



Operational Highlights & Financial Results for the Year Ended June 30, 2021

AUGUST 2021

ASX: MSB; Nasdaq: MESO

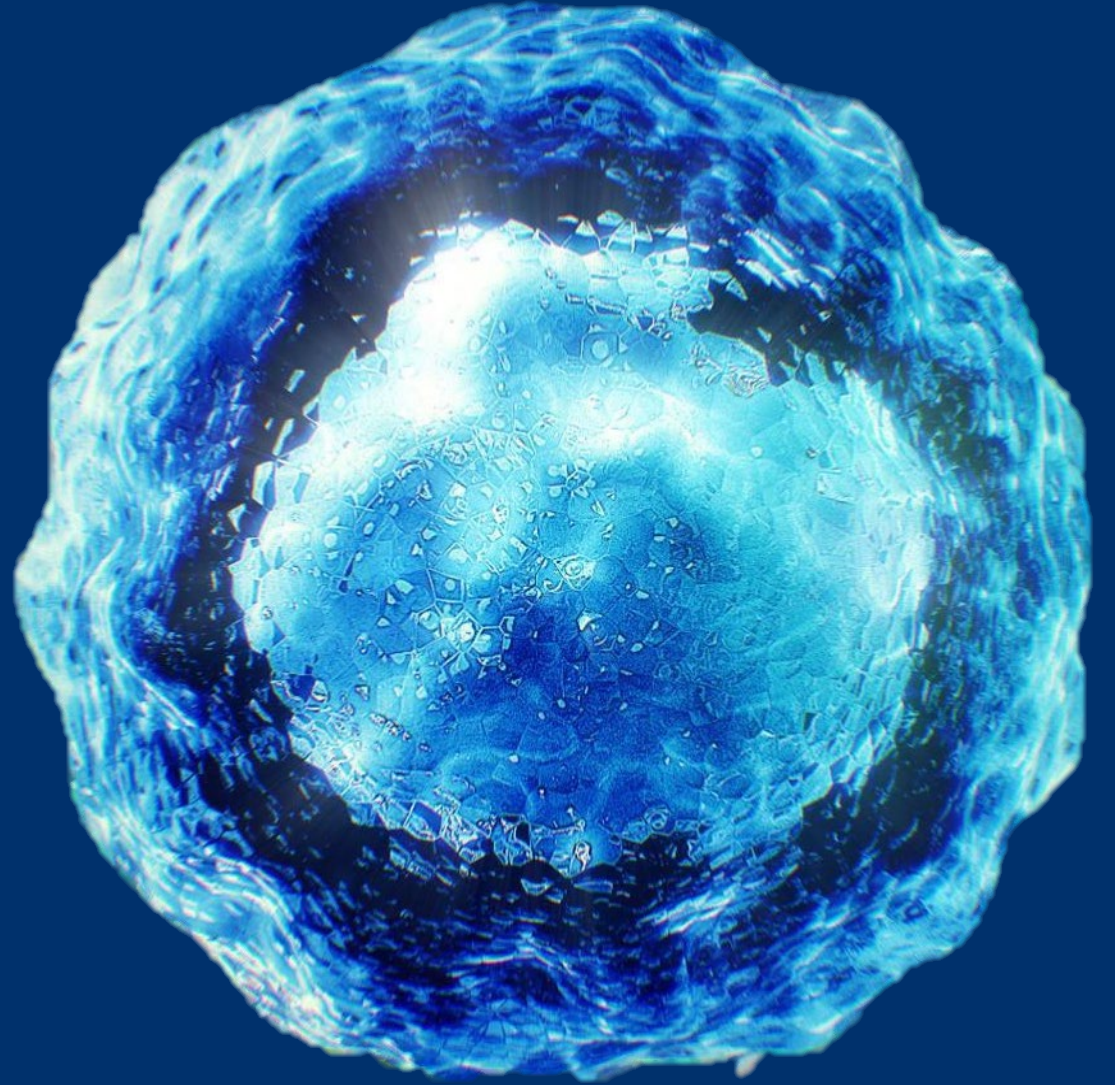


CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

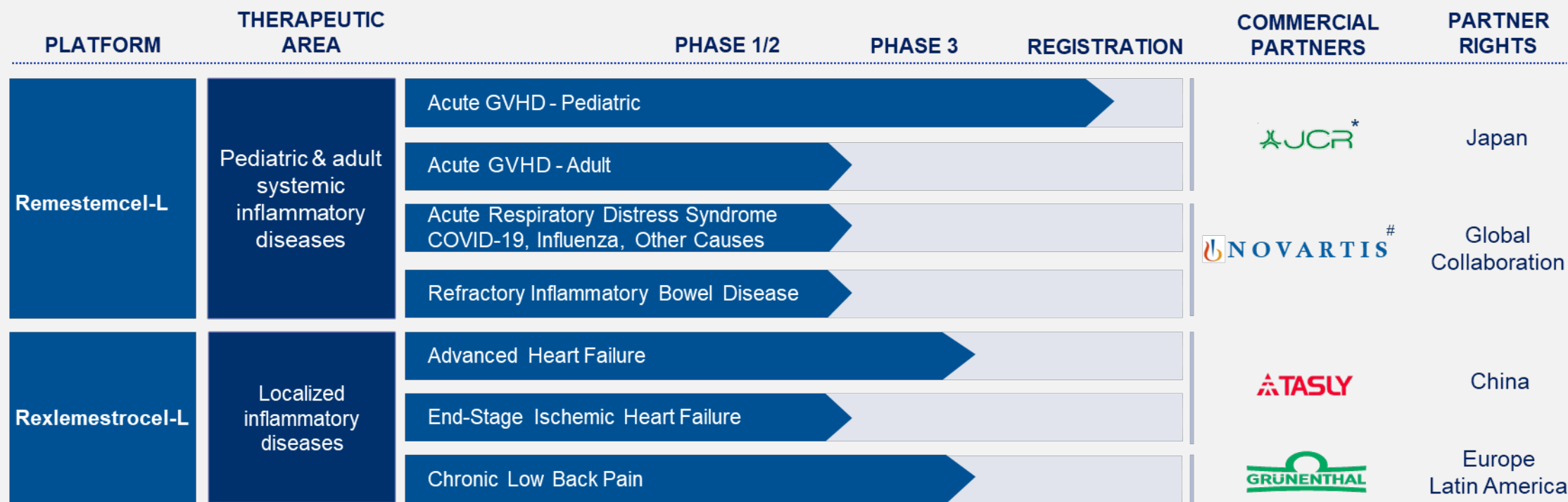
This presentation includes forward-looking statements that relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this presentation are forward-looking statements. Words such as, but not limited to, “believe,” “expect,” “anticipate,” “estimate,” “intend,” “plan,” “targets,” “likely,” “will,” “would,” “could,” and similar expressions or phrases identify forward-looking statements. We have based these forward-looking statements largely on our current expectations and future events, recent changes in regulatory laws, and financial trends that we believe may affect our financial condition, results of operation, business strategy and financial needs. These statements may relate to, but are not limited to: expectations regarding the safety or efficacy of, or potential applications for, Mesoblast's adult stem cell technologies; expectations regarding the strength of Mesoblast's intellectual property, the timeline for Mesoblast's regulatory approval process, and the scalability and efficiency of manufacturing processes; expectations about Mesoblast's ability to grow its business and statements regarding its relationships with current and potential future business partners and future benefits of those relationships; statements concerning Mesoblast's share price or potential market capitalization; and statements concerning Mesoblast's capital requirements and ability to raise future capital, among others. Forward-looking statements should not be read as a guarantee of future performance or results, and actual results may differ from the results anticipated in these forward-looking statements, and the differences may be material and adverse. You should read this presentation together with our financial statements and the notes related thereto, as well as the risk factors, in our most recently filed reports with the SEC or on our website. Uncertainties and risks that may cause Mesoblast's actual results, performance or achievements to be materially different from those which may be expressed or implied by such statements, include, without limitation: risks inherent in the development and commercialization of potential products; uncertainty of clinical trial results or regulatory approvals or clearances; government regulation; the need for future capital; dependence upon collaborators; and protection of our intellectual property rights, among others. Accordingly, you should not place undue reliance on these forward-looking statements. We do not undertake any obligations to publicly update or revise any forward-looking statements, whether as a result of new information, future developments or otherwise.

Our Mission

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



Pipeline



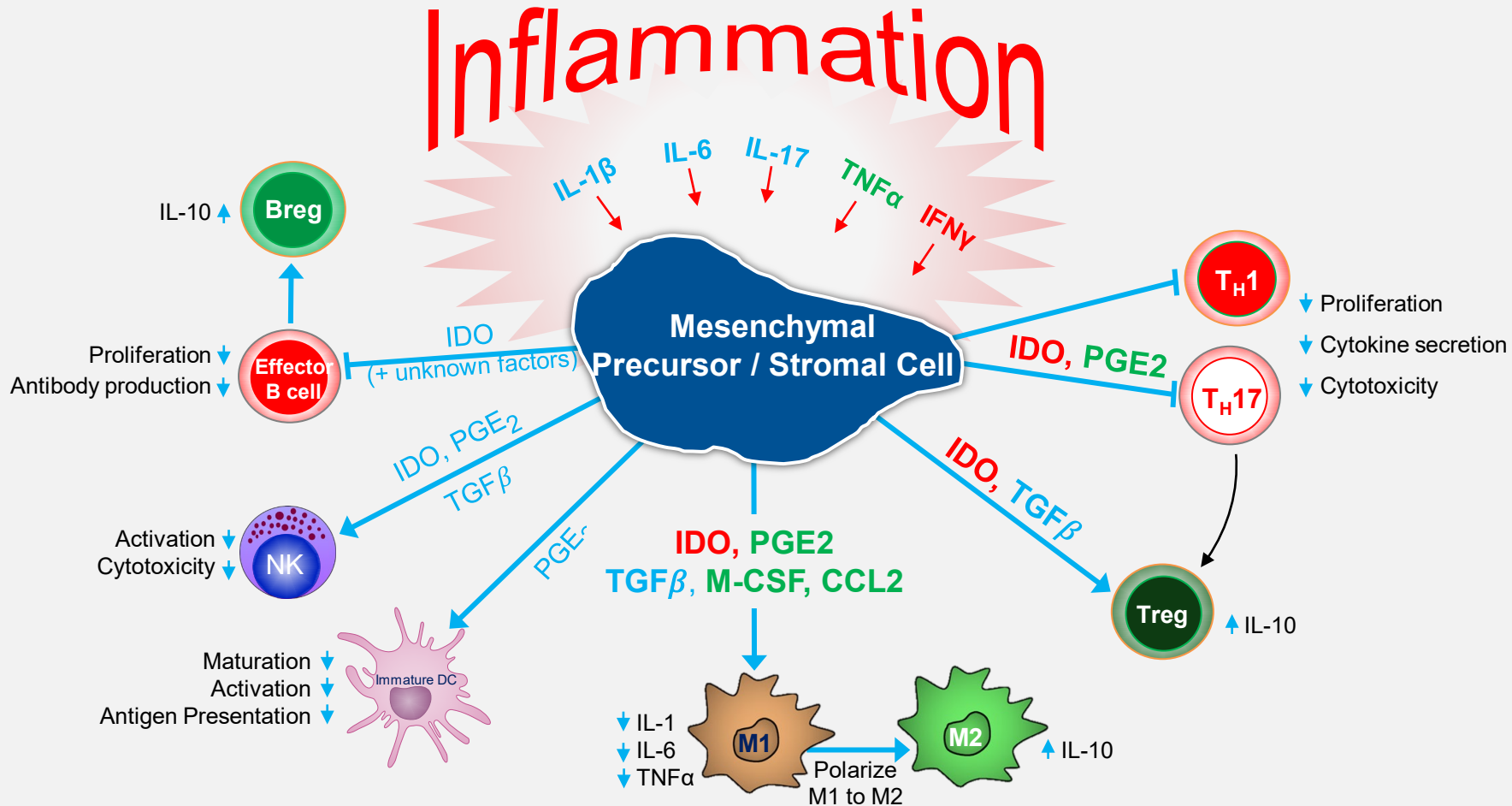
This chart is figurative and does not purport to show individual trial progress within a clinical program

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

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

Platform Technology – Mechanism of Action

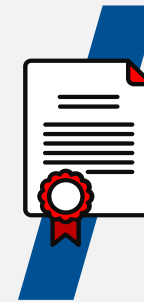
Our mesenchymal precursor/stromal cells respond to and are activated by multiple inflammatory cytokines through surface receptors, resulting in orchestration of an anti-inflammatory cascade



Source: Data on file

Global IP Estate Provides Substantial Competitive Advantage

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



Therapeutic Areas
Core commercial and non-core indications



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



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

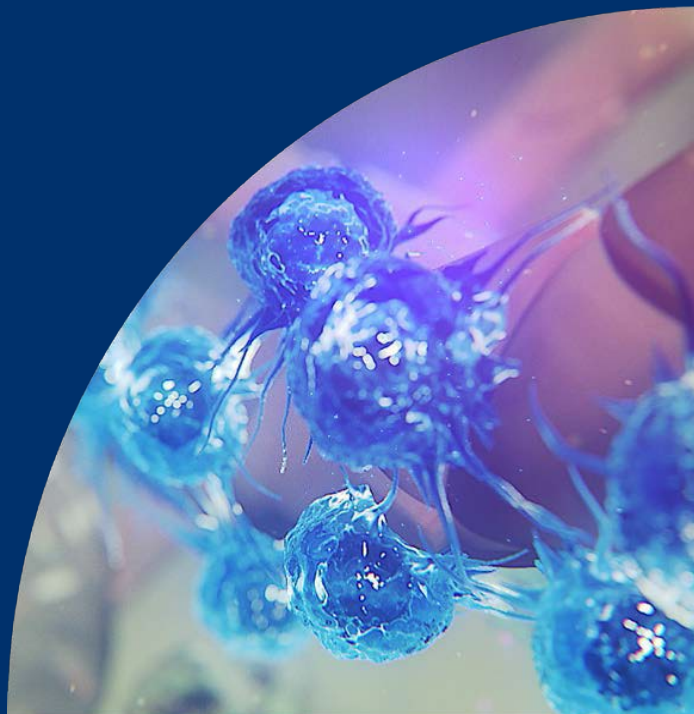
Commercial-scale Manufacturing Capabilities

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

Manufacturing Remestemcel-L



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Financial Results

Financial Highlights



- US\$136.9 million cash on hand at June 30, 2021
- 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 demand²
- Revenue from TEMCELL® royalties increased by 10% from the prior year period to US\$7.2 million in the year ended June 30, 2021
- Mesoblast has entered into a contractual amendment to extend the interest-only period of its current senior debt facility through to at least January 2022 and is in active discussions to refinance the facility
- Ongoing investment in remestemcel-L platform to support the regulatory pathway to potential approval, manufacturing scale up and life cycle management
- We expect to recognize the existing US\$21.9 million of remestemcel-L pre-launch inventory on the balance sheet if we receive FDA approval

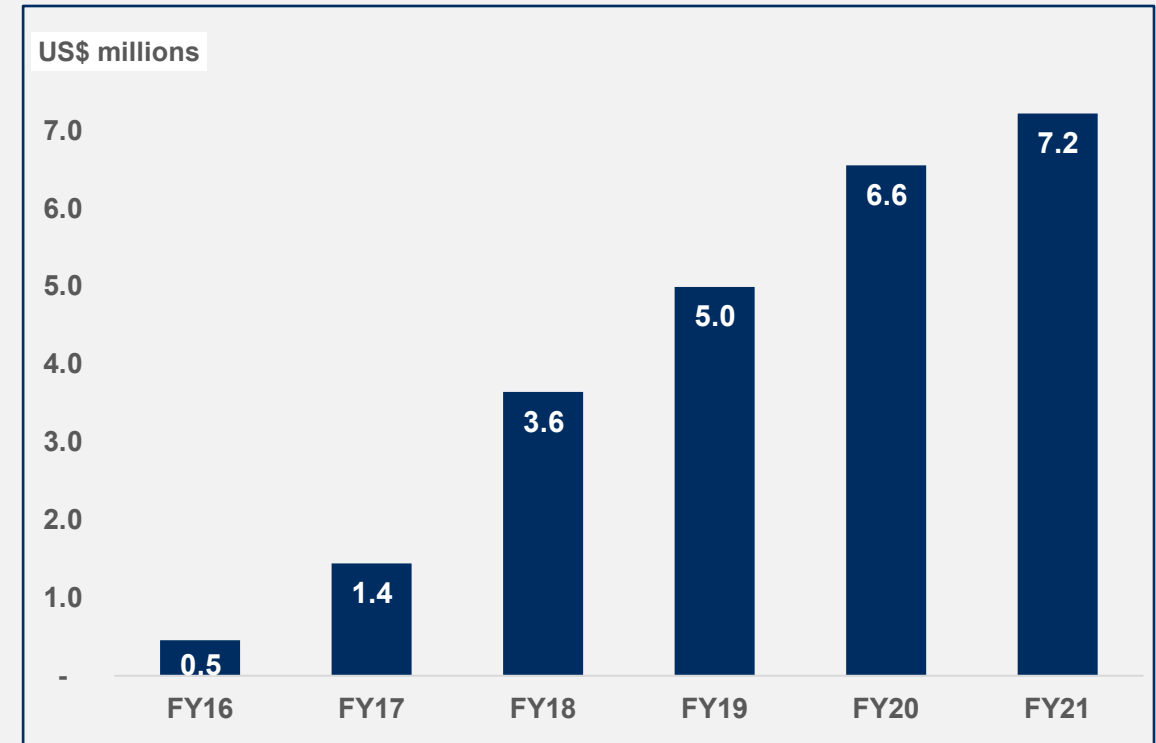
1. TEMCELL® HS Inj. is a registered trademark of JCR Pharmaceuticals Co. Ltd.

2. JCR Pharmaceuticals News Release: *Notice regarding Capital Expenditures to Increase Production Capacity at the Seishin Plant*. July 31, 2020

Continued Growth in Revenues from Sales of TEMCELL in Japan for SR-aGVHD

- JCR Pharmaceuticals has exclusive rights to Mesoblast's MSC technology for acute GVHD in Japan
- FY2021 revenue from TEMCELL® HS Inj¹ royalties increased by 10% from the prior year period to US\$7.2 million
- Product adoption and reimbursement informs Mesoblast US commercial strategy for remestemcel-L (RYONCIL) in acute GVHD
- US addressable market for acute GVHD in children and adults is ~ eight-fold larger than Japan due to greater patient numbers, incidence and pharmacoeconomics

Annual Revenue from TEMCELL Royalties in Japan



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

Ongoing Investment in Remestemcel-L Platform to Support the Regulatory Pathway to Approval, Manufacturing Scale Up & Life Cycle Management



P&L for the 12 mths ended (US\$m)	June 30, 2021	June 30, 2020
Commercialization revenue	7.4	6.6
Milestone revenue	-	25.0
Other revenue, including interest	0.1	0.5
Total Revenue	7.5	32.2
Research and development	(53.0)	(56.1)
Manufacturing	(32.7)	(25.3)
Management & administration	(30.9)	(25.6)
Contingent consideration	18.7	1.4
Other operating income & expenses	1.5	0.3
Finance costs	(10.7)	(14.1)
Loss before tax	(99.6)	(87.3)
Income tax benefit	0.8	9.4
Loss after tax	(98.8)	(77.9)

Figures are rounded

Revenue:

FY2020 included rexlemestrocel-L upfront & milestone payments from Grünenthal and Tasly

Research & Development:

54% of FY2021 (\$28.5 million) related to remestemcel-L, including:

- Clinical, medical & regulatory support (\$14.8 million)
- Process development (including potency assays & support costs) (\$9.5m)
- COVID ARDS Phase 3 clinical trial (\$4.2 million)

Manufacturing:

92% of FY2021 (\$30.2 million) related to remestemcel-L, including:

- Commercial readiness and next generation (\$13.6m)
- Pre-launch inventory (\$13.1m)
- Clinical cell supply for life cycle management (\$3.5m)

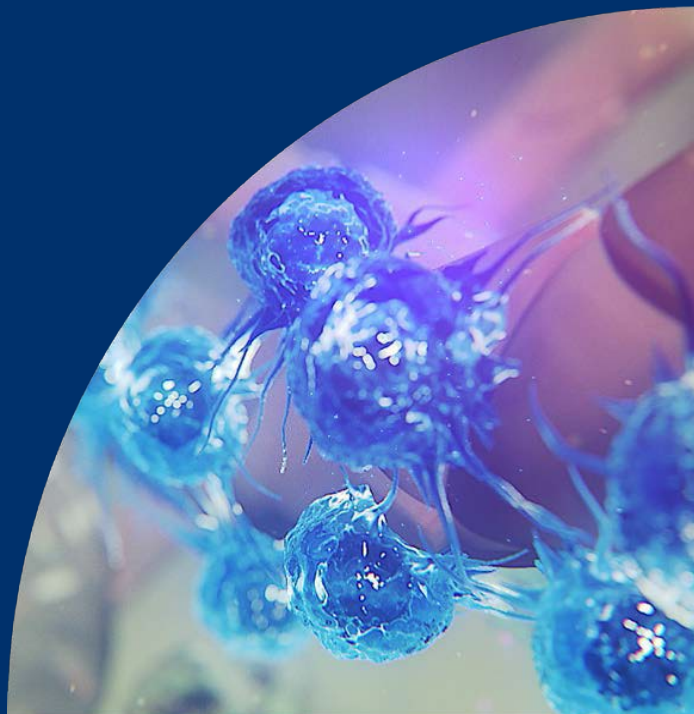
We expect to recognize the existing US\$21.9 million of remestemcel-L pre-launch inventory on the balance sheet if we receive FDA approval

Management & Administration:

Increased costs associated with insurance, BLA filing, debt refinancing and other corporate transactions

Contingent Consideration:

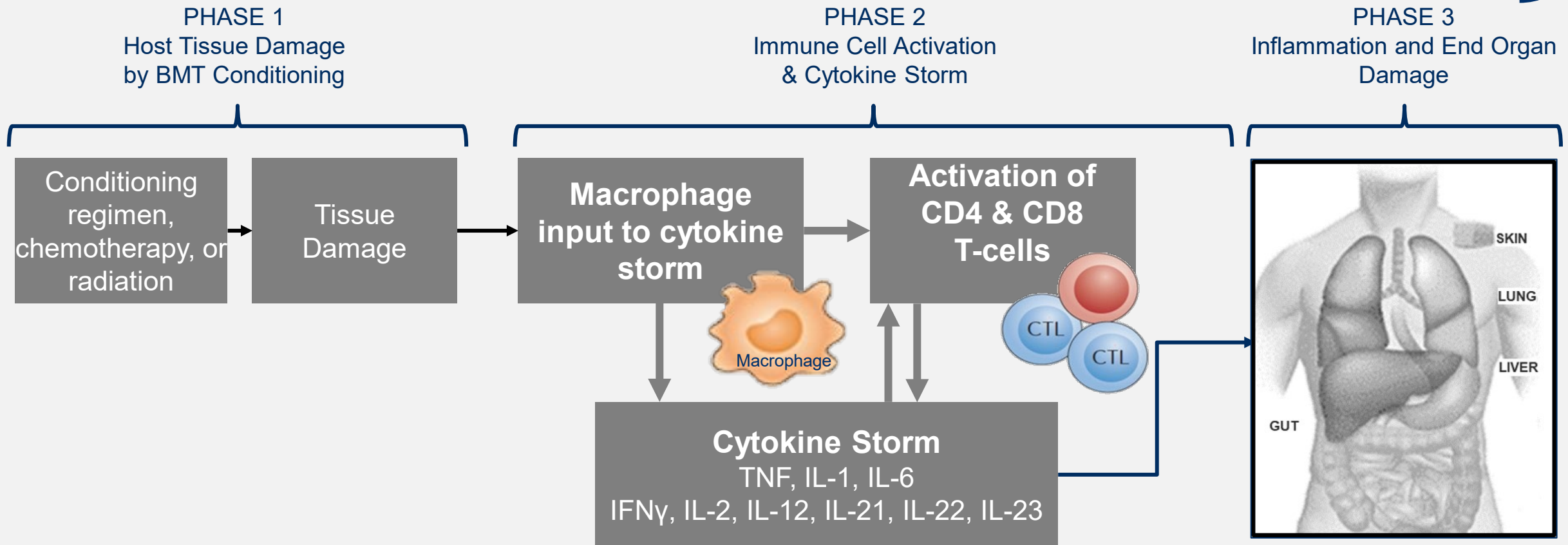
Gain reflects expected reduction in future third party payments



Remestemcel-L

- Acute Graft versus Host Disease (aGVHD)
- Acute Respiratory Distress Syndrome (ARDS)

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



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

Extremely high unmet medical need

- More than 2,000 allogeneic BMTs in children and adolescents in US¹
- Despite prophylaxis, ~50% will develop aGVHD²
- First-line treatment is corticosteroids
- Response rate is ~50%
- Children < 12 years of age have no approved treatment for steroid-refractory acute GVHD

Acute GVHD Primarily Affects Skin, GI Tract, and Liver

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



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

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



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

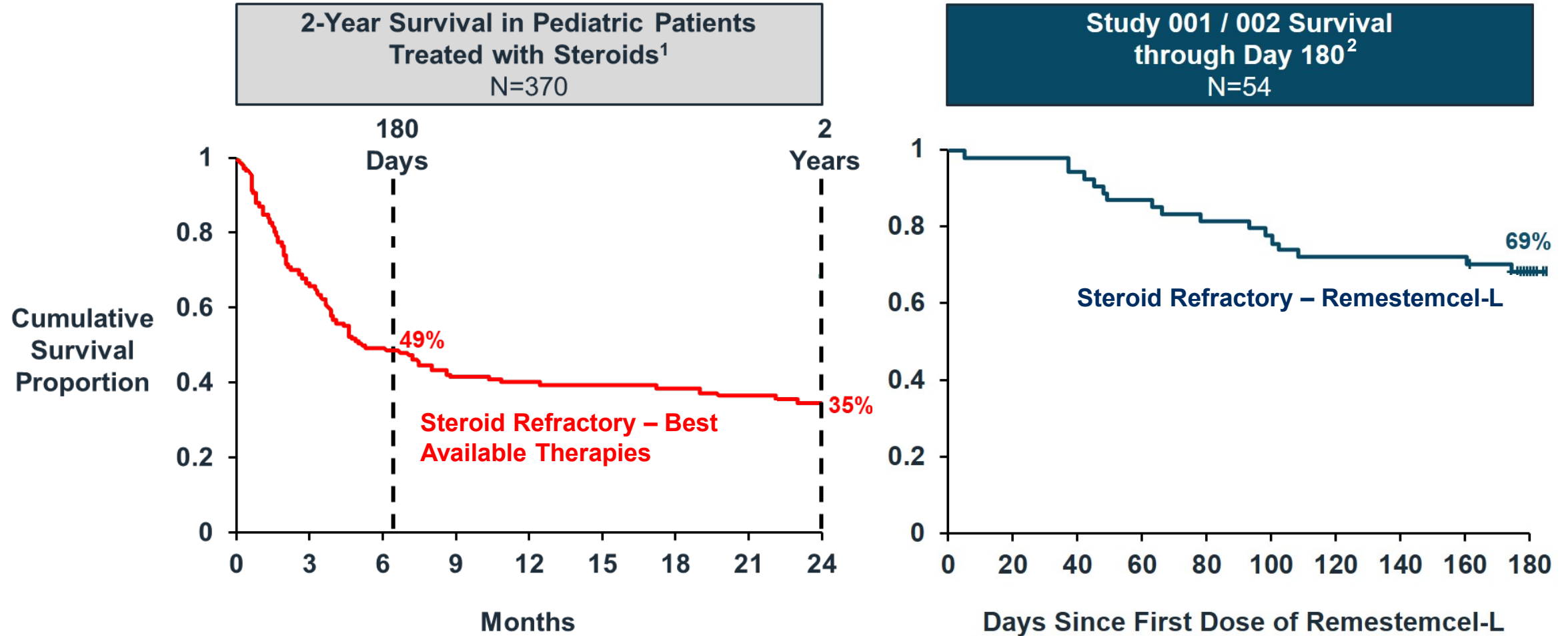
- Remestemcel-L was used as first-line therapy in a randomized controlled Phase 3 trial of 260 patients, with SR-aGVHD, including 27 children
- Remestemcel-L was used as salvage therapy in an expanded access program in 241 children with SR-aGVHD, 80% of whom had Grade C/D disease, and failed institutional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

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

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

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

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



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

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



- Mesoblast continues to be in discussion with the FDA through a well-established regulatory process that may include a BLA resubmission with a six month review with the aim of achieving approval
- Following the recommendation of FDA's Center for Biologics Evaluation and Research (CBER), Mesoblast as a next step will discuss with the Office of Tissue and Advanced Therapies (OTAT) our approach to address certain outstanding chemistry, manufacturing and controls (CMC) items, including potency assay validation
- Mesoblast intends to meet with OTAT in Q4 CY21, to address potency assays and other outstanding CMC items

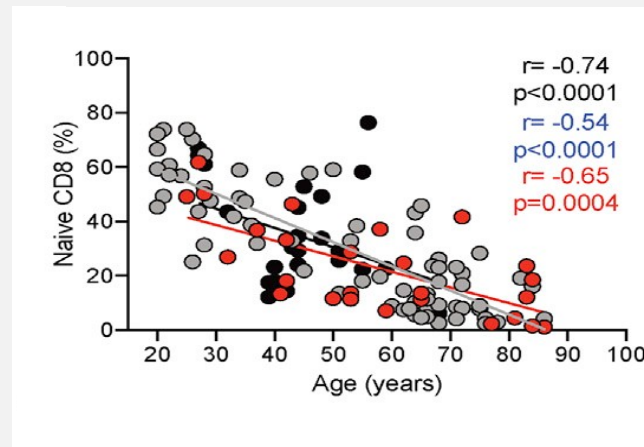
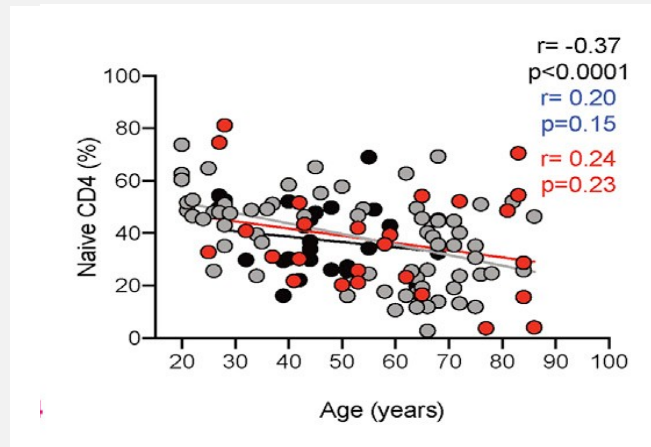


Overview – Remestemcel-L for ARDS due to COVID-19

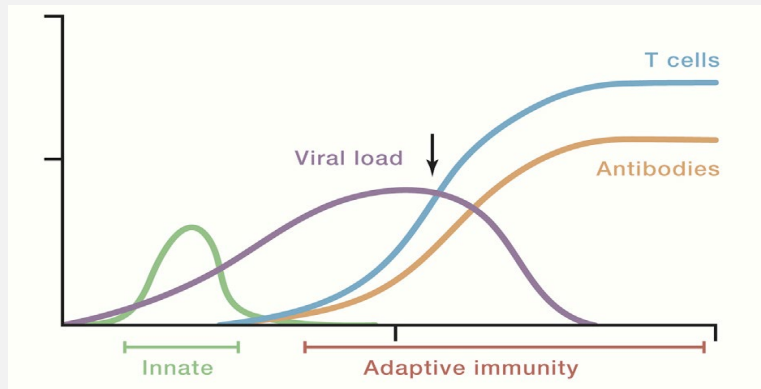
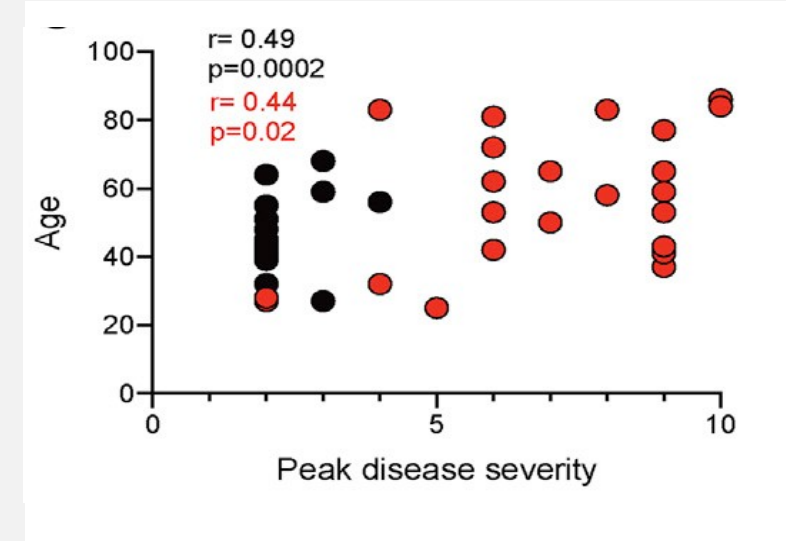
- COVID-19 is a respiratory virus with a high mortality due to a severe inflammatory condition of the lungs called acute respiratory disease syndrome (ARDS)
- ARDS is caused by cytokine storm in lungs of patients infected with COVID-19 and is the primary cause of death
- The extensive safety data of 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

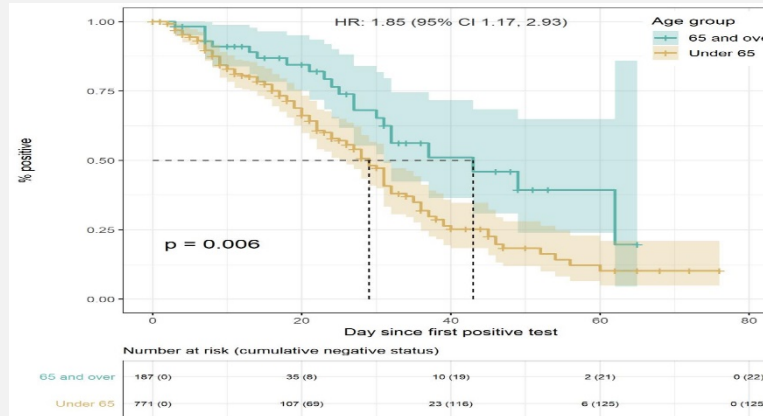
Naïve CD4 and CD8 T Cells reduced in age > 65



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



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)

Clinical Experience with Remestemcel-L in COVID-19 ARDS



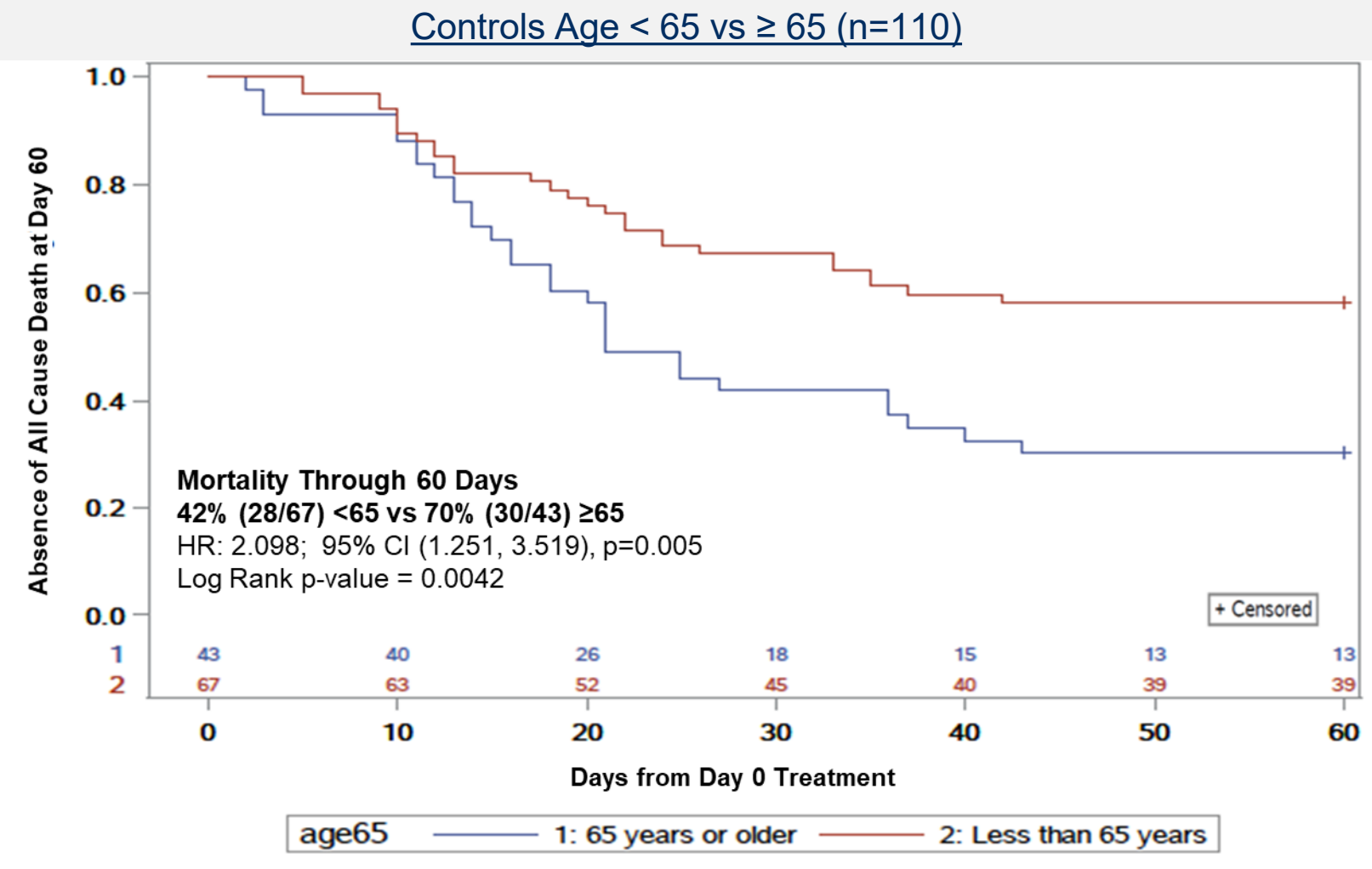
Emergency IND in Ventilator-Dependent COVID-19 ARDS

- **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

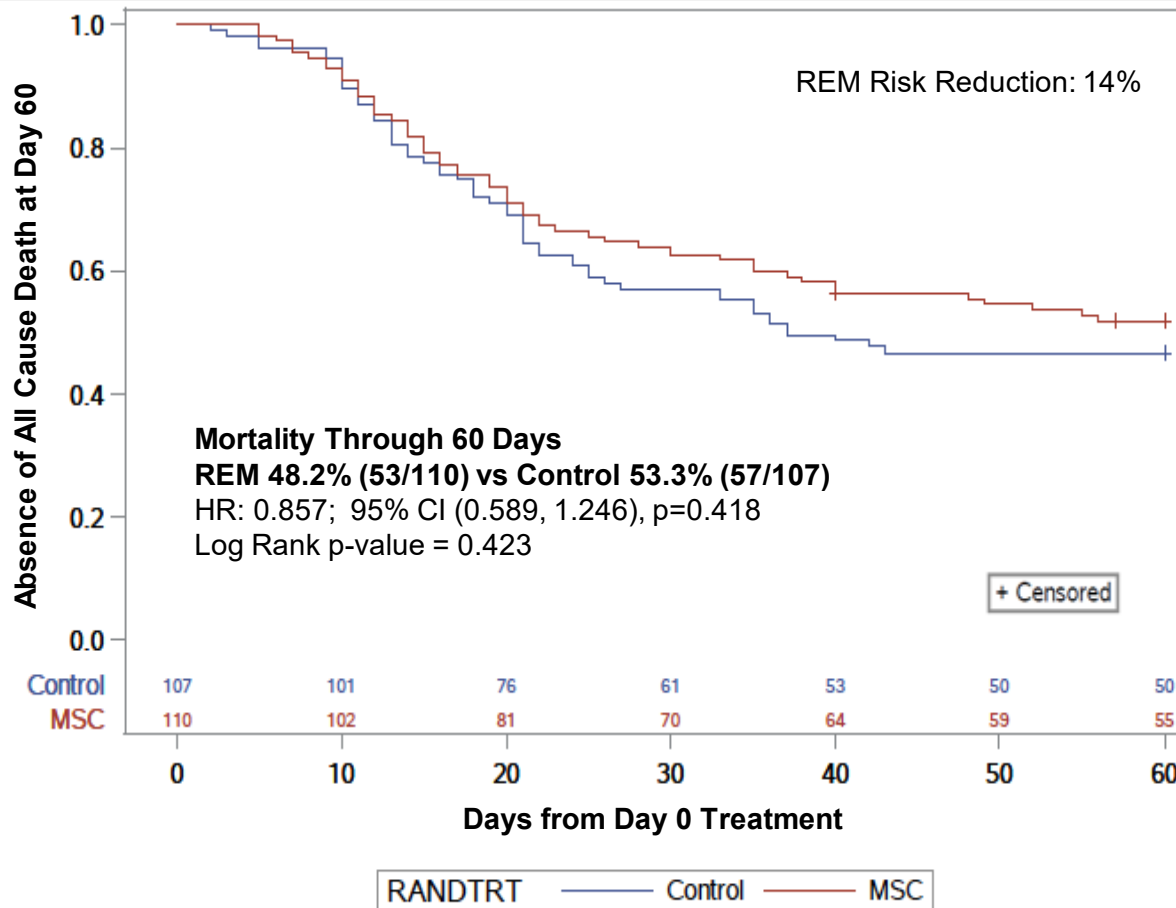
Greater Mortality through Day 60 in Control Patients Older than 65, Consistent with Other Trials



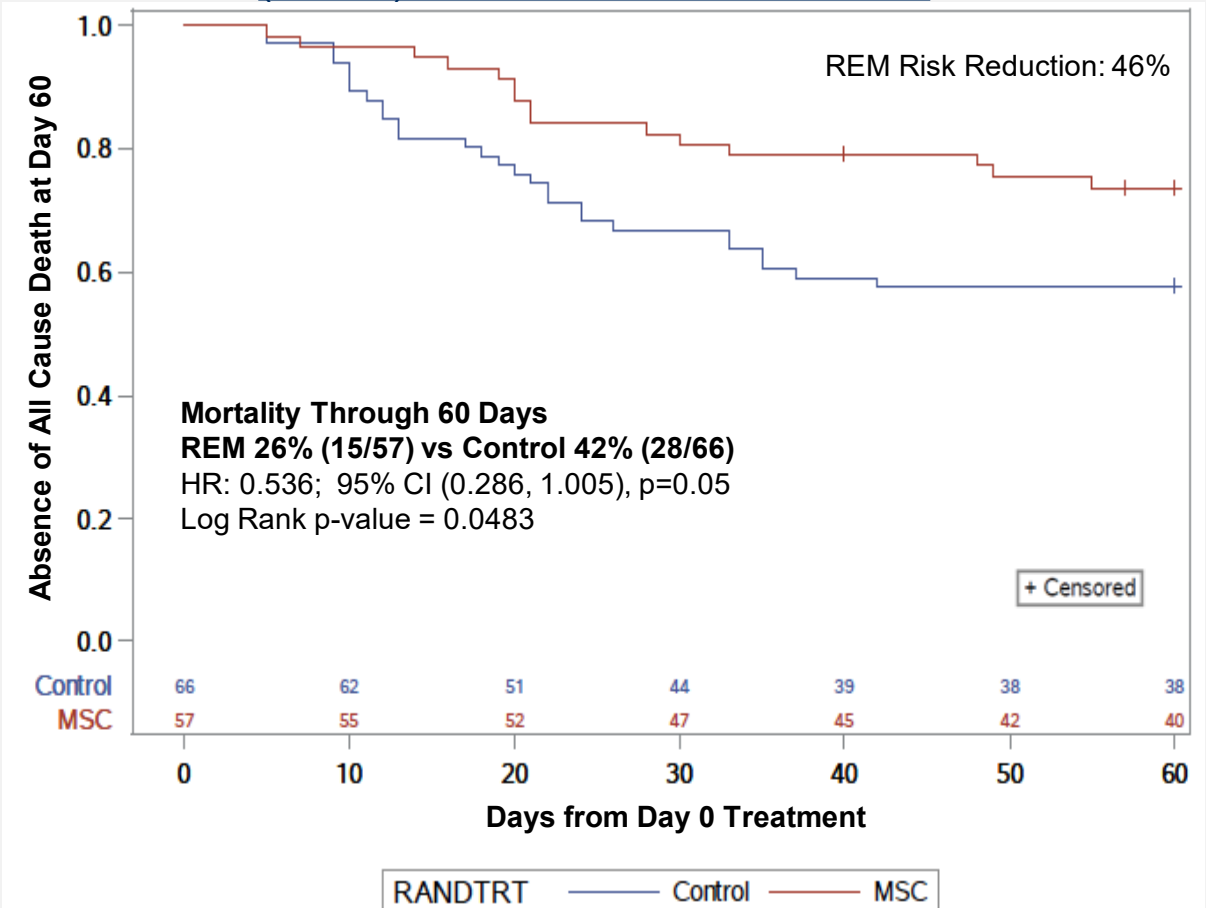
Greatest Mortality Reduction seen in Remestemcel-L Treated Patients < 65 years



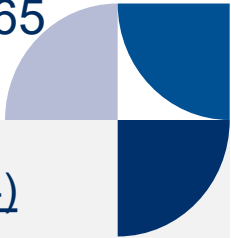
All Modified Intent to Treat (mITT) Patients (n=217)
Remestemcel-L vs Control



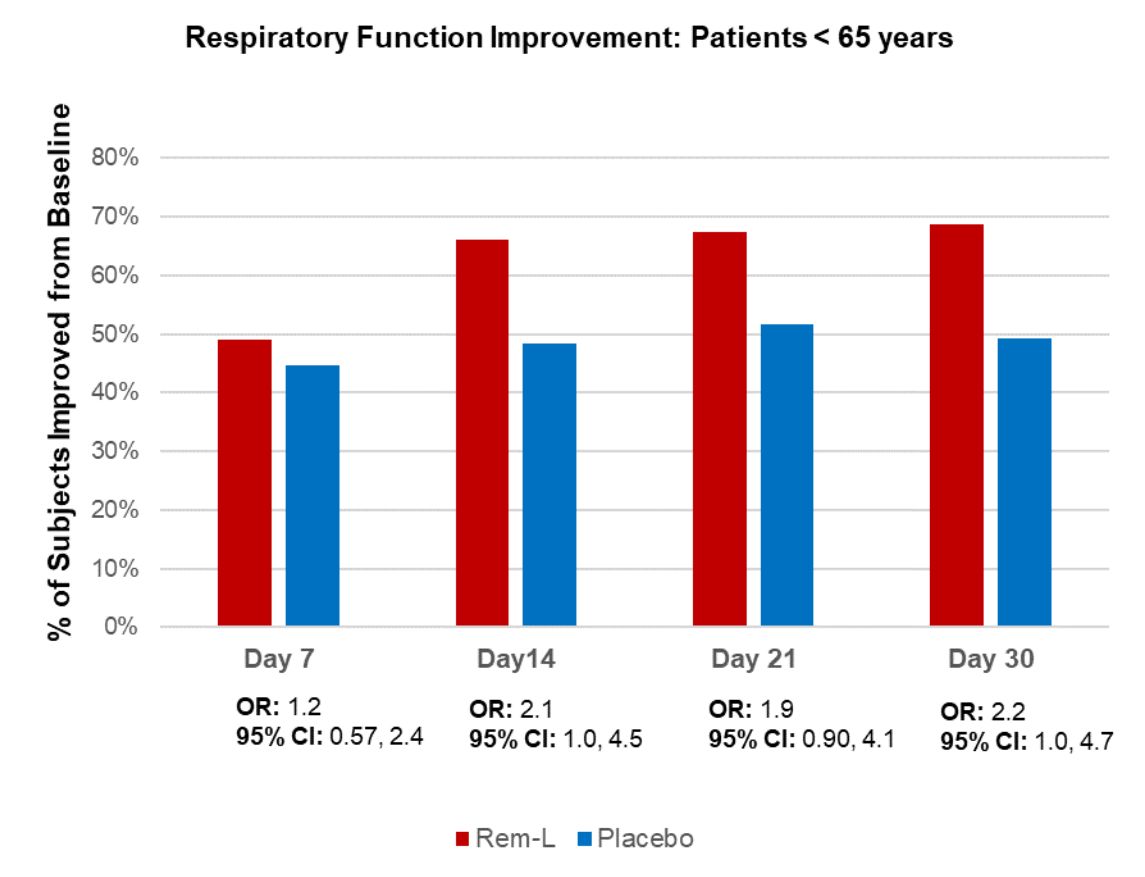
Modified Intent to Treat (mITT) Patients < 65 years old
(n=123), Remestemcel-L vs Control



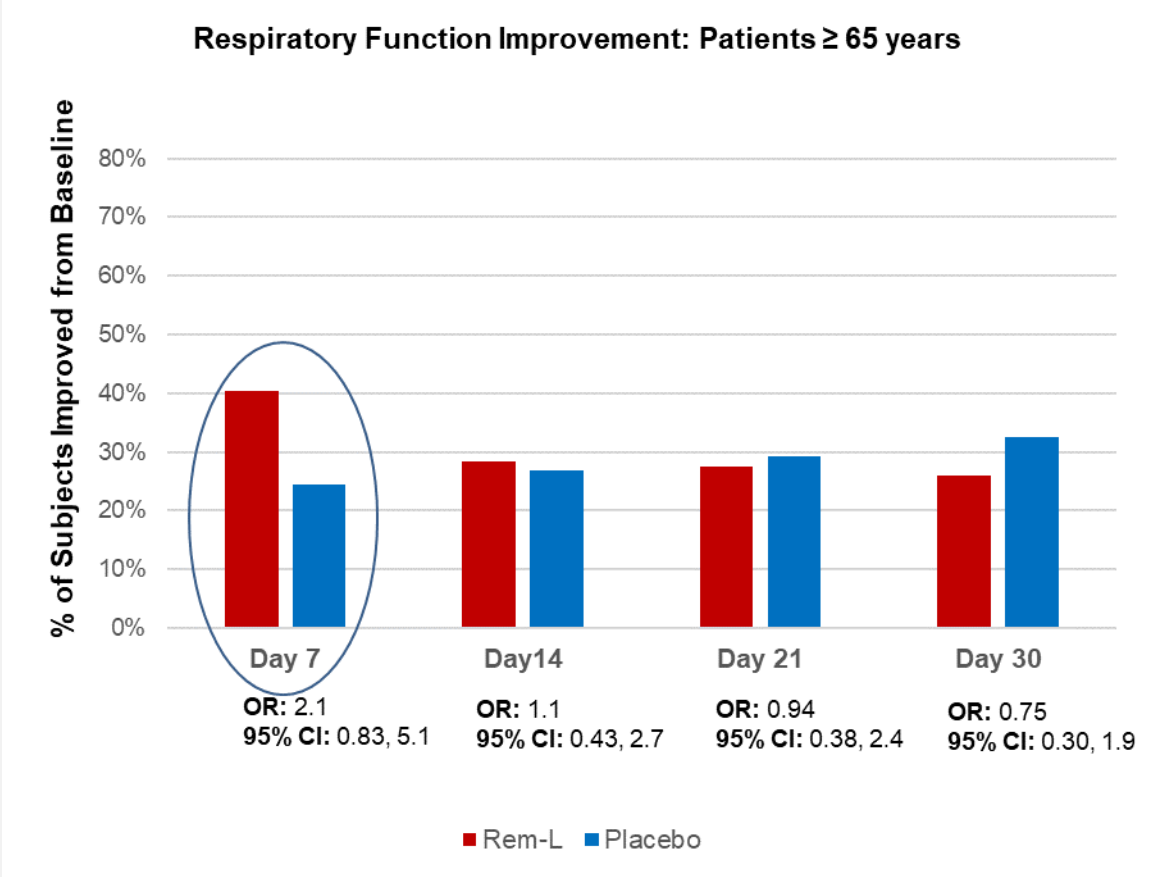
Remestemcel-L Improved ARDS Severity* in Patients < 65 years at All Time Points, and in Patients ≥ 65 years at Day 7: Supports Requirement for Higher or More Prolonged Dosing Regimen in ≥ 65 years



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



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

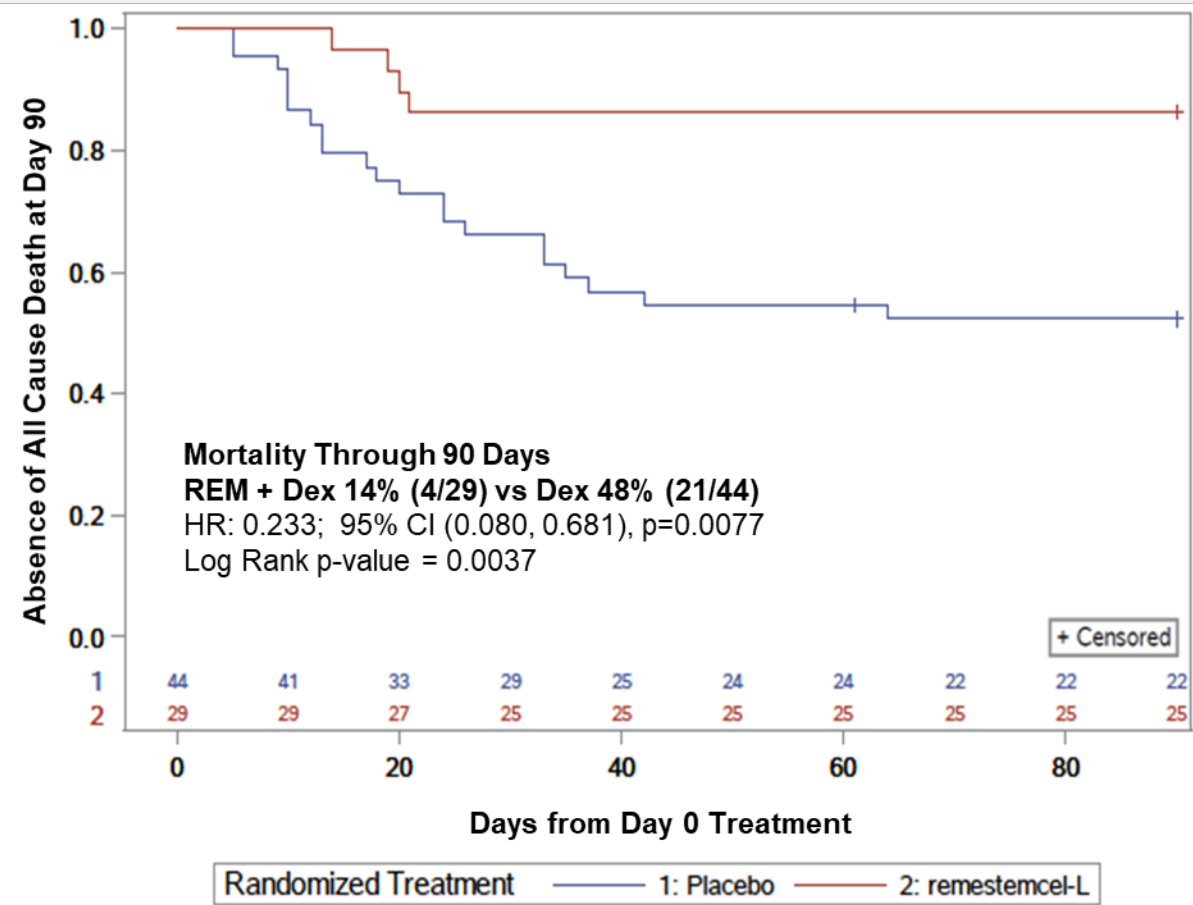


* Measured as resolution and/or improvement of ARDS as defined by the Berlin criteria at Days 7, 14, 21, and 30 post-randomizations

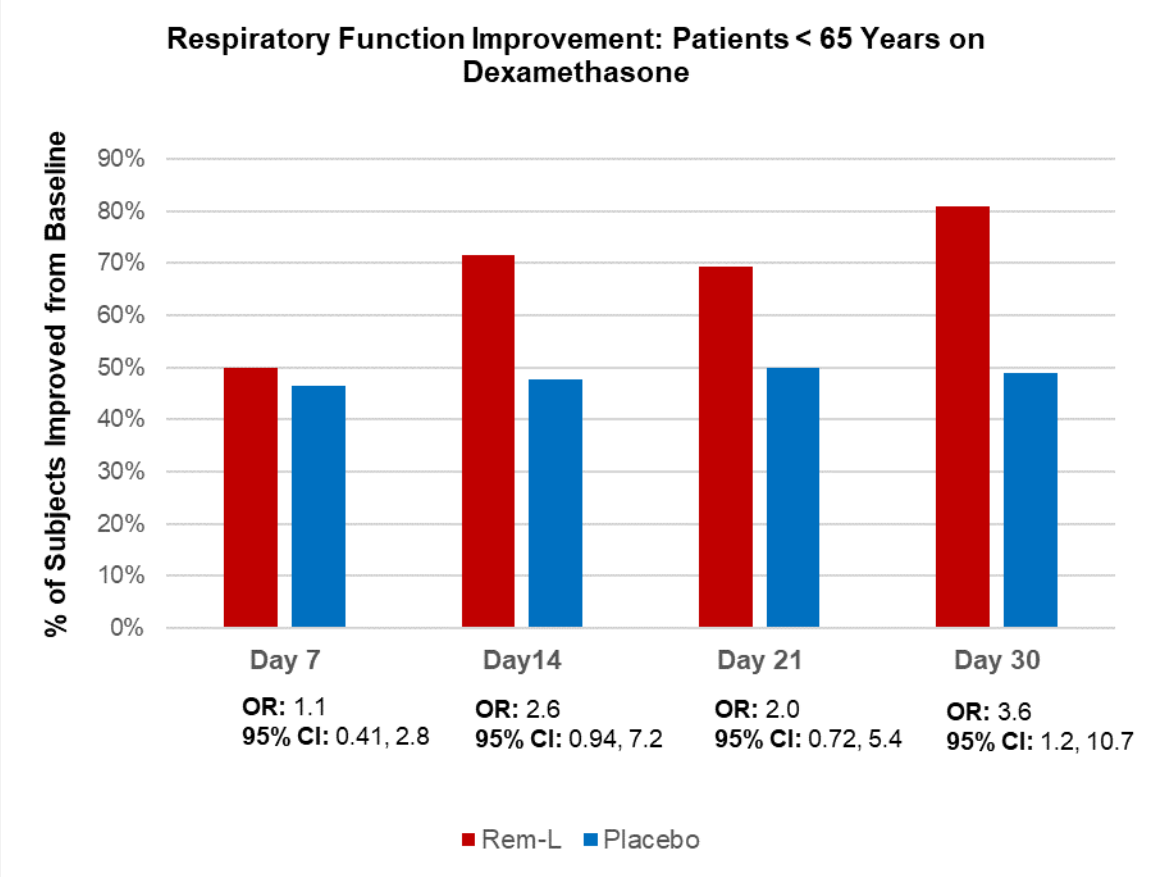
Remestemcel-L Plus Dexamethasone Shows Synergy in Mortality Reduction and Improvement in ARDS Severity in Exploratory Population < 65 years old



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

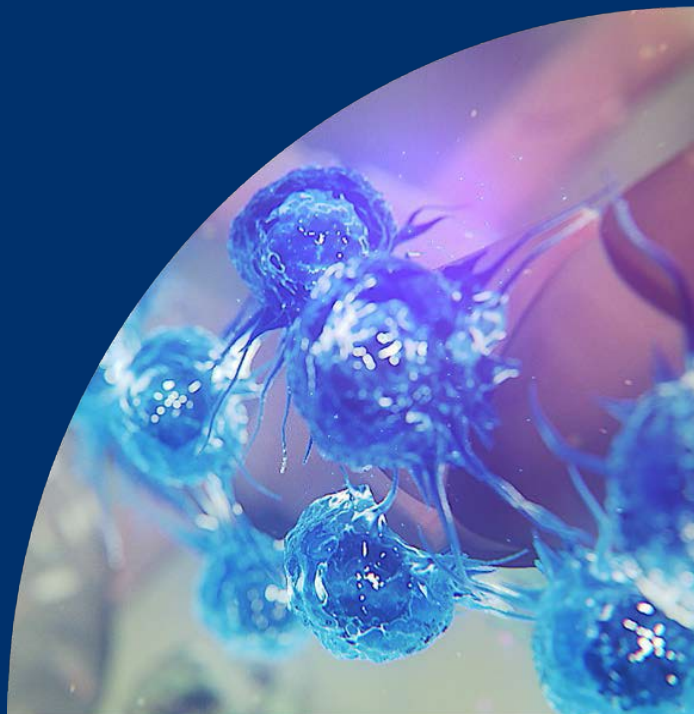
Outcome of Meeting with FDA on Regulatory Pathway for EUA in COVID ARDS



Mesoblast met with the United States Food & Drug Administration (FDA) in regard to potential emergency use authorization (EUA) for remestemcel-L in the treatment of ventilator-dependent patients with moderate or severe acute respiratory distress syndrome (ARDS) due to COVID-19. Outcomes from the meeting included:

- An additional clinical study in COVID ARDS would be required which, if statistically positive, could provide a dataset in conjunction with the recently completed 222 patient clinical study that might be sufficient to support an EUA
- 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 Biologics License Application (BLA) 125706 for pediatric steroid-refractory acute graft versus host disease (SR-aGVHD)
- Potency assays must be established and agreed prior to commencement of the proposed Phase 3 clinical trial
- Potency assays currently in development appeared to be reasonable based on in vitro results provided in the briefing document, the in vitro activity of the product appears to be relatively well established, though the relationship between in vitro activity and the product's actual mechanism of action remains theoretical

Mesoblast intends to meet with FDA's Office of Tissue and Advanced Therapies (OTAT) in Q4 CY21 to address potency assays for remestemcel-L in relation to SR-aGvHD, attributes which we believe to be also relevant to COVID ARDS



Rexlemestrocel-L

- Chronic Heart Failure (CHF)
- Chronic Low Back Pain (CLBP)

Chronic Heart Failure: Rising Incidence & High Mortality



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

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

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

DREAM HF: Overview of Phase 3 Trial

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

Conclusions: Rexlemestrocel-L Phase 3 Trial in Chronic Heart Failure

- Rexlemestrocel-L may provide a major breakthrough in reducing heart failure progression and mortality when used early (class II disease), and may provide durable protection from heart attacks or strokes in high-risk patients
 - 60% reduction in incidence of ischemic MACE (heart attack or stroke) across entire 537 patient study population, irrespective of NYHA class II or III, ischemic or non-ischemic etiology (p=0.002)
 - 30% reduction in incidence of three-point MACE (cardiac death, heart attack or stroke) across entire 537 patient study population (p=0.027)
 - 55% reduction in incidence of three-point MACE (cardiac death, heart attack or stroke) in NYHA class II patients (n=206) (p=0.009)
 - 60% reduction in cardiac death in NYHA class II patients (p=0.037) and prevention of progression to NYHA class III rate of cardiac death
- Based on observed reduction in mortality and morbidity in this Phase 3 trial, Mesoblast expects to receive feedback in the next quarter from FDA on potential approval pathways

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 condition¹
- Inflicts substantial direct and indirect costs on the healthcare system¹, including excessive use of opioids in this patient population

Minimal Treatment Options

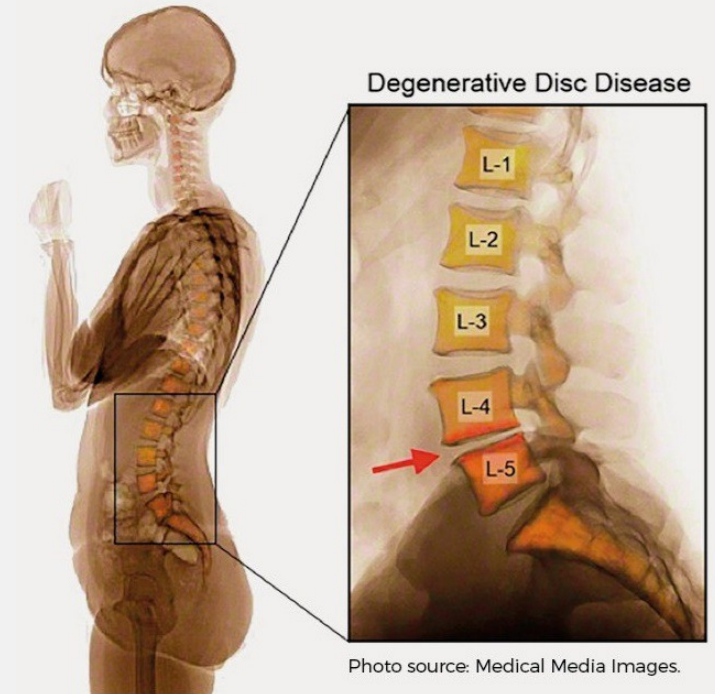
- Minimal treatment options for patients with chronic low back pain (CLBP) who fail conservative therapy include opioids and surgery
- 50% of opioid prescriptions are for CLBP

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.^{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



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.

Phase 3 Trial MSB-DR003 – Rexlemestrocel-L (MPC-06-ID)



- Randomized placebo-controlled three-arm trial
- Patients with >6 months chronic discogenic low back pain not responsive to conservative measures, including NSAIDs, opioids or epidural steroid injection
- Diagnosis of degenerative disc disease by MRI, exclusion of non-discogenic causes
- 404 enrolled patients, randomized to single intra-discal injection of saline, MPC or MPC + hyaluronic acid (HA) carrier
- Randomization stratification required balanced numbers of opioid users across treatment arms

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
- Based on the above results from this Phase 3 trial, Mesoblast expects to receive feedback in the next quarter from FDA on potential approval pathways

Key Initiatives and Upcoming Milestones

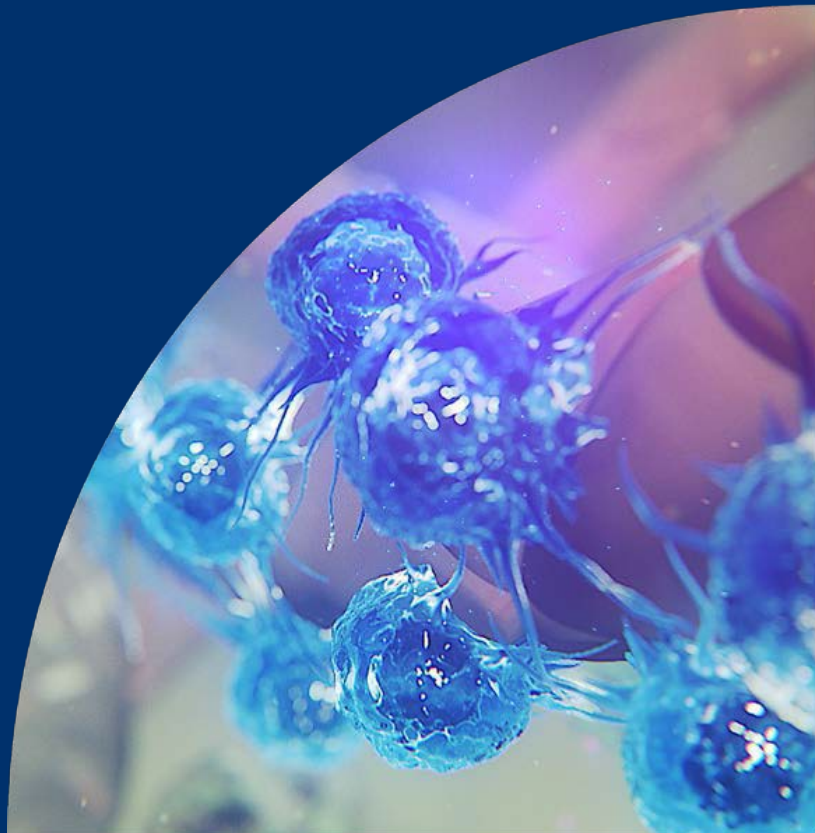


Remestemcel-L for children and adults with systemic inflammatory diseases

- Mesoblast continues to be in discussion with the FDA through a well-established regulatory process for potential approval of remestemcel-L in the treatment of SR-aGVHD in children
- During the next quarter Mesoblast plans to meet with FDA to address certain outstanding CMC items, including potency assay development, required for a potential BLA resubmission and a six month review
- Mesoblast intends to reach agreement with the FDA on the final protocol and potency assay required for an additional Phase 3 trial in COVID-19 ARDS with the objective to obtain an EUA
- The license and collaboration agreement between Mesoblast and Novartis for the development, manufacture, and commercialization of remestemcel-L, with an initial focus on the development of the treatment of ARDS, remains subject to certain closing conditions, including time to analyze the results from the COVID-19 ARDS trial

Rexlemestrocel-L programs for chronic heart failure and chronic low back pain

- Mesoblast expects to receive feedback from the FDA in the next quarter on the potential pathways to US regulatory approval for its rexlemestrocel-L technology platform following the recently completed Phase 3 trials in patients with chronic heart failure and chronic low back pain



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