoint of 43% reduction in mortality at 30 days for treatment with remestemcel-L on top of maximal care. The DSMB recommended that the trial complete with the enrolled 222 patients, and that all be followed-up as planned.

Mesoblast Limited
ABN 68 109 431 870

www.mesoblast.com

Corporate Headquarters
Level 38
55 Collins Street
Melbourne 3000
Victoria Australia

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

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

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

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

T +65 6570 0635
F +65 6570 0176

At follow-up through day 60, remestemcel-L showed a positive but non-significant trend in overall mortality reduction across the entire population of treated patients (n=217). In the pre-specified population of patients under age 65 (n=123), remestemcel-L reduced mortality through day 60 by 46%, but not in patients 65 or older (n=94). In an exploratory analysis through day 60, 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.

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 rexlemestrocel-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

Footnotes

1. All p-values are descriptive and not adjusted for multiplicity
2. Hazard Ratios calculated using Cox regression proportional hazards model without adjustment; p-value from log rank test
3. COVID-19: Developing Drugs and Biological Products for Treatment or Prevention - Guidance for Industry. *U.S. Department of Health and Human Services; Food and Drug Administration; Center for Drug Evaluation and Research (CDER); Center for Biologics Evaluation and Research (CBER)*. February 2021

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. All statements other than statements of historical fact, including our intention to discuss a regulatory pathway with the FDA, are forward-looking statements, which are often indicated by terms such as "anticipate," "believe," "could," "estimate," "expect," "goal," "intend," "likely," "look forward to," "may," "plan," "potential," "predict," "project," "should," "will," "would" and similar expressions and variations thereof. 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. The risks, uncertainties and other factors that may impact our forward-looking statements include, but are not limited to: the timing, progress and results of Mesoblast's preclinical and clinical studies; Mesoblast's ability to advance product candidates into, enroll and successfully complete, clinical studies; the timing or likelihood of regulatory filings and approvals; whether the FDA agrees to a regulatory pathway; and the pricing and reimbursement of Mesoblast's product candidates, if approved; 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. 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. Unless required by law, 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.

Mesoblast Limited
ABN 68 109 431 870

www.mesoblast.com

Corporate Headquarters
Level 38
55 Collins Street
Melbourne 3000
Victoria Australia

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

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

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

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

T +65 6570 0635
F +65 6570 0176

Release authorized by the Chief Executive.

For more information, please contact:

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

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

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