UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 6-K

Report of Foreign Private Issuer
Pursuant to Rule 13a-16 or 15d-16 under the Securities Exchange Act of 1934

For the month of November 2021

Commission File Number 001-37626

Mesoblast Limited

(*Exact name of Registrant as specified in its charter*)

Not Applicable
(*Translation of Registrant's name into English)*

Australia
(*Jurisdiction of incorporation or organization)*

Silviu Itescu
Chief Executive Officer and Executive Director
Level 38
55 Collins Street
Melbourne 3000
Australia
(*Address of principal executive offices*)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F:

Form 20-F ☑ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Yes ☐ No ☑

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Yes ☐ No ☑

INFORMATION CONTAINED ON THIS REPORT ON FORM 6-K

On November 29, 2021, Mesoblast Limited filed with the Australian Securities Exchange the Chairman's Annual General Meeting address, presentation to Annual General Meeting and results of Annual General Meeting, which are attached hereto as Exhibit 99.1, Exhibit 99.2 and Exhibit 99.3, and are incorporated herein by reference.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly organized.

MESOBLAST LIMITED

/s/ Niva Sivakumar

Niva Sivakumar
Company Secretary

Dated: December 2, 2021

INDEX TO EXHIBITS

Item	
99.1	Chairman's Annual General Meeting address, dated November 29, 2021.
99.2	Presentation to Annual General Meeting, dated November 29, 2021.
99.3	Results of Annual General Meeting, dated November 29, 2021.

asx announcement

mesoblast
the regenerative medicine company

CHAIRMAN'S ADDRESS TO SHAREHOLDERS
2021 MESOBLAST ANNUAL GENERAL MEETING

2021 has been a rollercoaster year for the world, and a challenging year of both meaningful progress as well as some setbacks for Mesoblast. We have gone from the elation of seeing a United States Food and Drug Administration (FDA)-compiled panel of experts vote in favour of our lead product, a potentially company-transforming partnership with global pharma, and some very impressive clinical results, to delays in our foundational submissions to the US regulatory authority.

But despite these challenges, our core therapies – remestemcel-L and rexlemestrocel-L – have continued to deliver results that demonstrate their lifesaving potential in addressing four complex medical disorders: graft versus host disease, acute respiratory distress syndrome, advanced heart failure, and chronic lower back pain.

Over the past 12 months, nothing has given me greater pride than seeing the progress of our remestemcel-L therapy in young children suffering from steroid-refractory acute graft versus host disease (GvHD). This is surely one of the cruellest diseases, striking – and often taking the lives of – innocent young children who have already undergone the ordeal of a bone marrow transplant.

Following a presentation of study results to the FDA's advisory panel last year, and the panel voting overwhelmingly in favour that the data supported the efficacy of our GvHD therapy, we were very disappointed that an approval did not materialise. However, we have regrouped and, after addressing the outstanding items that the FDA requested, we are confident that our collegial collaboration could lead to a resubmission of our current Biologic License Application.

The additional investments we have made with respect to remestemcel-L will also support commencement of a second Phase 3 trial for acute respiratory distress syndrome (ARDS) associated with COVID-19 – a deadly combination of inflammatory reactions that has claimed so many lives during this pandemic. Promising results from our first ARDS trial, together with a recent constructive meeting with the FDA, pave the way for a highly anticipated follow-up study and a pathway to potential emergency use authorisation for patients with the highest risk of mortality.

Our second cell therapy, rexlemestrocel-L, has also received a recent boost with its presentation at the American Heart Association's 2021 Scientific Sessions, where the latest results were outlined from a five-year Phase 3 trial involving 565 patients – the largest-ever trial of a cell therapy for heart disease. Mesoblast is excited by these results, which are due to be published by a major medical journal and will inform the progress of our other major submission before the FDA.

As a Board, we are focused on our governance responsibilities as well as our need to improve diversity on the Board in order to benefit from a wider perspective that having a diverse membership brings. We are committed to enhancing gender diversity in particular as we bring on new directors. Our Board membership has transitioned in recent years as Mesoblast heads towards the potential approval of its first product, with new appointments being Ms Shawn Tomasello, Mr Philip Facchina and myself. We have all brought diverse experiences to the Board - Shawn with more than 30 years' commercial and transactional experience in the pharmaceutical and biotech industries, Philip with more than 35 years' experience with corporate strategy, capital markets and business development, and myself with more than four decades of healthcare leadership experience as a payor and provider executive. In addition, I have served as Chairman of the Institute for Diversity for Healthcare Management and currently serve as an advisor to the National Association of Corporate Directors Center for Inclusive Governance.

With the new appointments well settled into the Board, we are committed to a program of Board renewal with two of our long-standing Australian directors standing down in the next six to 12 months, and a search having commenced for successor Australian directors.

The next 12 months will be a pivotal period in the evolution of our company, as a number of regulatory processes draw towards a close with the assiduous support of our clinical staff. I would like to take this opportunity to thank all the remarkable researchers and healthcare professionals who make this possible, as well as the diverse investment community who continue to show such faith in our work. I would particularly like to thank our Chief Executive, Dr Silviu Itescu, our management team, and our employees for their resilience, resourcefulness and incredible dedication over the past 12 months.

This has been a tough and unprecedented period, particularly for the world's clinical community – but at Mesoblast we continue to be awed by the deep commitment and compassion that our healthcare professionals and scientists have demonstrated throughout this pandemic. I am proud to have seen these same qualities reflected across all levels of the Mesoblast team, as we continue to navigate the hurdles to bring our lead therapies to the millions of people whose lives could be improved by them.

About Mesoblast

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

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

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

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

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

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product candidates, if any are approved, to be withdrawn from the market due to patient adverse events or deaths; the potential benefits of strategic collaboration agreements and Mesoblast's ability to enter into and maintain established strategic collaborations; Mesoblast's ability to establish and maintain intellectual property on its product candidates and Mesoblast's ability to successfully defend these in cases of alleged infringement; the scope of protection Mesoblast is able to establish and maintain for intellectual property rights covering its product candidates and technology; estimates of Mesoblast's expenses, future revenues, capital requirements and its needs for additional financing; Mesoblast's financial performance; developments relating to Mesoblast's competitors and industry; and the pricing and reimbursement of Mesoblast's product candidates, if approved. You should read this press release together with our risk factors, in our most recently filed reports with the SEC or on our website. Uncertainties and risks that may cause Mesoblast's actual results, performance or achievements to be materially different from those which may be expressed or implied by such statements, and accordingly, you should not place undue reliance on these forward-looking statements. We do not undertake any obligations to publicly update or revise any forward-looking statements, whether as a result of new information, future developments or otherwise.

Release authorized by the Chief Executive.

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Exhibit 99.2

mesoblast

Annual General Meeting
Chief Executive's Presentation

NOVEMBER 29, 2021

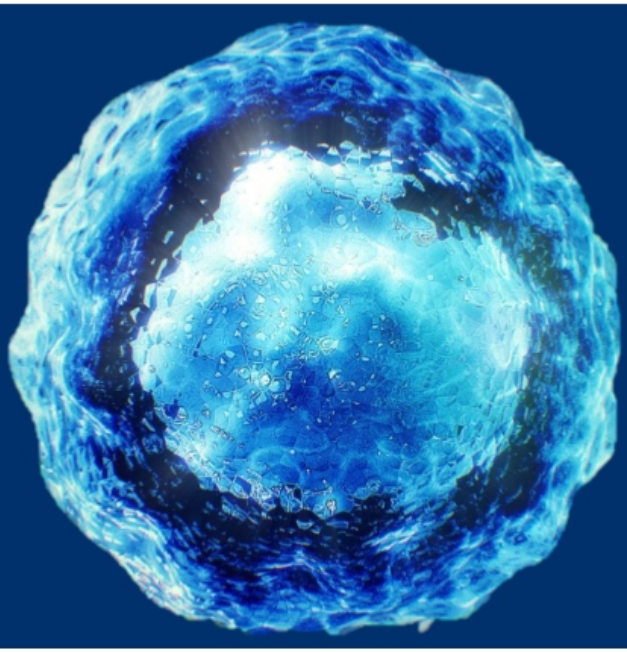
ASX: MSB; Nasdaq: MESO

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.

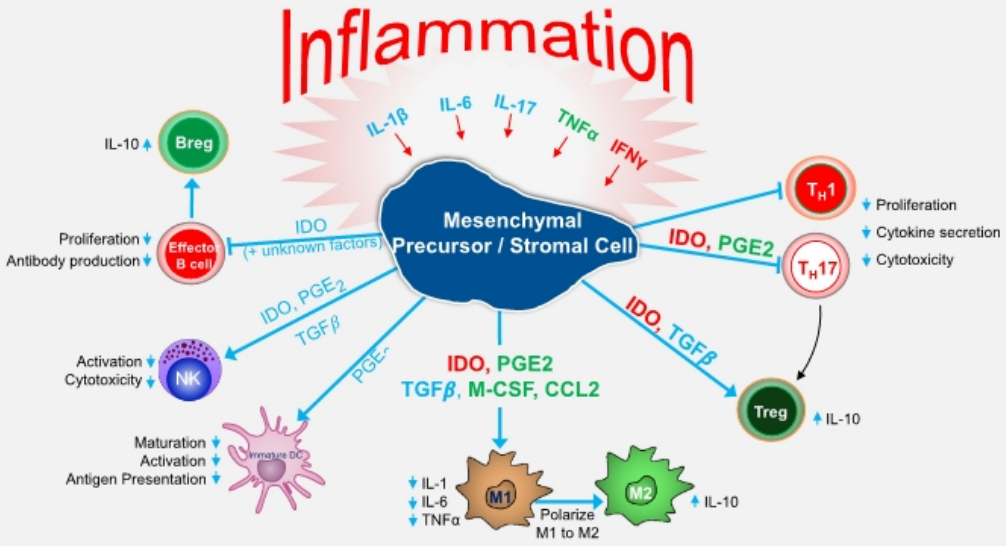
Our Mission

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



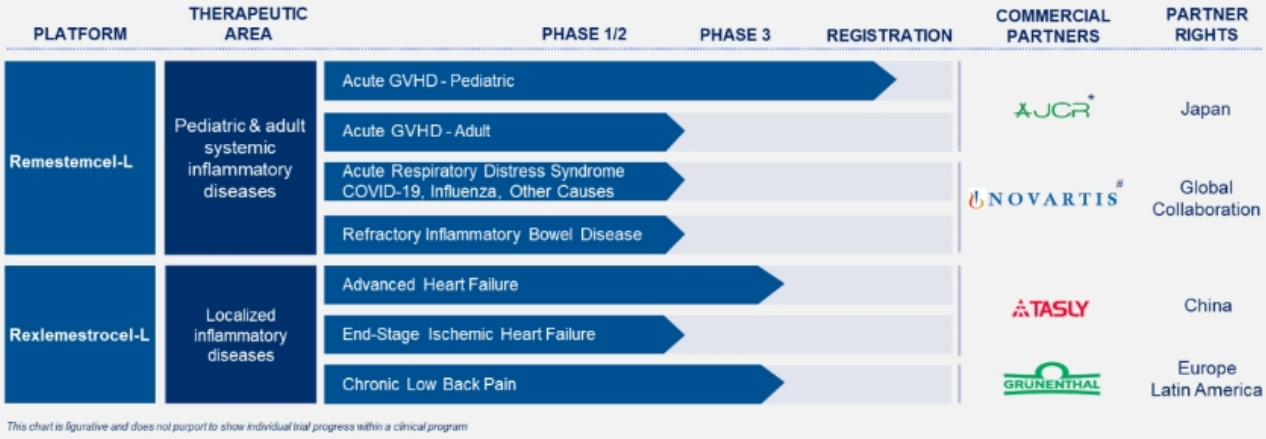
Platform Technology – Mechanism of Action

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

Pipeline



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

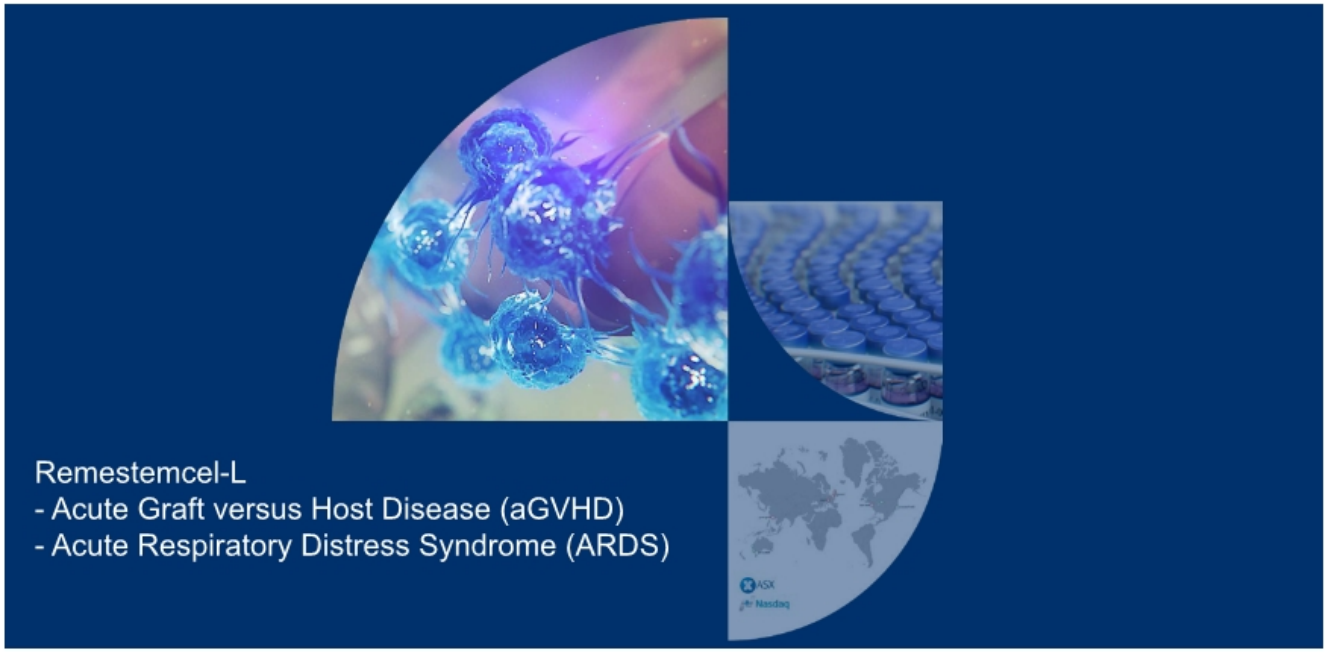
* Mesoblast has the right to use data generated by JCR Pharmaceuticals Co Ltd in Japan to support its development and commercialization plans for remestemcel-L in the US and other major healthcare markets, including for GVHD and Hypoxic Ischemic Encephalopathy

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

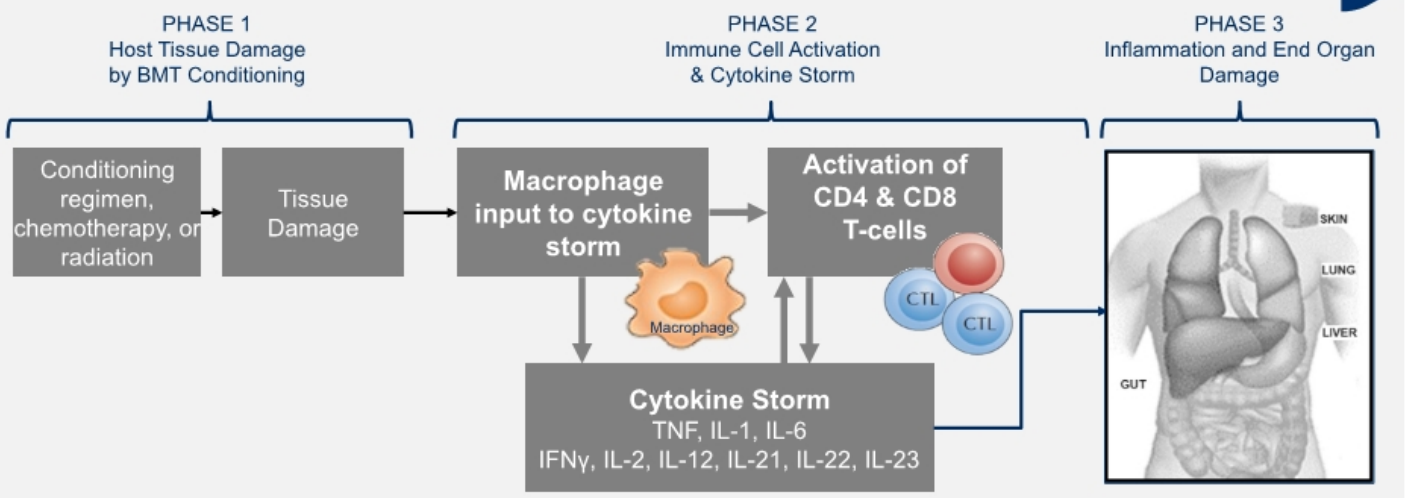
Financial Highlights

- Successfully entered into a refinancing and expansion of our senior debt facility with Oaktree Capital Management. The new US$90 million, 5-year secured facility has a 3-year interest only period after which time 40% of the principal amortizes over two years and a final payment due no later than November 2026
- Cash on hand at September 30, 2021, the most recent balance sheet date, was US$116.0 million
- Sales of TEMCELL® HS Inj.[1] in Japan by licensee JCR for the treatment of aGVHD have re-established a steady growth trajectory after plant capacity was expanded to meet growing demand[2]
  - Revenue from TEMCELL® royalties increased by 10% from the prior year period to US$7.2 million in the year ended June 30, 2021
  - In the most recent quarter ended September 30, 2021, revenues from TEMCELL® royalties were US$2.4 million, an increase of 22% on the previous quarter, and of 90% on the comparative quarter last year
- In the most recent quarter, net operating cash usage was US$19.6 million, a reduction of US$8.6 million on the comparative quarter
- Approximately 50% of net operating cash usage was to support the regulatory pathway to approval, manufacturing scale-up, and lifecycle management of the remestemcel-L platform

1. TEMCELL® HS Inj. is a registered trademark of JCR Pharmaceuticals Co. Ltd.
2. JCR Pharmaceuticals News Release: *Notice regarding Capital Expenditures to Increase Production Capacity at the Seishin Plant.* July 31, 2020


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

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



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

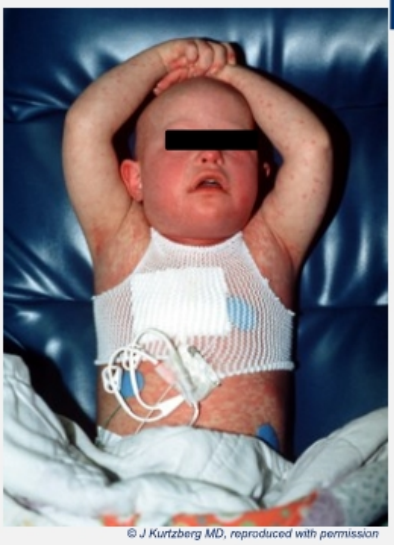
Children with Steroid-Refractory Acute GVHD at High Risk of Treatment Failure and Death

Extremely high unmet medical need

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

Acute GVHD Primarily Affects Skin, GI Tract, and Liver

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



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

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

Consistent efficacy and safety outcomes in a total of 309 children from three studies:

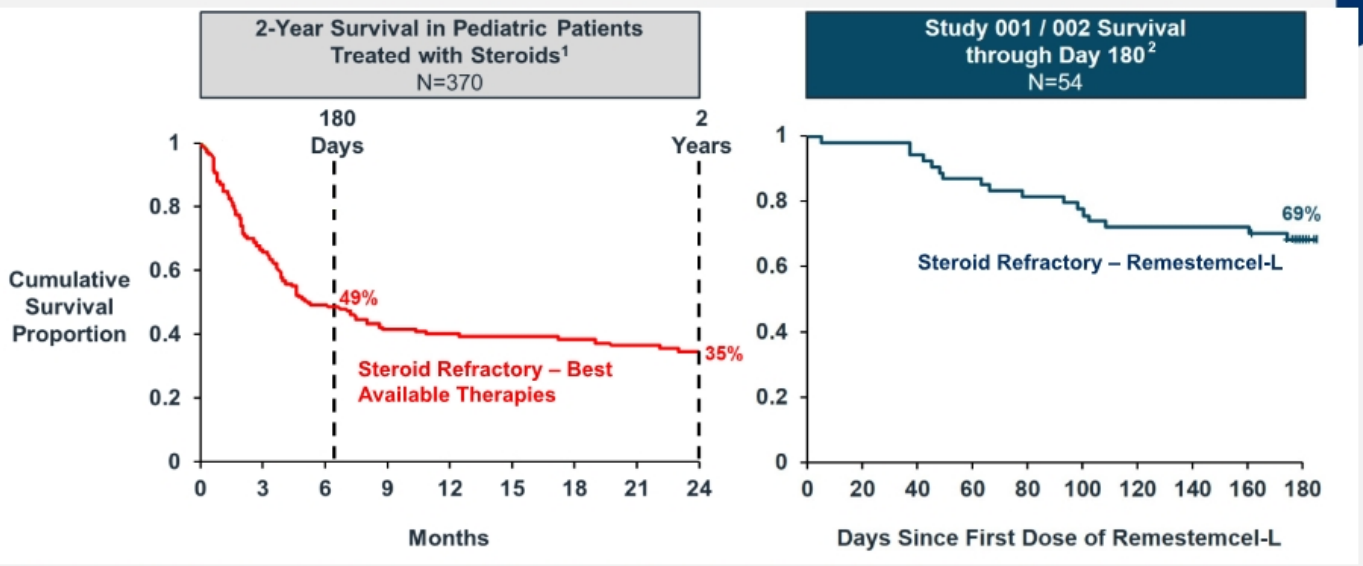
- Remestemcel-L was used as first-line therapy in a randomized controlled Phase 3 trial of 260 patients, with SR-aGVHD, including 27 children
- Remestemcel-L was used as salvage therapy in an expanded access program in 241 children with SR-aGVHD, 80% of whom had Grade C/D disease, and failed institutional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

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

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

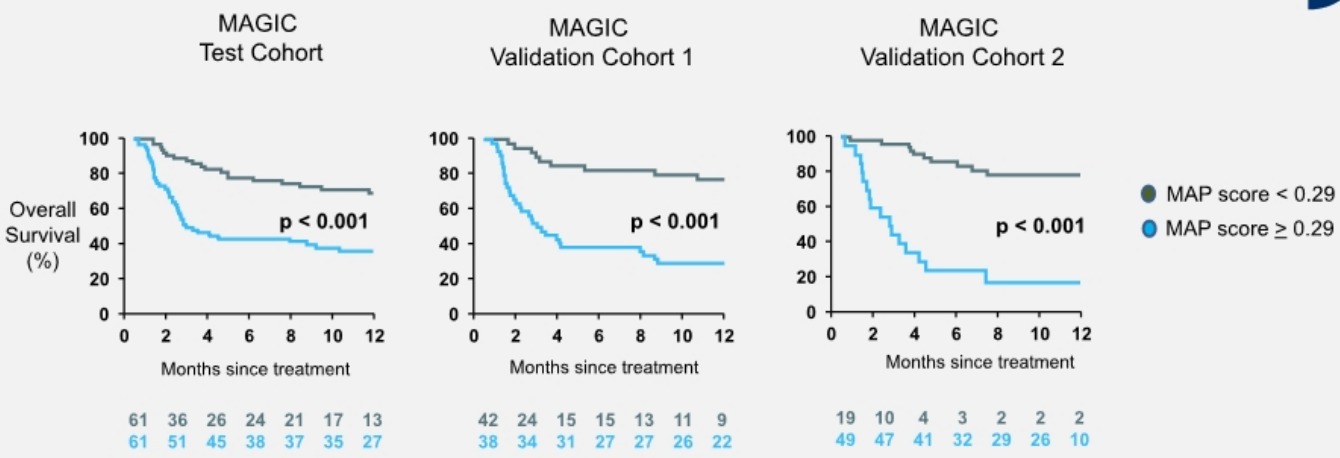
1. Mount Sinai Acute GVHD International Consortium (MAGIC) - a group of ten BMT centers throughout the US and Europe whose purpose is to conduct ground-breaking clinical trials in GVHD, including developing informative biorepositories that assist in developing treatments that can guide GVHD therapy.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

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



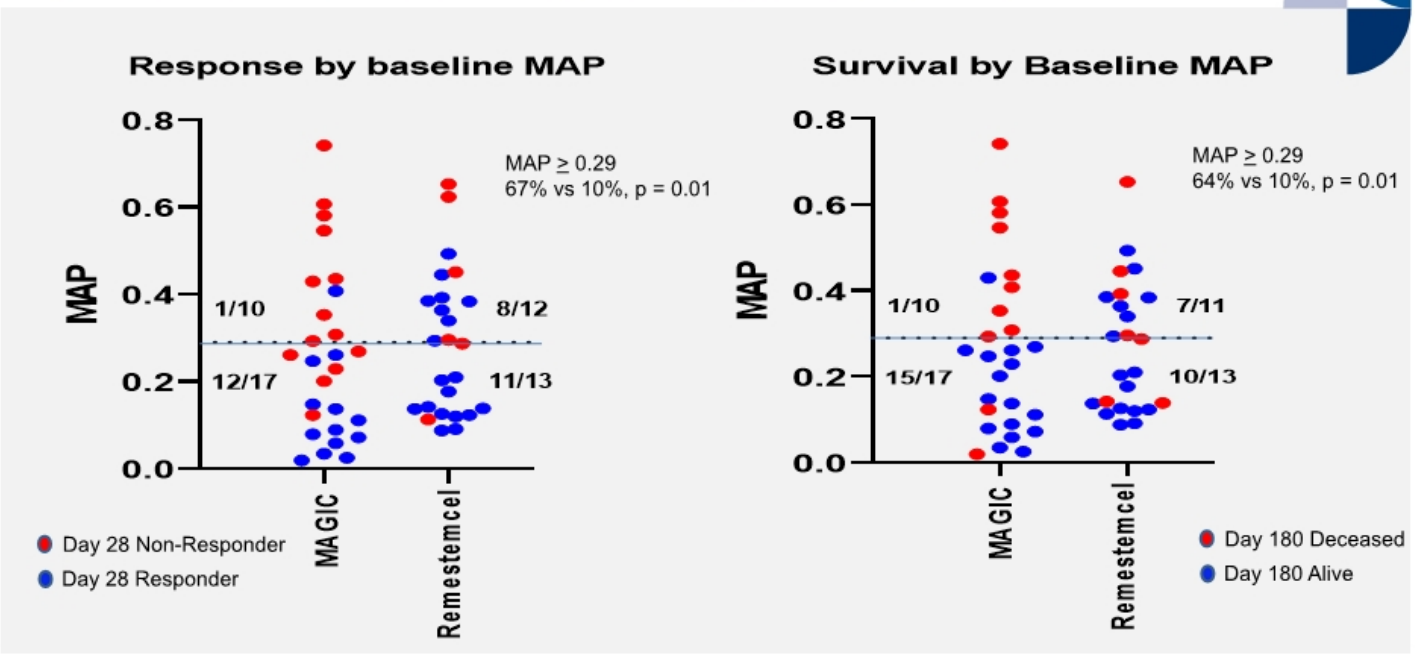
1. Adapted and redrawn from Figure 2 of MacMillan, M.L. et al. Pediatric acute GVHD: clinical phenotype and response to upfront steroids. Bone Marrow Transplant 55, 165–171 (2020); 2. Kurtzberg, J. et al. A Phase 3, Single-Arm, Prospective Study of Remestemcel-L, Ex Vivo Culture-Expanded Adult Human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

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



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

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



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

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

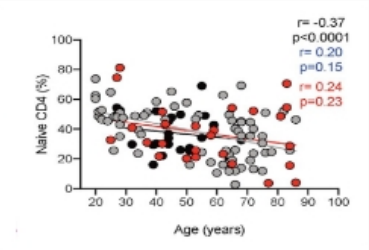
- These data provide further support for the proposed anti-inflammatory mechanism of action of remestemcel-L and its immunomodulatory activity in patients with SR-aGVHD, resulting in improved survival outcomes
- Mesoblast has an upcoming scheduled meeting with United States Food & Drug Administration's (FDA) Office of Tissues and Advanced Therapies (OTAT) to address the appropriateness of potency assays related to remestemcel-L's proposed anti-inflammatory mechanism of action
- These discussions are part of the ongoing process to resolve outstanding items with the goal of resubmission of the Biologics License Application (BLA) and ultimately achieving approval for remestemcel-L in the treatment of SR-aGVHD in children

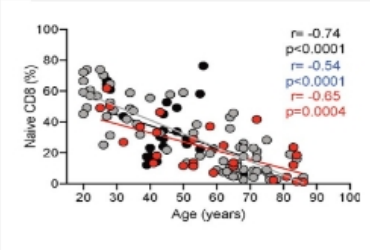
Overview – Remestemcel-L for ARDS due to COVID-19

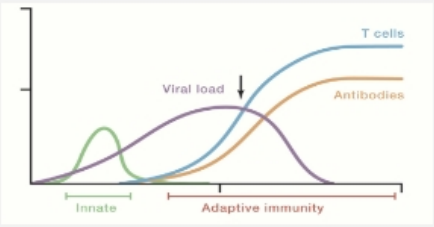
- COVID-19 is a respiratory virus with a high mortality due to a severe inflammatory condition of the lungs called acute respiratory disease syndrome (ARDS)
- ARDS is caused by cytokine storm in lungs of patients infected with COVID-19 and is the primary cause of death
- The extensive safety data of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

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

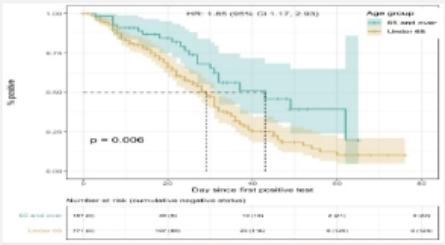
Naïve CD4 and CD8 T Cells reduced in age > 65





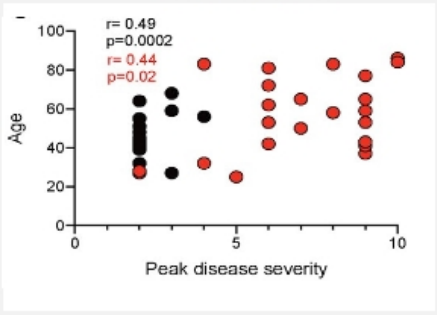


SARS-CoV-2-specific CD4 T cells and CD8 T cells limit disease severity



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

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



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

Clinical Experience with Remestemcel-L in COVID-19 ARDS

Emergency IND in Ventilator-Dependent COVID-19 ARDS

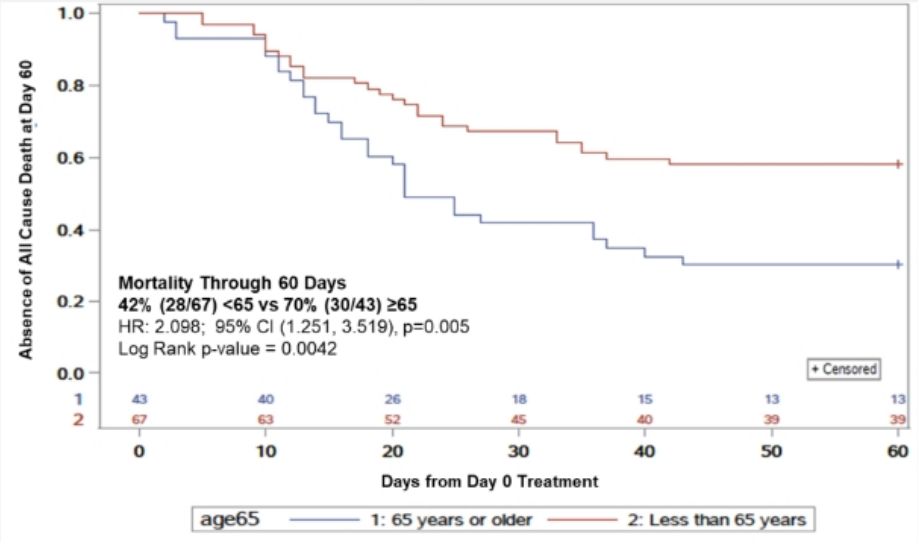
- **11 patients (10/11 were < 65 years)** with moderate/severe ARDS on ventilators at Mt. Sinai Hospital in New York
- Patients received two infusions of remestemcel-L 2 million cells/kg within five days
- Nine patients (82%) successfully came off ventilator and were discharged from the ICU
- Experience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

Phase 3 Randomized Controlled Trial in COVID-19 ARDS

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

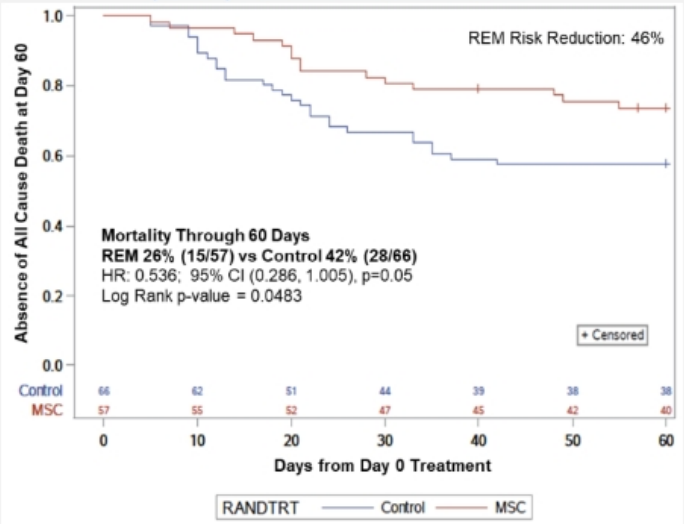
Greater Mortality through Day 60 in Control Patients Older than 65, Consistent with Other Trials

Controls Age < 65 vs ≥ 65 (n=110)

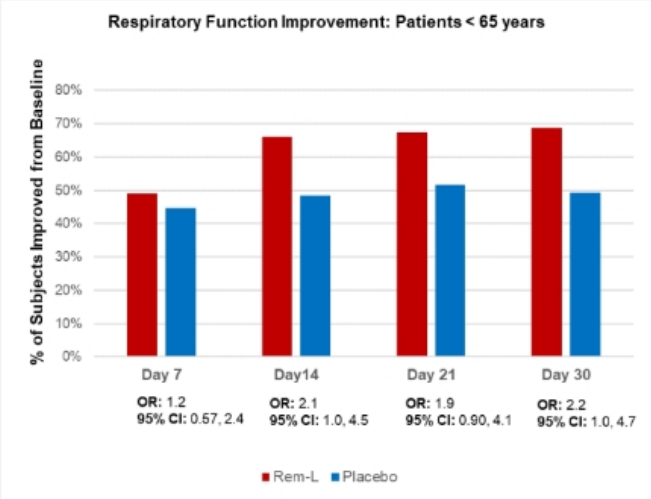


Greatest Mortality Reduction Improved ARDS Severity* Seen in Remestemcel-L Treated Patients < 65 years

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



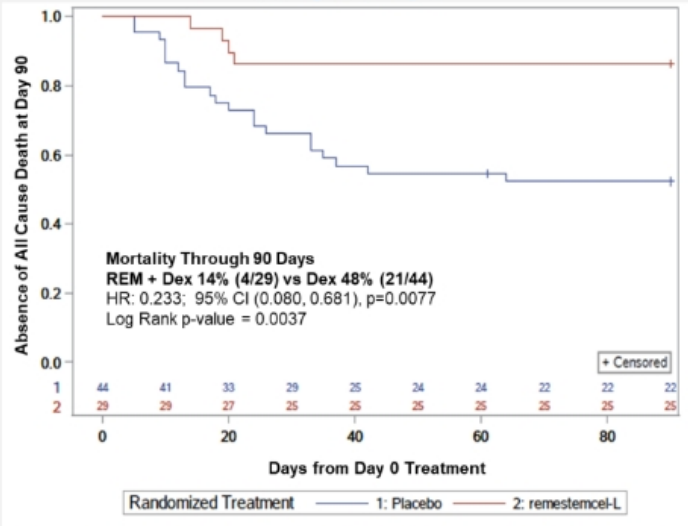
Treated Patients (mITT) **< 65 years old** (n=123) Remestemcel-L vs Control



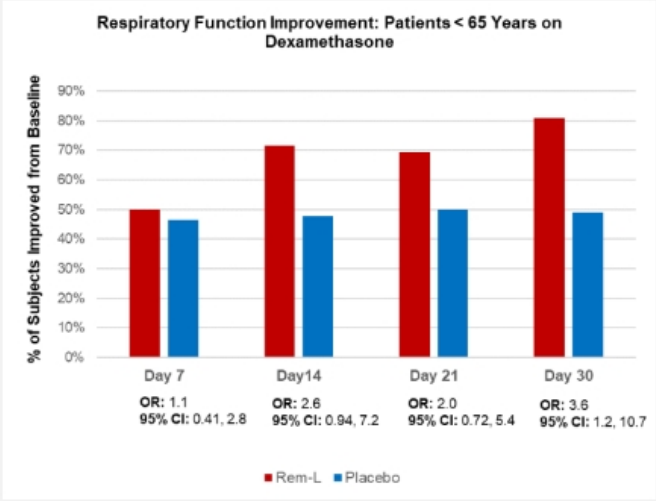
* Measured as resolution and/or improvement of ARDS as defined by the Berlin criteria at Days 7, 14, 21, and 30 post-randomizations

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

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



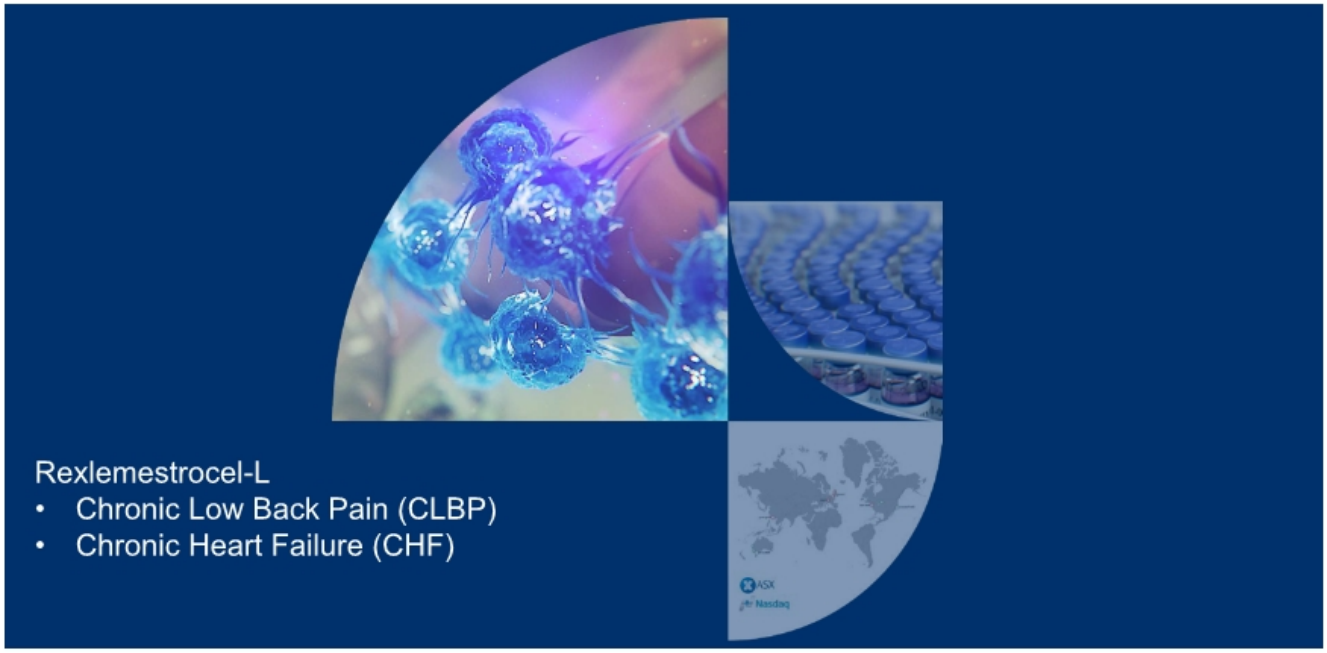
Treated Patients (mITT) < 65 years old on Dexamethasone (n=73)



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

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

- Mesoblast met with the FDA in regard to potential Emergency Use Authorization (EUA) for remestemcel-L in the treatment of ventilator-dependent patients with moderate or severe ARDS due to COVID-19
- The FDA advised that an additional clinical study in COVID ARDS, if statistically positive, could provide a dataset in conjunction with the recently completed 222 patient clinical study that might be sufficient to support an EUA
- FDA indicated that potency assays must be established and agreed prior to commencement of the proposed Phase 3 clinical trial
- FDA provided guidance that the existing COVID ARDS Investigational New Drug (IND) file and future submissions for remestemcel-L in this indication may continue to cross-reference manufacturing information in BLA for pediatric SR-aGVHD
- Mesoblast has an upcoming meeting with FDA's OTAT regarding potency assays for remestemcel-L in relation to SR-aGvHD, attributes which we believe to be also relevant to COVID ARDS
- Mesoblast plans to move forward with an additional Phase 3 trial in COVID-19 ARDS with the next step being to agree with the FDA the final protocol and potency assay


Rexlemestrocel-L
• Chronic Low Back Pain (CLBP)
• Chronic Heart Failure (CHF)
ASX
Nasdaq

Rexlemestrocel-L: A New Paradigm for Treatment of Chronic Low Back Pain due to Degenerative Disc Disease

Burden of Illness

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

Minimal Treatment Options

- Minimal treatment options for patients with chronic low back pain (CLBP) who fail conservative therapy include opioids and surgery
- 50% of opioid prescriptions are for CLBP

Unmet Need

- Disease modifying therapy for durable improvement in pain and function has potential to prevent progression to opioid use or surgical intervention

Market Opportunity

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

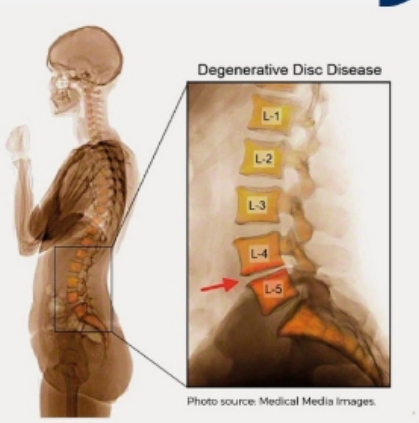


Photo source: Medical Media Images.

1. Williams, J., NG, Nawi, Pelzter, K. (2015) Risk factors and disability associated with low back pain in older adults in low-and middle-income countries. Results from the WHO Study on global ageing and adult health (SAGE). PloS One. 2015; 10(6): e0127880., 2. Simon, J., McAuliffe, M., Shamim, F. (2015) Discogenic Low Back Pain. Phys Med Rehabil Clin N Am 25 (2014)305–317., 3.Decision Resources: Chronic Pain December 2015., 4. LEK & NCI opinion leader interviews, and secondary analysis., 5. Navigant: Commercial Assessment for a Proprietary Cell-Based Therapy for DDD in the U.S. and the EU3 – August 2014., 6. HealthCare Utilization and Cost of Discogenic Lower Back Pain in the US – Anthem/HealthCore.

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

- Achievement of substantial 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), substantially 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

Chronic Heart Failure: Rising Incidence & High Mortality

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

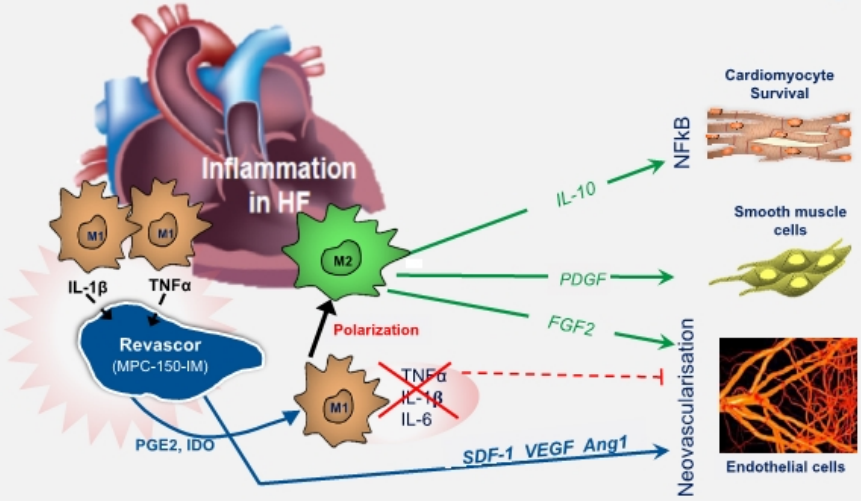
New therapies for chronic heart failure reduce recurrent hospitalizations due to cardiac decompensation, however they do not materially improve cardiac mortality or major ischemic events (heart attacks/strokes)

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

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

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

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



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

Late Breaking Presentation at American Heart Association Annual Meeting

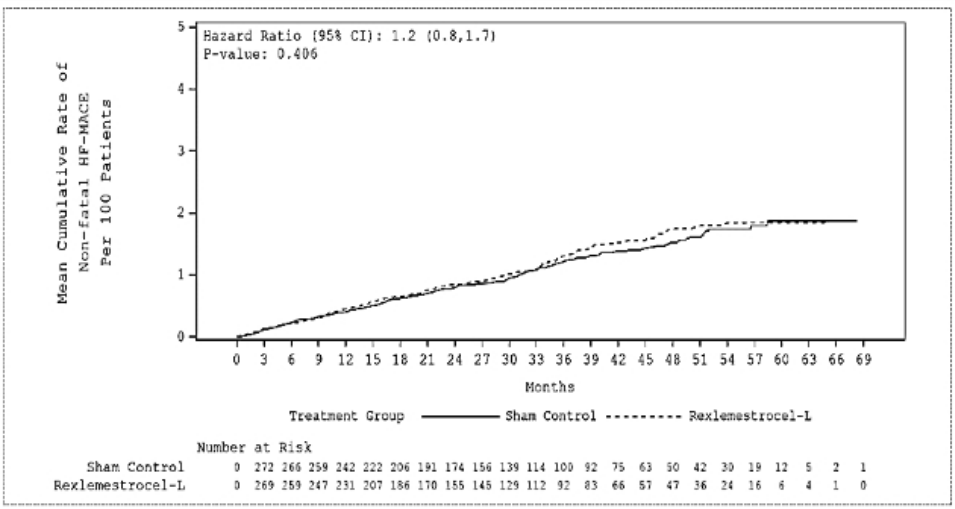
- Data from the randomized, controlled Phase 3 trial of rexlemestrocel-L in 565 patients with NYHA class II and class III HFrEF were presented as a late breaking presentation at the AHA annual Scientific Sessions during a featured program titled 'Building on the Foundations of Treatment: Advances in Heart Failure Therapy'
- The trial's co-principal investigator Dr Emerson Perin, Medical Director of Texas Heart Institute, and Clinical Professor, Baylor College of Medicine, gave the presentation titled *'Randomized Trial of Targeted Transendocardial Delivery of Mesenchymal Precursor Cells in High-Risk Chronic Heart Failure Patients with Reduced Ejection Fraction'*
- Newly presented data from the landmark study showing a significant relationship between presence of systemic inflammation as quantified by high-sensitivity C-reactive protein (hs-CRP) and treatment benefit with rexlemestrocel-L on risk of cardiovascular mortality, heart attacks or strokes

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

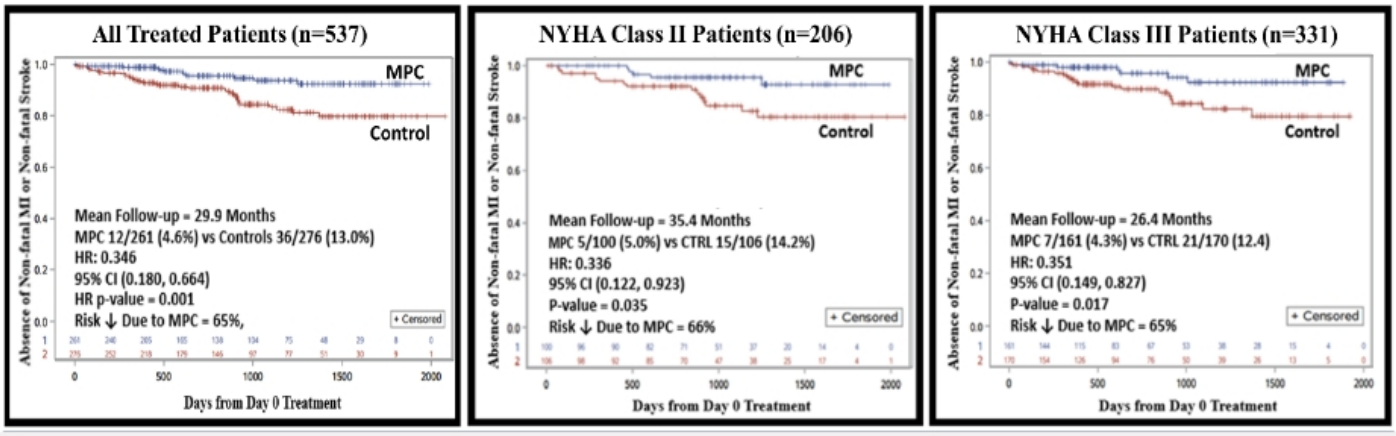
All Patients (n=537)

HR: 1.2

p=0.4

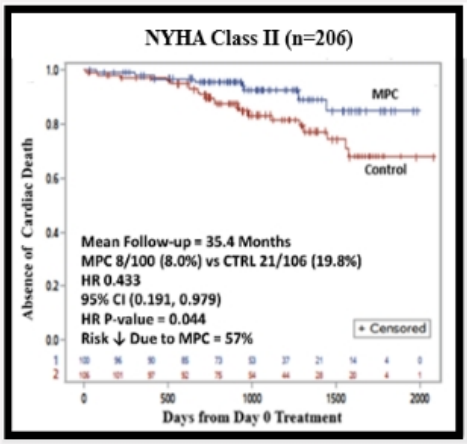


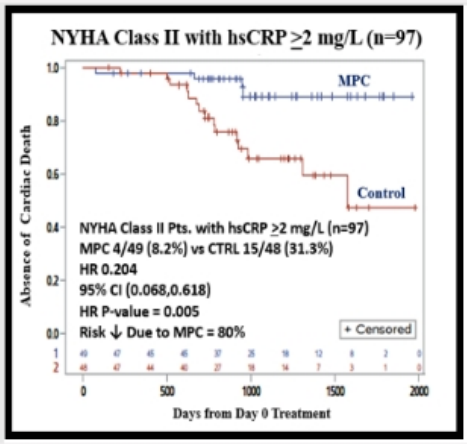
Rexlemestrocel-L Reduced Incidence of Non-fatal MI or Non-fatal Stroke Over Standard of Care Alone

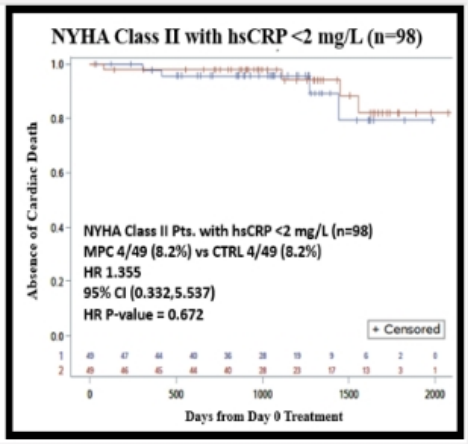


Rexlemestrocel-L Reduced Incidence of Cardiac Death, Particularly in Patients with Inflammation

Time-to-Cardiac Death in NYHA Class II Patients

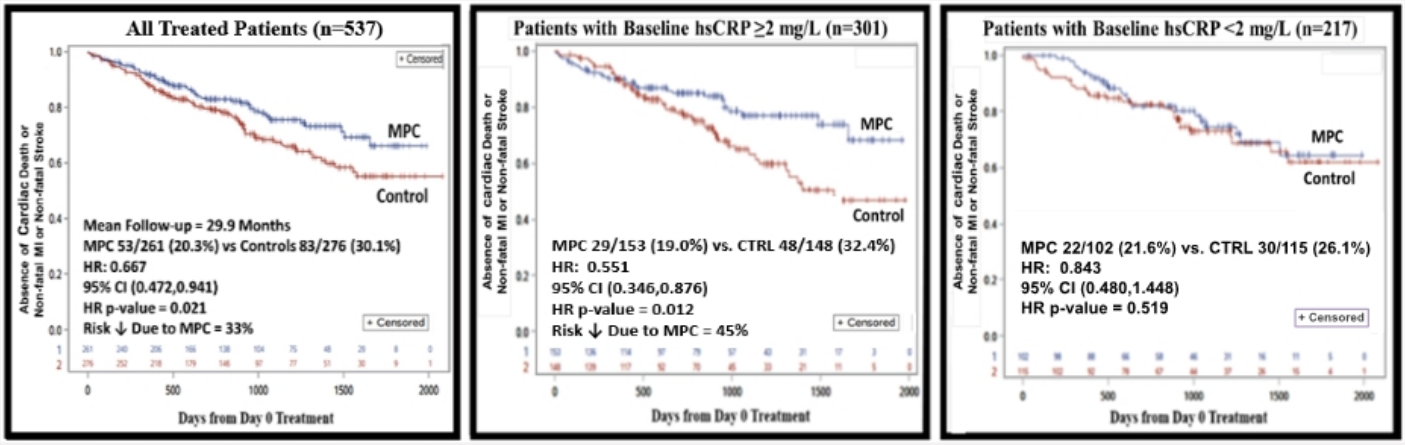






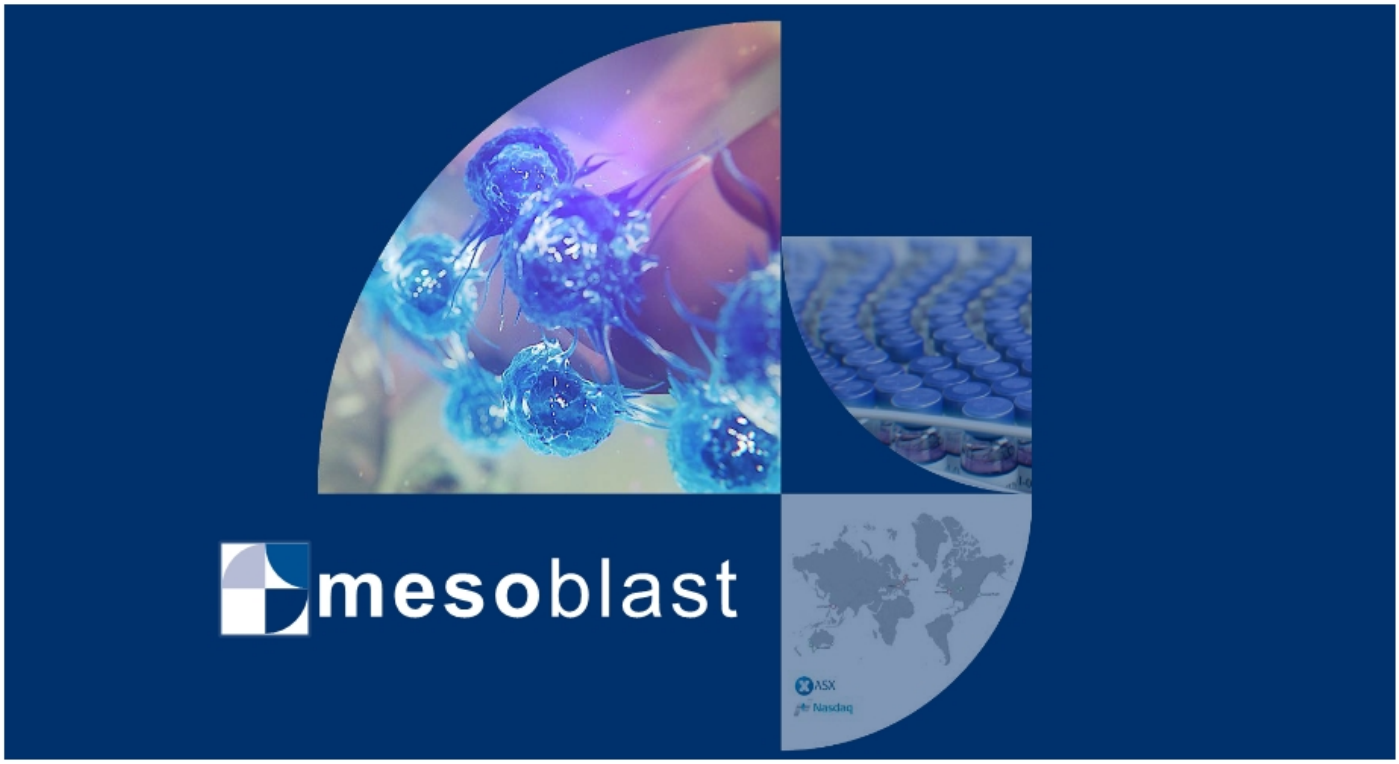
Rexlemestrocel-L Reduced Incidence of 3-Point MACE (Cardiac Death or MI or Stroke) in all 537 Treated Patients, and Especially in Those with Inflammation

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



Conclusions

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


mesoblast
ASX
Nasdaq

29 November 2021

Mesoblast Limited (MSB)
Results of Annual General Meeting Held 29 November 2021

In accordance with ASX Listing Rule 3.13.2 and section 251AA of the Corporations Act 2001 (Cth), we advise details of the resolutions and the proxies received in respect of each resolution as per the attached report.

All resolutions were passed and decided by way of a poll.

Release authorized by the Chief Executive.

Yours faithfully

Niva Sivakumar
Company Secretary

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MESOBLAST LIMITED

ANNUAL GENERAL MEETING
Monday, 29 November 2021

RESULT OF ANNUAL GENERAL MEETING (ASX REPORT)

As required by section 251AA(2) of the Corporations Act 2001 (Commonwealth) the following statistics are provided in respect of each resolution on the agenda.

Resolution Voted on at the meeting			Proxy Votes (as at proxy close)				Total votes cast in the poll (where applicable)			
No	**Short Description**	Strike **Y/N/NA**	***For***	***Against***	***Discretionary (open votes)***	***Abstain***	***For***	***Against***	***Abstain *****	***Result***
2	ADOPTION OF THE REMUNERATION REPORT	N	138,772,244 97.23%	3,024,992 2.12%	929,555 0.65%	1,039,889	140,571,367 97.75%	3,233,813 2.25%	1,063,889	Carried
3	ELECTION OF MR PHILIP J. FACCHINA AS A DIRECTOR	NA	208,954,608 98.63%	1,947,789 0.92%	956,987 0.45%	866,224	210,989,984 99.09%	1,947,789 0.91%	890,224	Carried
4A	RE-ELECTION OF MR MICHAEL SPOONER AS A DIRECTOR	NA	129,943,526 80.78%	29,964,151 18.63%	944,868 0.59%	51,873,062	131,694,503 81.32%	30,256,431 18.68%	51,877,062	Carried
4B	RE-ELECTION OF MR JOSEPH R. SWEDISH AS A DIRECTOR	NA	186,333,202 87.95%	24,577,446 11.60%	940,743 0.45%	874,217	188,083,487 88.32%	24,870,293 11.68%	874,217	Carried
4C	RE-ELECTION OF MS SHAWN CLINE TOMASELLO AS A DIRECTOR	NA	198,791,806 93.82%	12,006,064 5.67%	1,080,754 0.51%	846,984	200,682,102 94.23%	12,298,911 5.77%	846,984	Carried
5	APPROVAL OF PROPOSED ISSUE OF OPTIONS TO NEWLY-APPOINTED DIRECTOR, MR PHILIP J FACCHINA	NA	104,536,073 73.17%	37,416,804 26.19%	906,137 0.64%	907,666	106,262,748 73.82%	37,694,655 26.18%	911,666	Carried
6	APPROVAL OF PROPOSED ISSUE OF OPTIONS TO CHIEF EXECUTIVE, DR SILVIU ITESCU, IN CONNECTION WITH HIS REMUNERATION FOR THE 2021/2022 FINANCIAL YEAR	NA	119,319,136 83.68%	22,383,141 15.70%	885,303 0.62%	1,179,100	120,888,977 84.13%	22,800,992 15.87%	1,179,100	Carried
7	RENEWAL OF PROPORTIONAL TAKEOVER APPROVAL PROVISIONS IN THE COMPANYS CONSTITUTION	NA	208,871,627 98.65%	1,942,148 0.92%	922,167 0.43%	989,665	210,787,183 99.05%	2,027,148 0.95%	1,013,665	Carried
8	RATIFICATION OF ISSUE OF SECURITIES TO EXISTING AND NEW INSTITUTIONAL INVESTORS	NA	192,643,698 91.07%	17,802,482 8.42%	1,083,996 0.51%	1,195,432	194,668,803 91.56%	17,939,762 8.44%	1,219,432	Carried

** - Note that votes relating to a person who abstains on an item are not counted in determining whether or not the required majority of votes were cast for or against that item