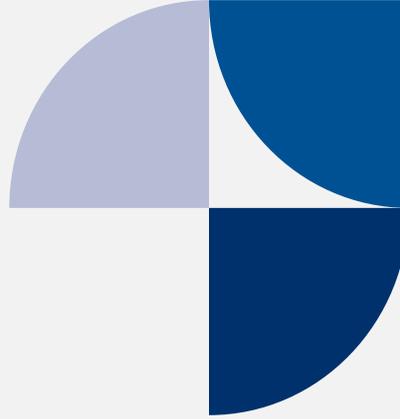




## Operational Highlights & Financial Results for the Period Ended March 31, 2021

JUNE 2021

ASX: MSB; Nasdaq: MESO

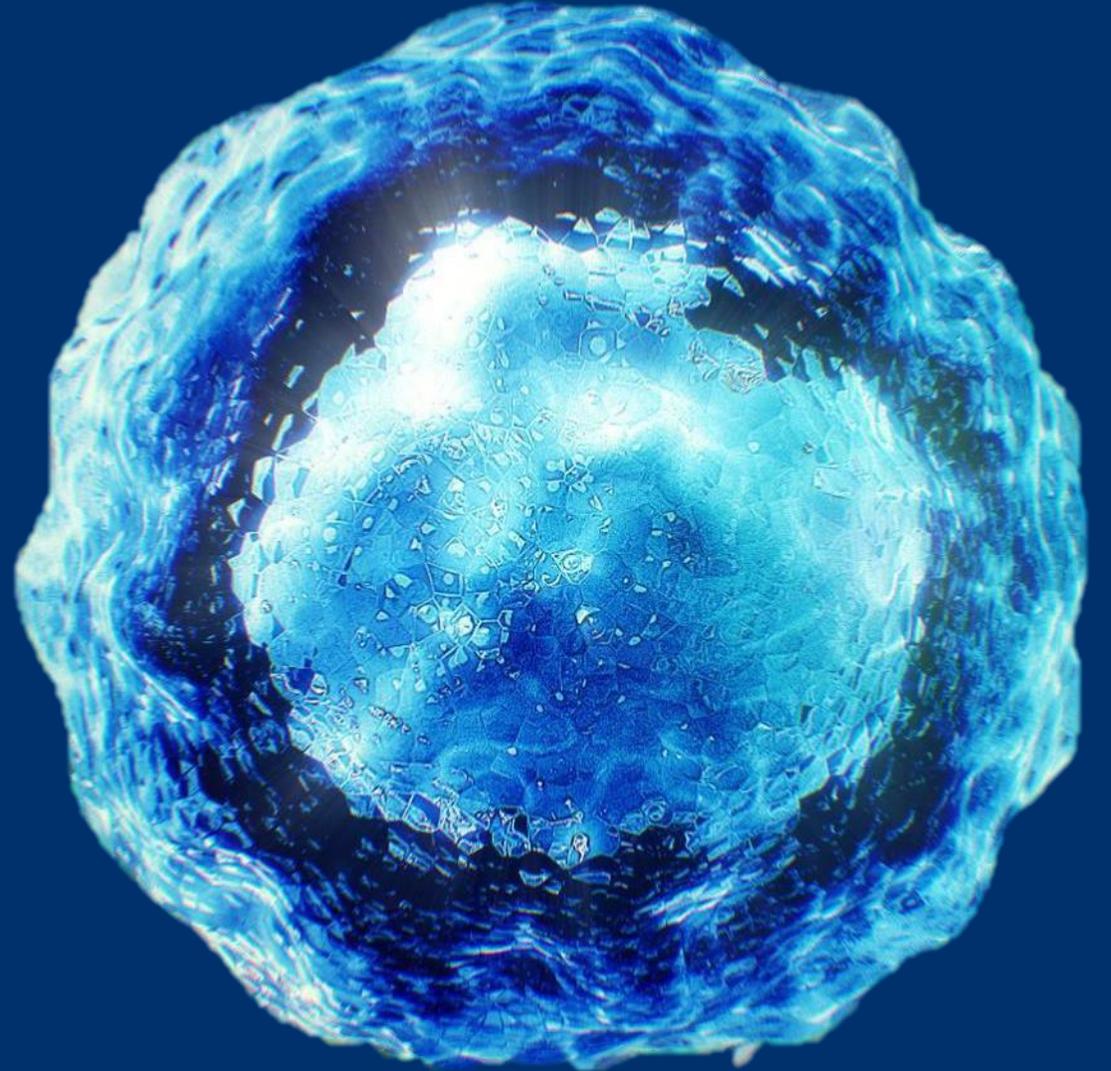


## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

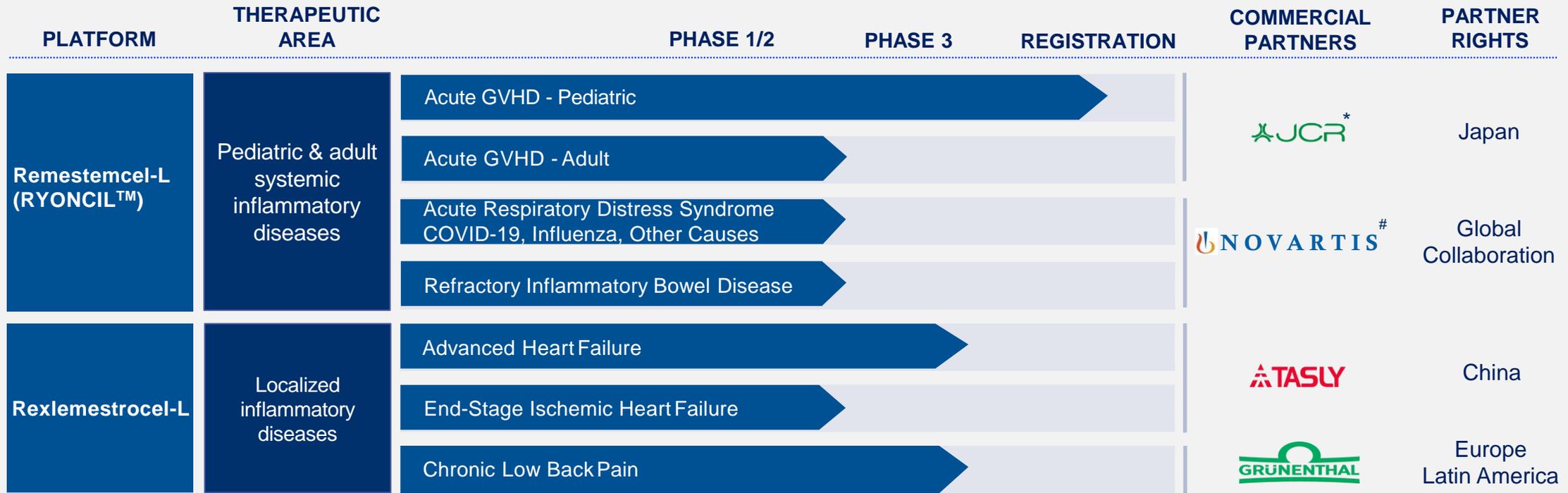
This presentation includes forward-looking statements that relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from any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

## Our Mission

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



# Pipeline



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

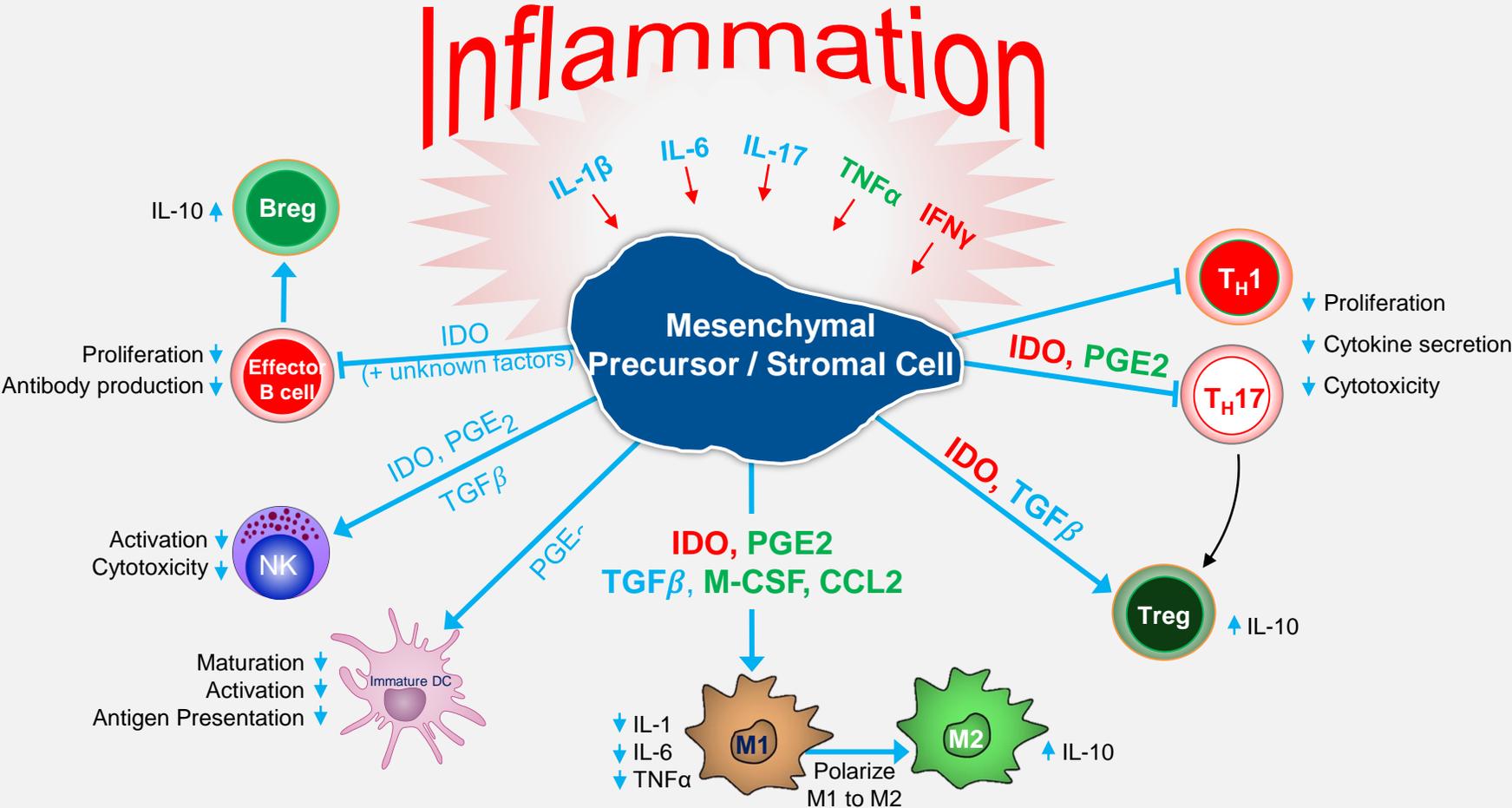
\* Mesoblast has the right to use data generated by JCR Pharmaceuticals Co Ltd in Japan to support its development and commercialization plans for remestemcel-L in the US and other major healthcare markets, including for GVHD and Hypoxic Ischemic Encephalopathy

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

# Platform Technology – Mechanism of Action



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



Source: Data on file

# Global IP Estate Provides Substantial Competitive Advantage

- Extensive patent portfolio with protection extending through 2040 in all major markets
- Over 1,100 patents and patent applications (82 patent families) across all major jurisdictions
- Covers composition of matter, manufacturing, and therapeutic applications of mesenchymal lineage cells
- Provides strong global protection in areas of our core commercial focus against cell-based competitor products
- When outside our core commercial areas, may consider granting rights to third parties who require access to our patent portfolio to commercialize their products
- Mesoblast receives royalty income from its patent licensee TiGenix, S.A.U., a wholly owned subsidiary of Takeda, on its worldwide sales of its product Alofisel® for the treatment of complex perianal fistulas in adult patients with Crohn's disease, as well as milestone payments



**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

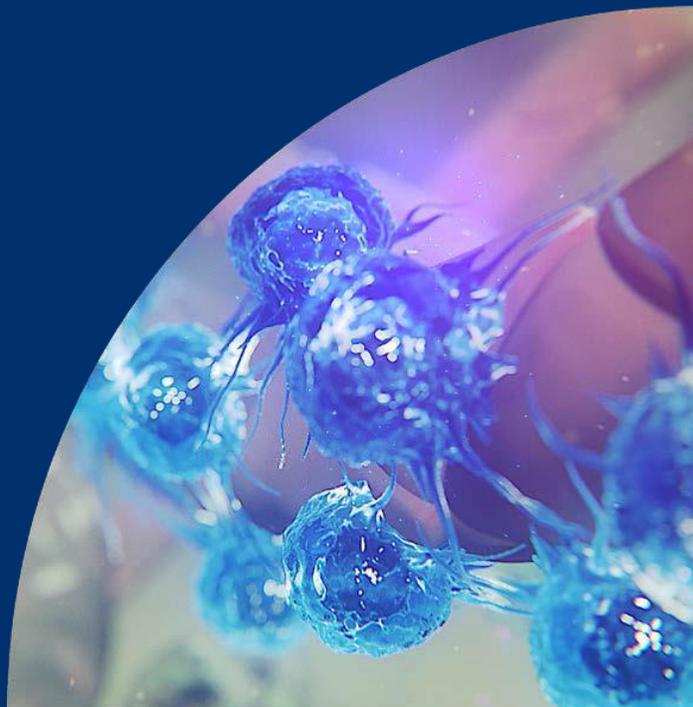
- Scalable allogeneic “off-the-shelf” cellular platforms
- Manufacturing meets stringent criteria of international regulatory agencies
- Robust quality assurance processes ensure final product with batch-to-batch consistency and reproducibility
- Projected increase in capacity requirements for maturing 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



## Strengthened Balance Sheet After Recent Capital Raise



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

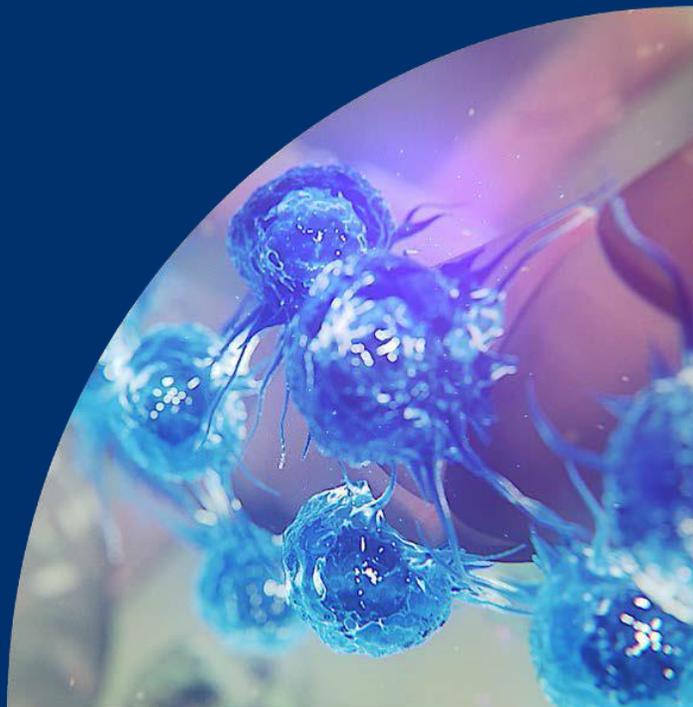
# Ongoing Investment in R&D and Manufacturing



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

Figures are rounded

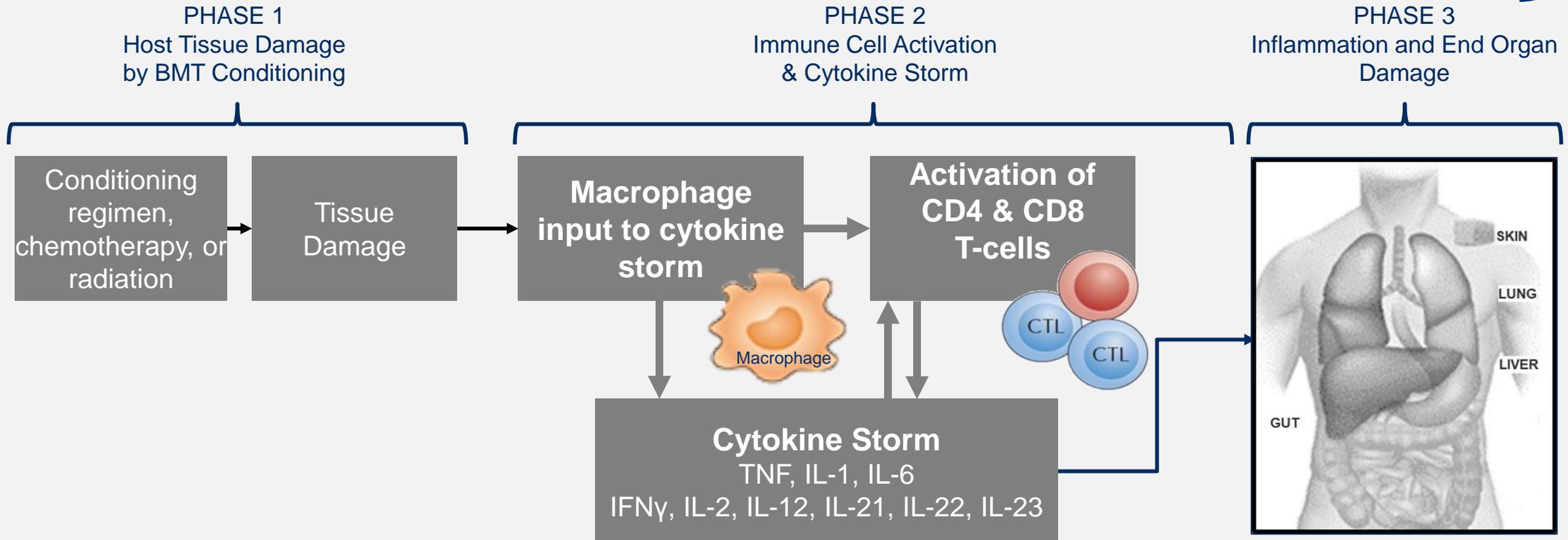
\*Increase was predominantly due to one-off expenditure in legal and professional fees associated with financing and FDA regulatory activities



## Remestemcel-L

- Acute Graft versus Host Disease
- Acute Respiratory Distress Syndrome

# 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 US<sup>1</sup>
- Despite prophylaxis, ~50% will develop aGVHD<sup>2</sup>
- 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%<sup>2-5</sup> when involving gut and liver



© J Kurtzberg MD, reproduced with permission

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

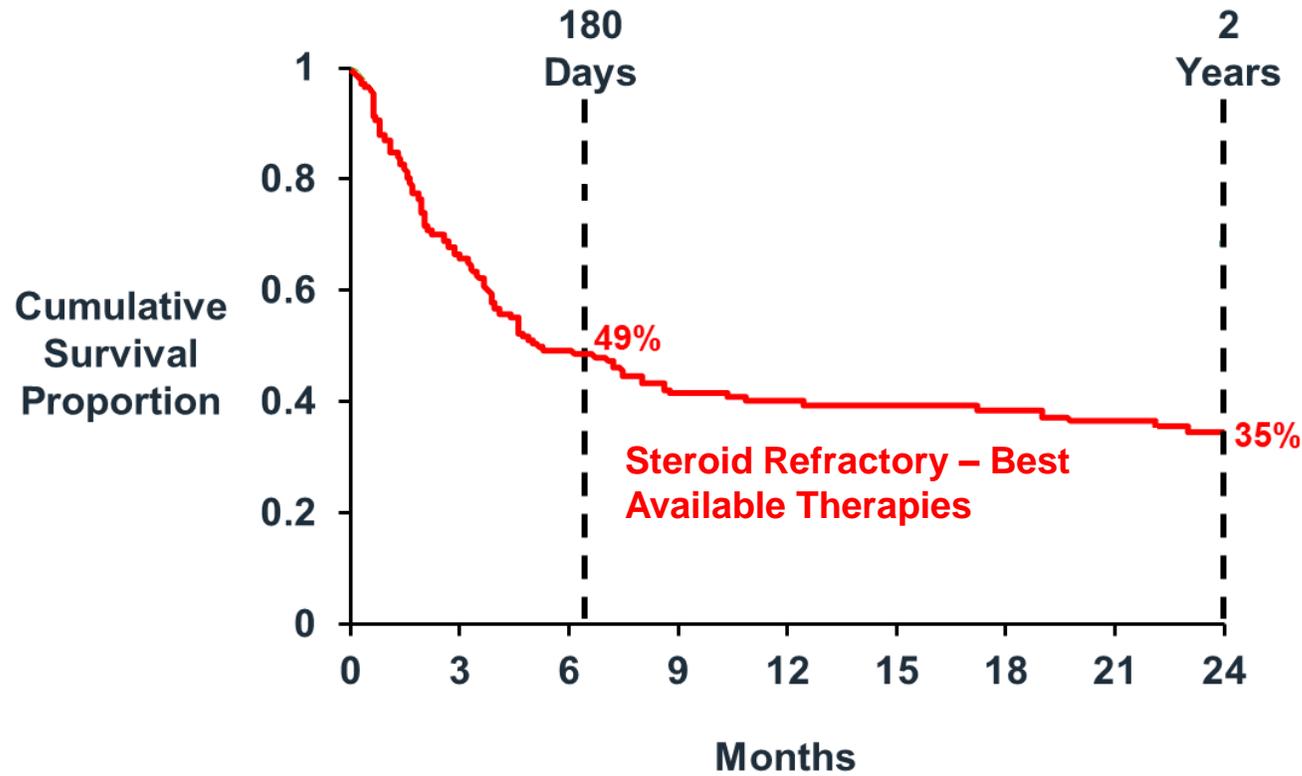
Source: ODAC Advisory Committee Briefing Document and Presentation August 2020.

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

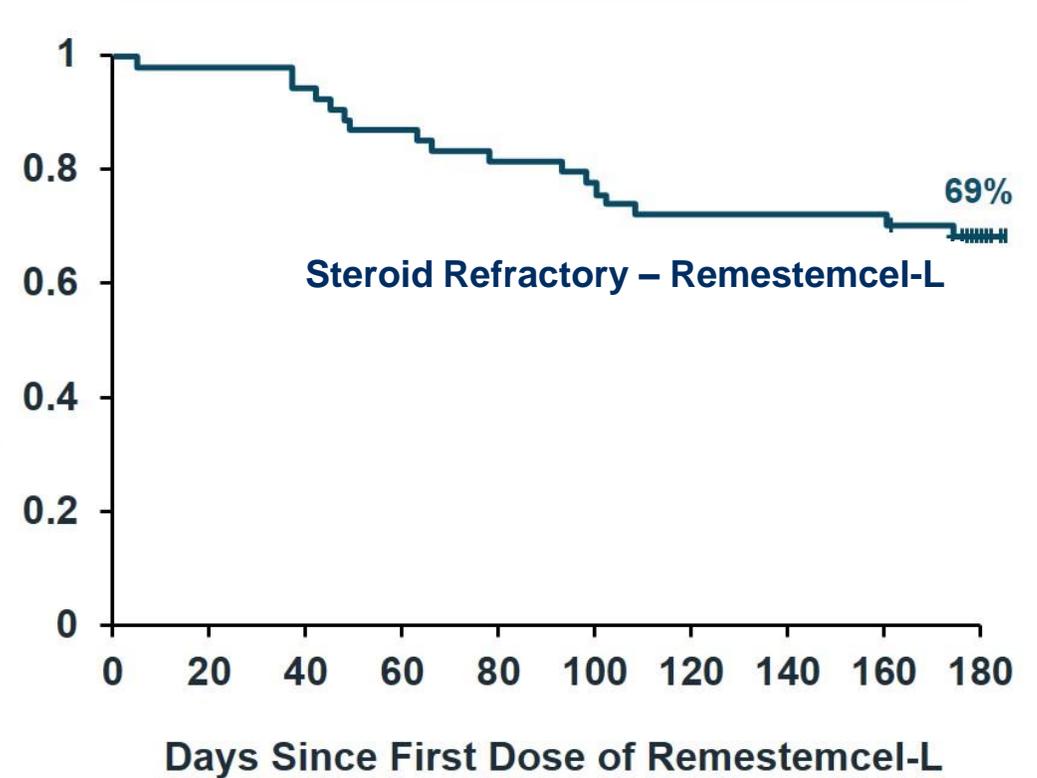
# Remestemcel-L Improved Dismal Survival in Children with SR-aGVHD



**2-Year Survival in Pediatric Patients Treated with Steroids<sup>1</sup>**  
N=370



**Study 001 / 002 Survival through Day 180<sup>2</sup>**  
N=54



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

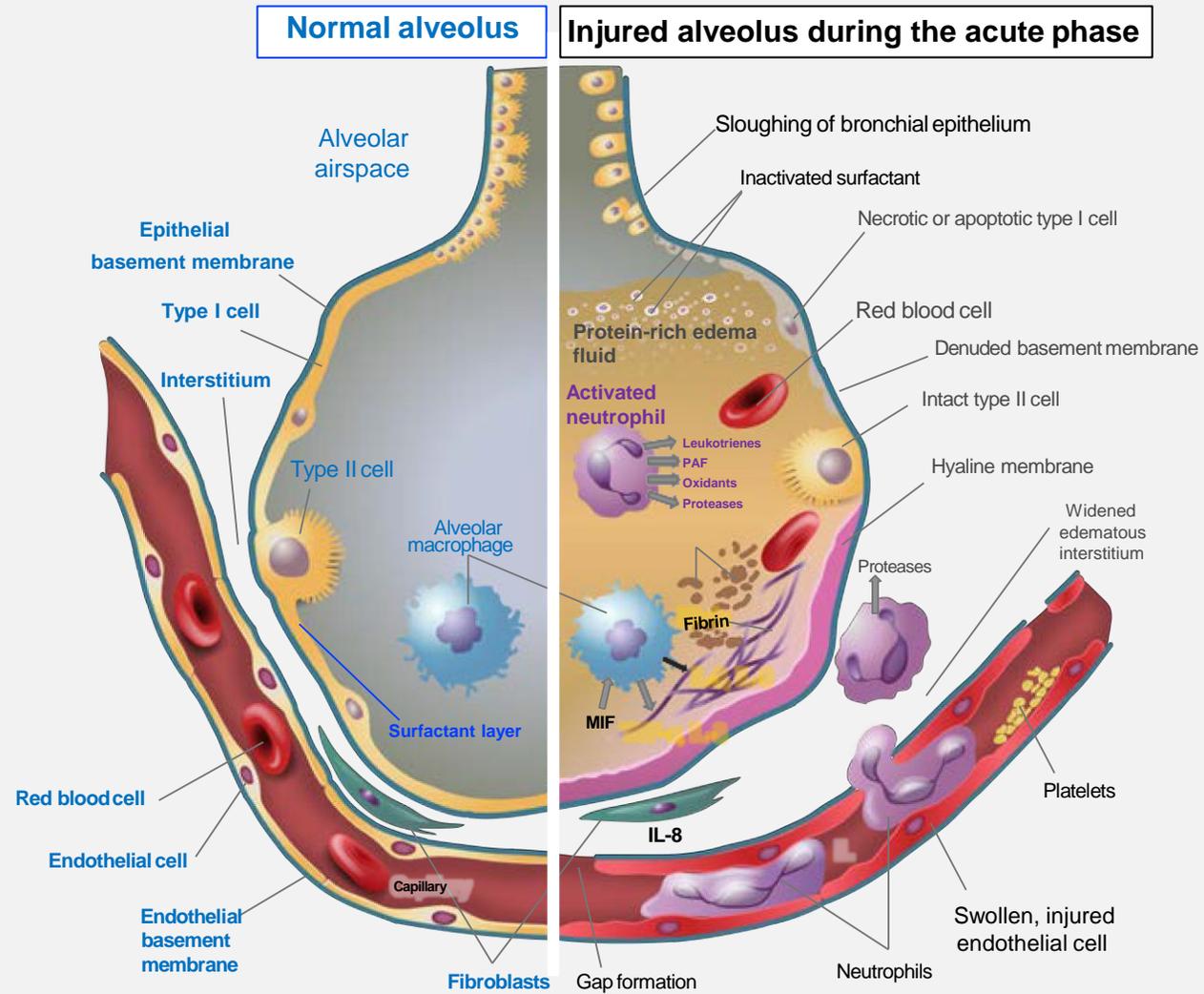
# Remestemcel-L: Regulatory & Commercial Update for SR-aGVHD



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

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

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



Source: Matthay MA, Zimmerman GA. Am J Respir Cell Mol Biol. 2005;33:319-27

## Acute respiratory distress syndrome (ARDS)

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

## Pathophysiology

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

1. Matthay MA., et al. Acute Respiratory Distress Syndrome. Nature 2019 5:18. doi: 10.1038/s41572-019-0069-0; 2. Bellani G, Laffey JG, Pham T, et al. Epidemiology and patterns of care, and mortality for patients with acute respiratory distress syndrome in intensive care units in 50 countries. JAMA 2016;315:788-800; 3. Petrilli CM et al. Factors associated with hospitalization and critical illness among 4,103 patients with Covid-19 disease in New York City. MedRxiv 2020; 4. Gibson PG., et al. COVID-19 ARDS: clinical features and differences to “usual” pre-COVID ARDS. Med J Aust. 24 April 2020

# 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  $\geq 65$  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  $\geq 65$ : 125 patients < 65 years, 97 patients  $\geq 65$  years

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

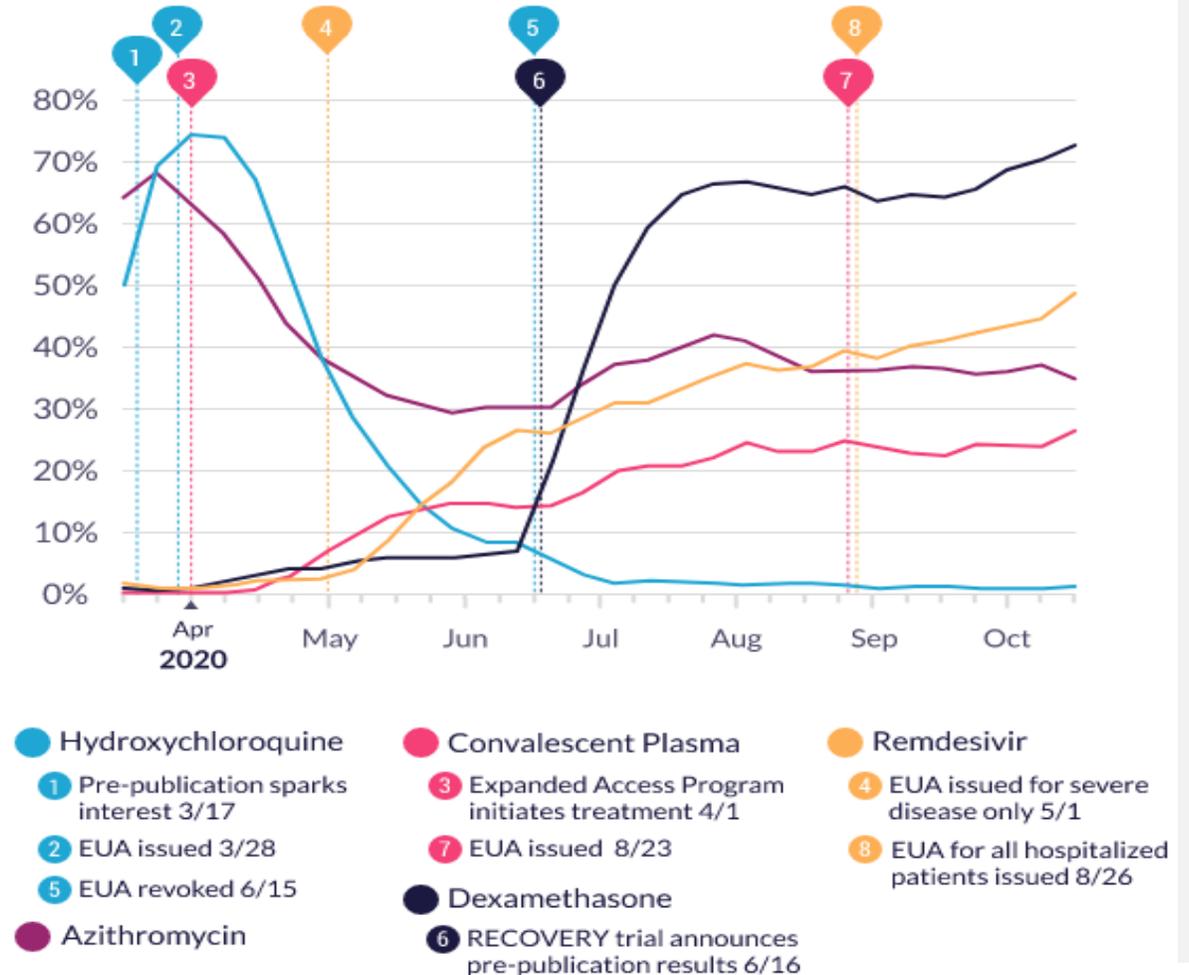
- Recent experience suggests that mortality benefits in ARDS patients are most likely to be seen when using anti-inflammatory therapy early and prior to mechanical ventilation<sup>1</sup>
- During the conduct of the trial overall mortality in hospitalized COVID-19 patients dropped from 25.6% to 7.6%<sup>2</sup> due to widespread use of corticosteroids, antivirals and better supportive care
- Mortality benefits in hospitalized COVID-19 patients seen predominantly in younger patients (<65 years old)
- As a result of widespread use of anti-inflammatory agents and high flow nasal oxygen prior to mechanical ventilation, ventilated COVID-19 ARDS patients enrolled midway through the trial were significantly older and more refractory to all therapies

<sup>1</sup> Gordon AC, et al. Interleukin-6 Receptor Antagonists in Critically Ill Patients with Covid-19 – Preliminary report. doi.org/10.1101/2021.01.07.21249390

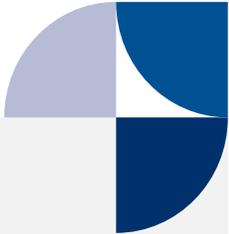
<sup>2</sup> Horwitz LI, Et al. Trends in COVID-19 Risk-Adjusted Mortality Rates. *Jnl Hosp Med.* Oct 2020

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

## Primary Treatments

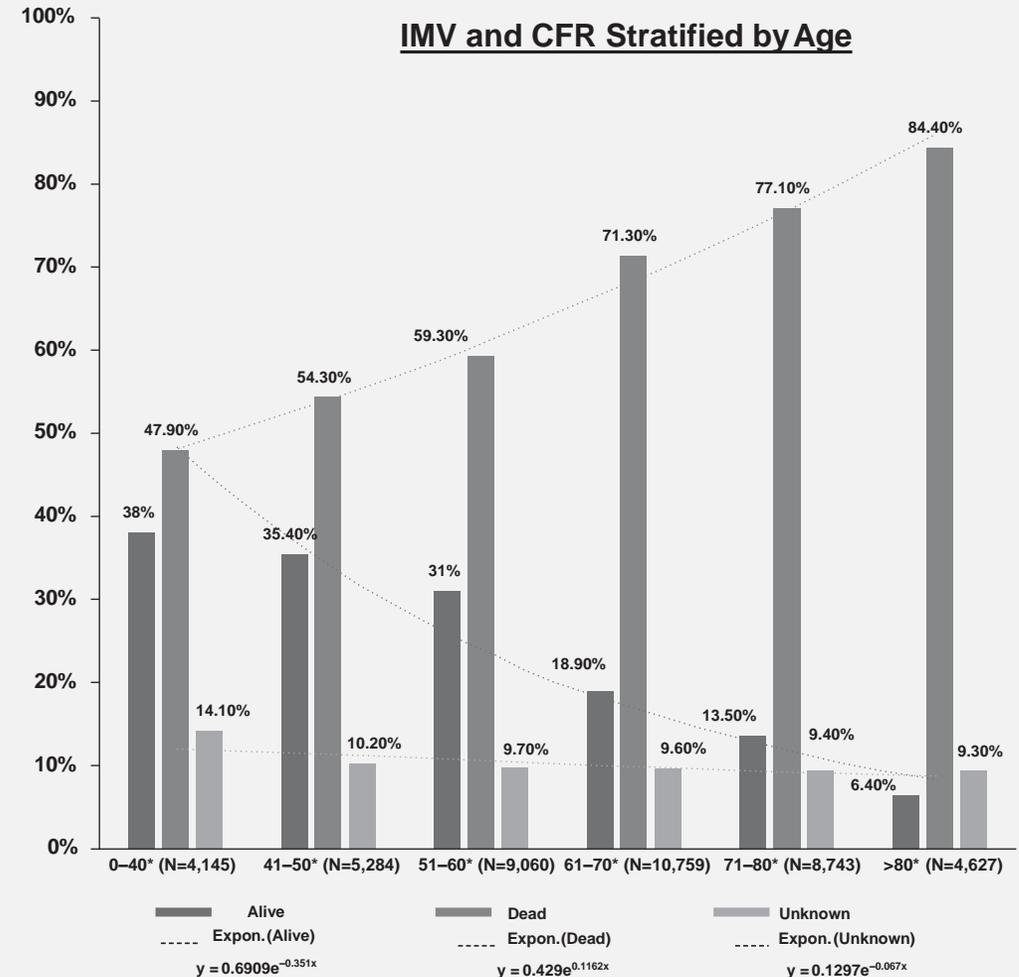


# Meta-Analysis of Case Fatality Rates (CFR) for COVID-19 Patients on Invasive Mechanical Ventilation (IMV): Mortality Significantly Increases with Age



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

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

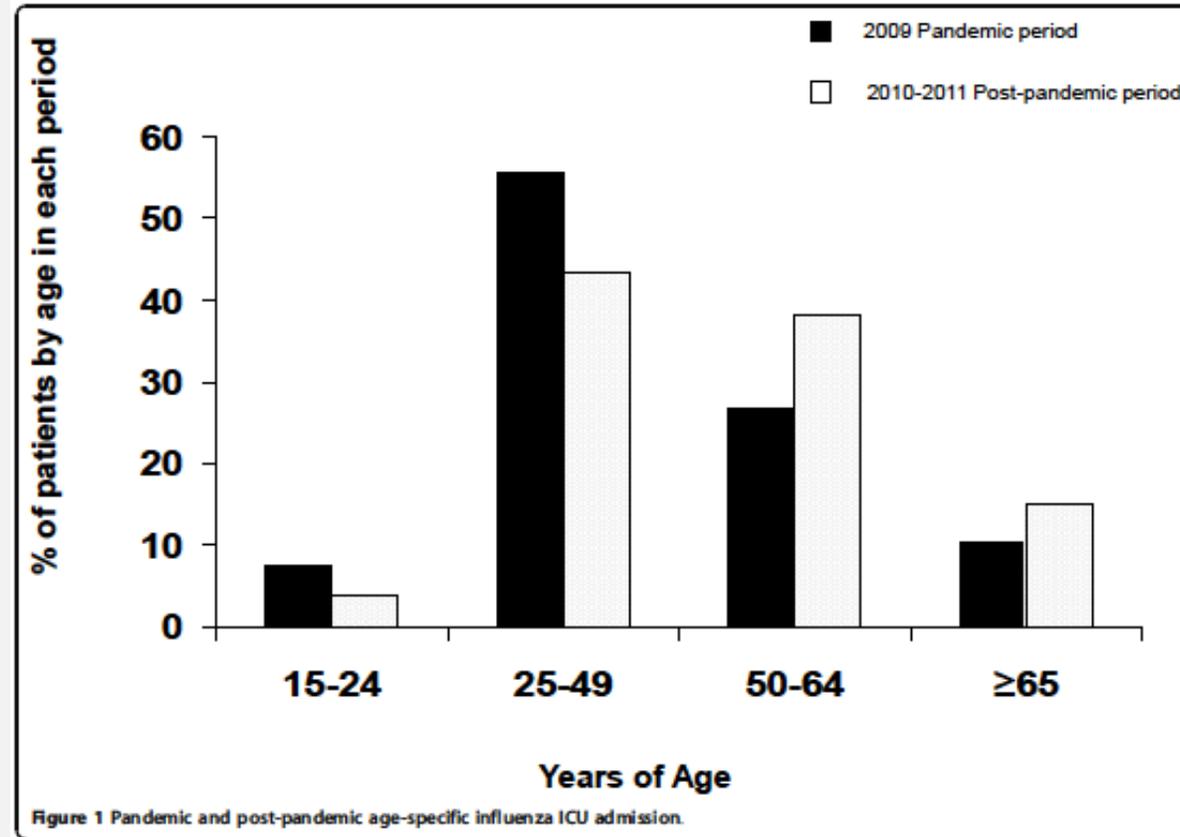


Source: Am J Respir Crit Care Med Vol 203, Issue 1, pp 54–66, Jan 1, 2021. Sixty-nine studies were included, describing 57,420 adult patients with COVID-19 who received IMV. Fifty-four of 69 studies stated whether hospital outcomes were available but provided a definitive hospital outcome on only 13,120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

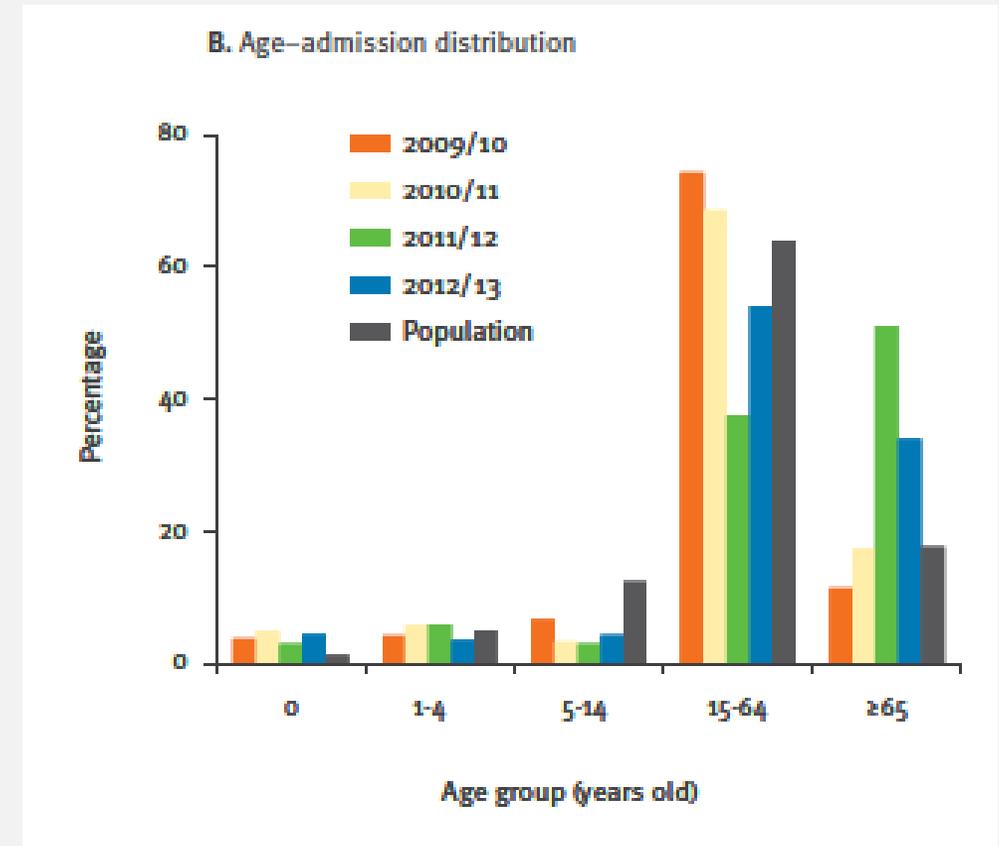
# Viral ARDS ICU Admissions Are Predominantly Comprised Of Patients < 65 Years of Age



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



Severe Influenza Admissions To ICU In France Over Time<sup>2</sup>

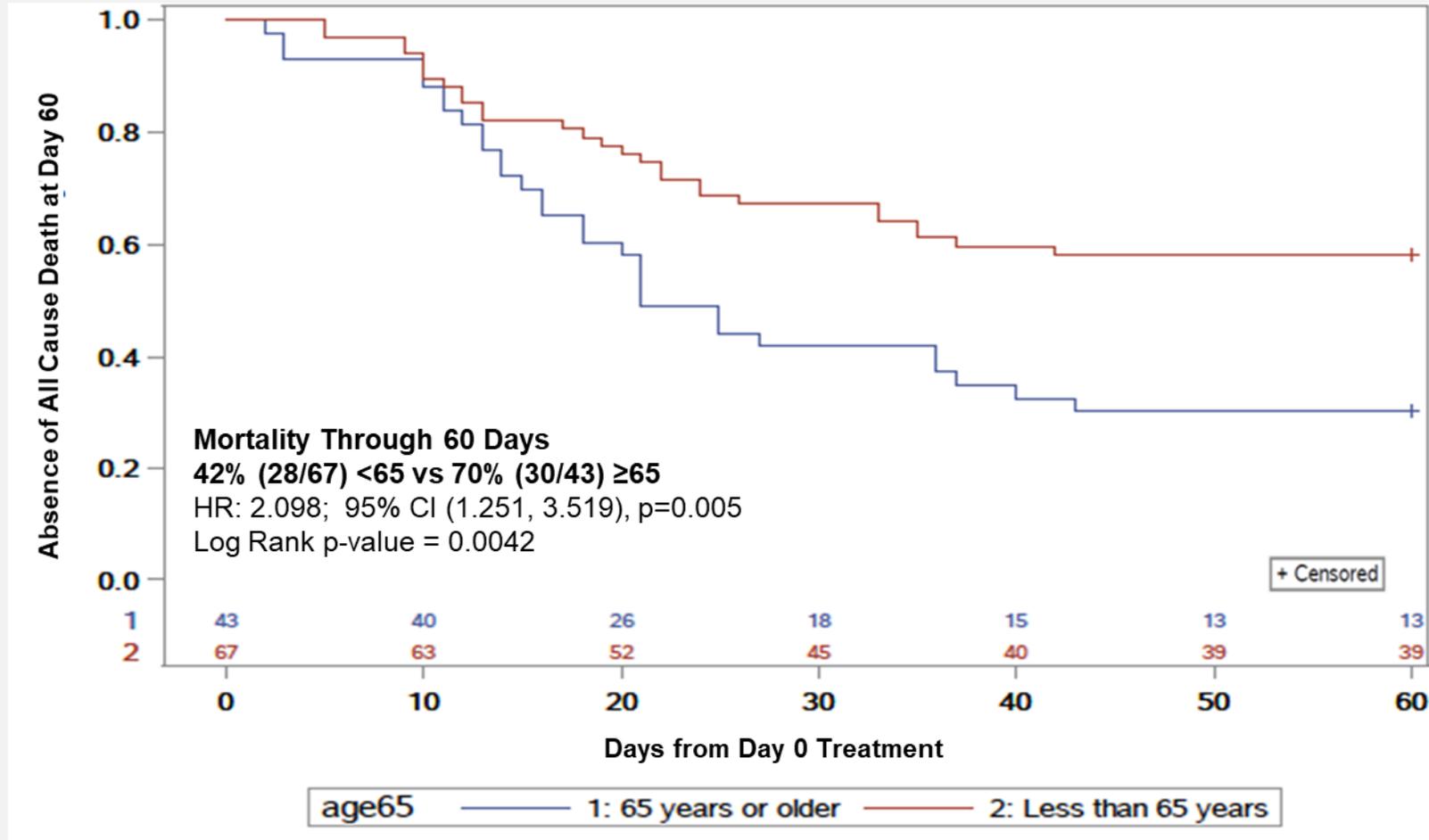


1. Martin-Loeches et al. Pandemic and post-pandemic Influenza A (H1N1) infection in critically ill patients *Critical Care* 2011, 15:R286
2. Bonmarin I et al. Intensive care unit surveillance of influenza infection in France: the 2009/10 pandemic and the three subsequent seasons. *Euro Surveill.* 2015;20(46)

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



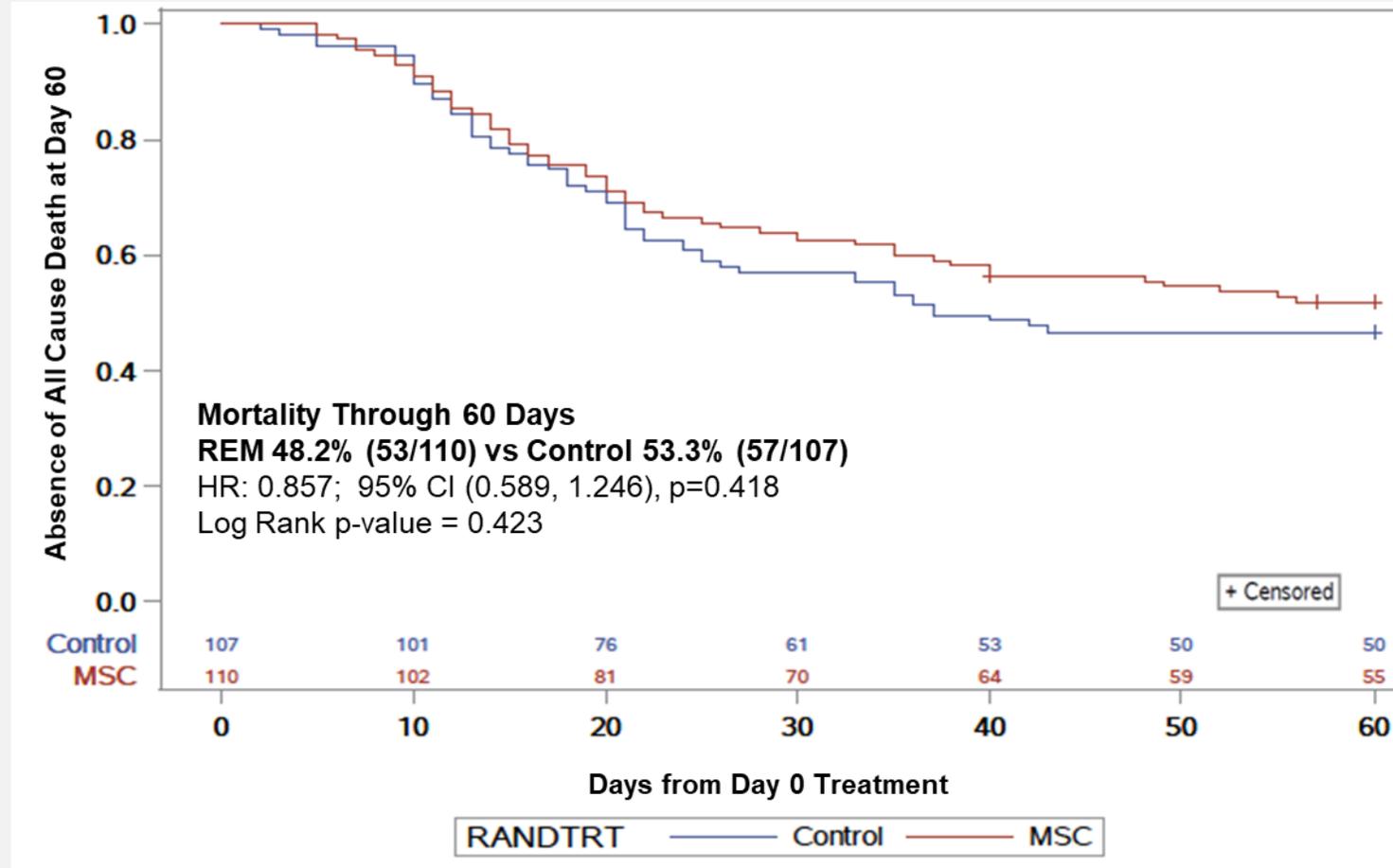
Controls Age < 65 vs ≥ 65 (n=110)



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



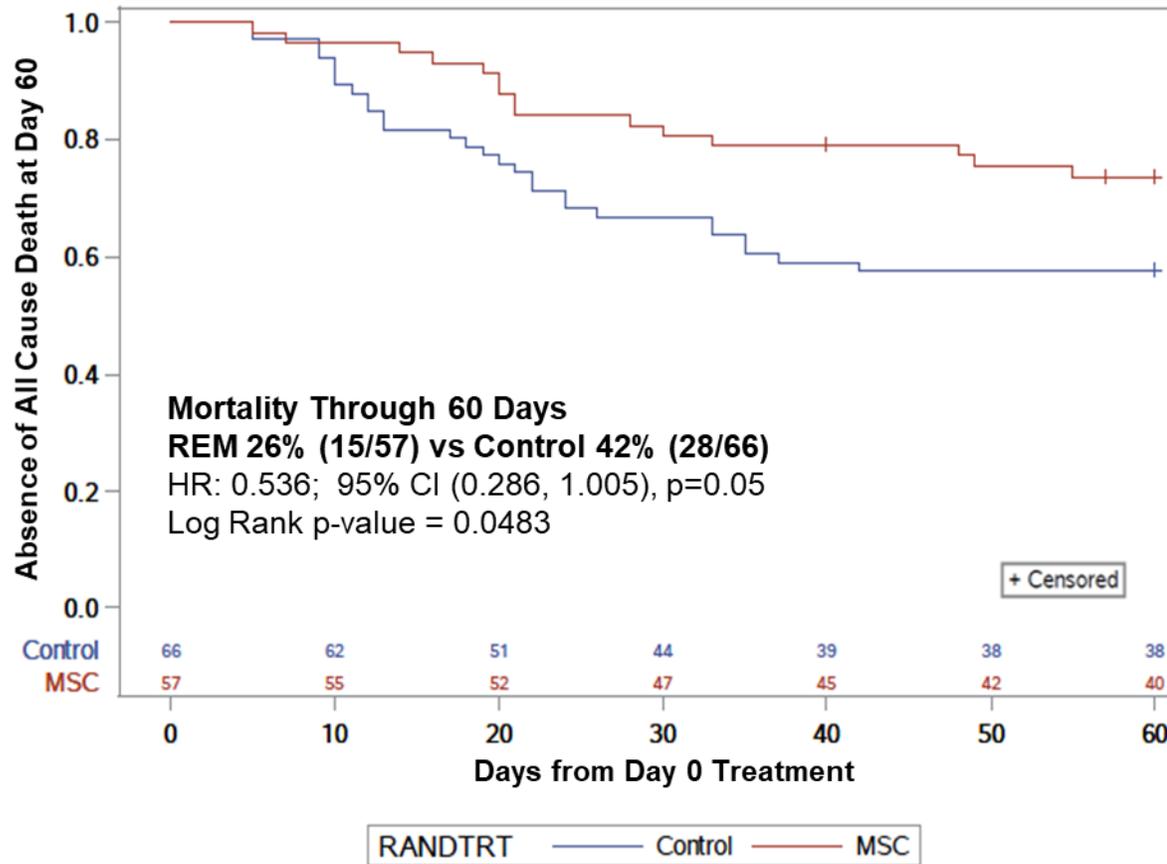
All Modified Intent to Treat Patients (n=217), REM vs Control



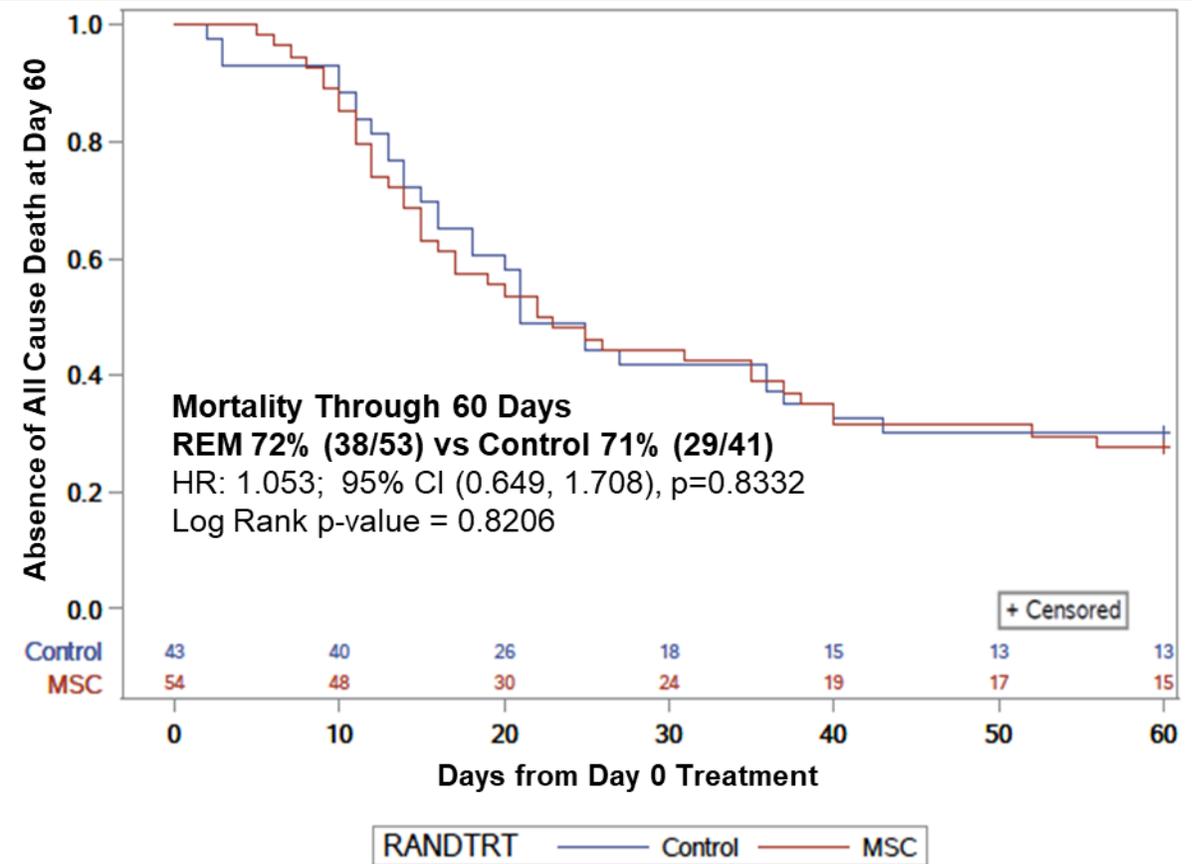
# Remestemcel-L vs Controls: Pre-Specified Mortality Analysis through 60 Days < or ≥ 65 Years Old



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



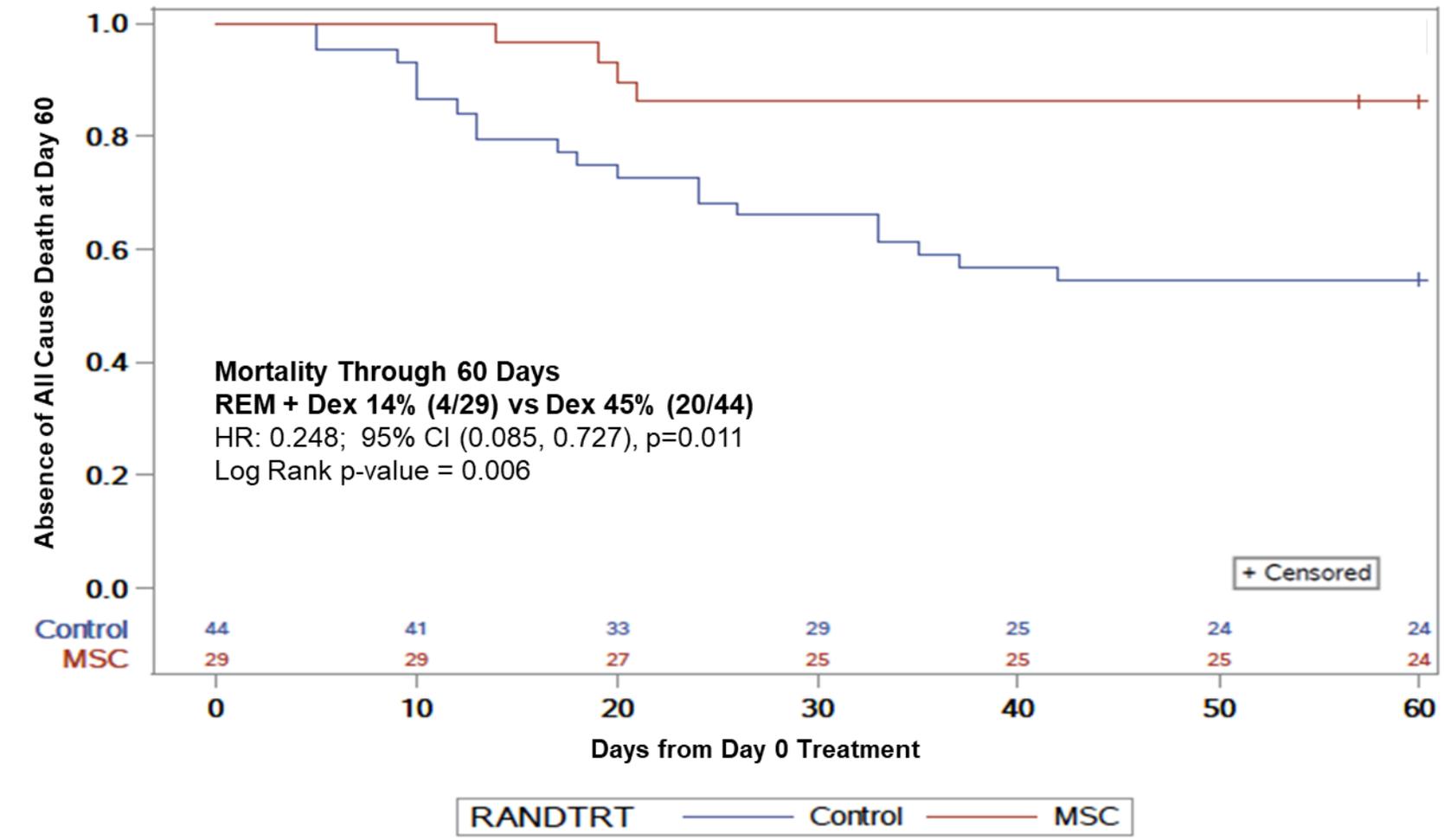
Modified Intent to Treat Patients ≥ 65 years old (n=94)  
REM vs Control



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



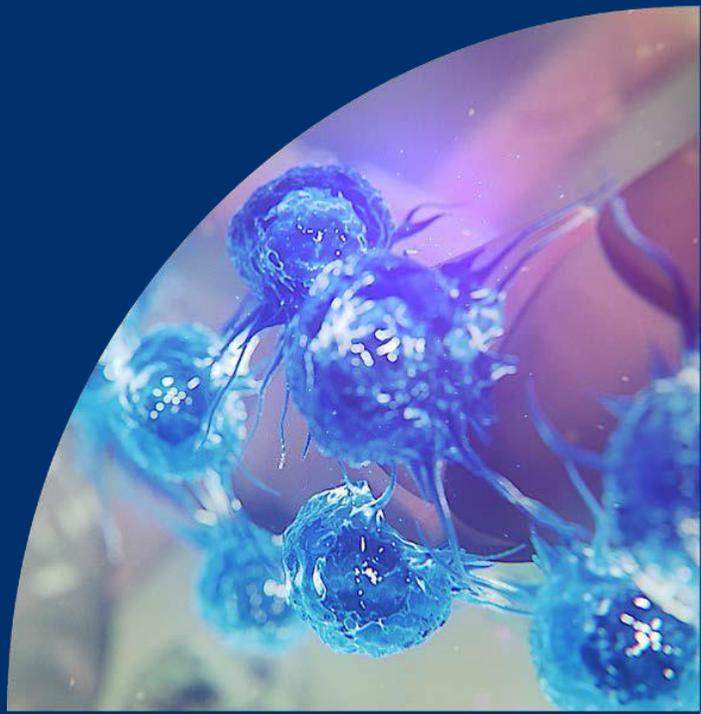
All Treated Patients < 65 years old  
on Dexamethasone (n=73)



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



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



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



# Chronic Heart Failure: Rising Incidence & High Mortality

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

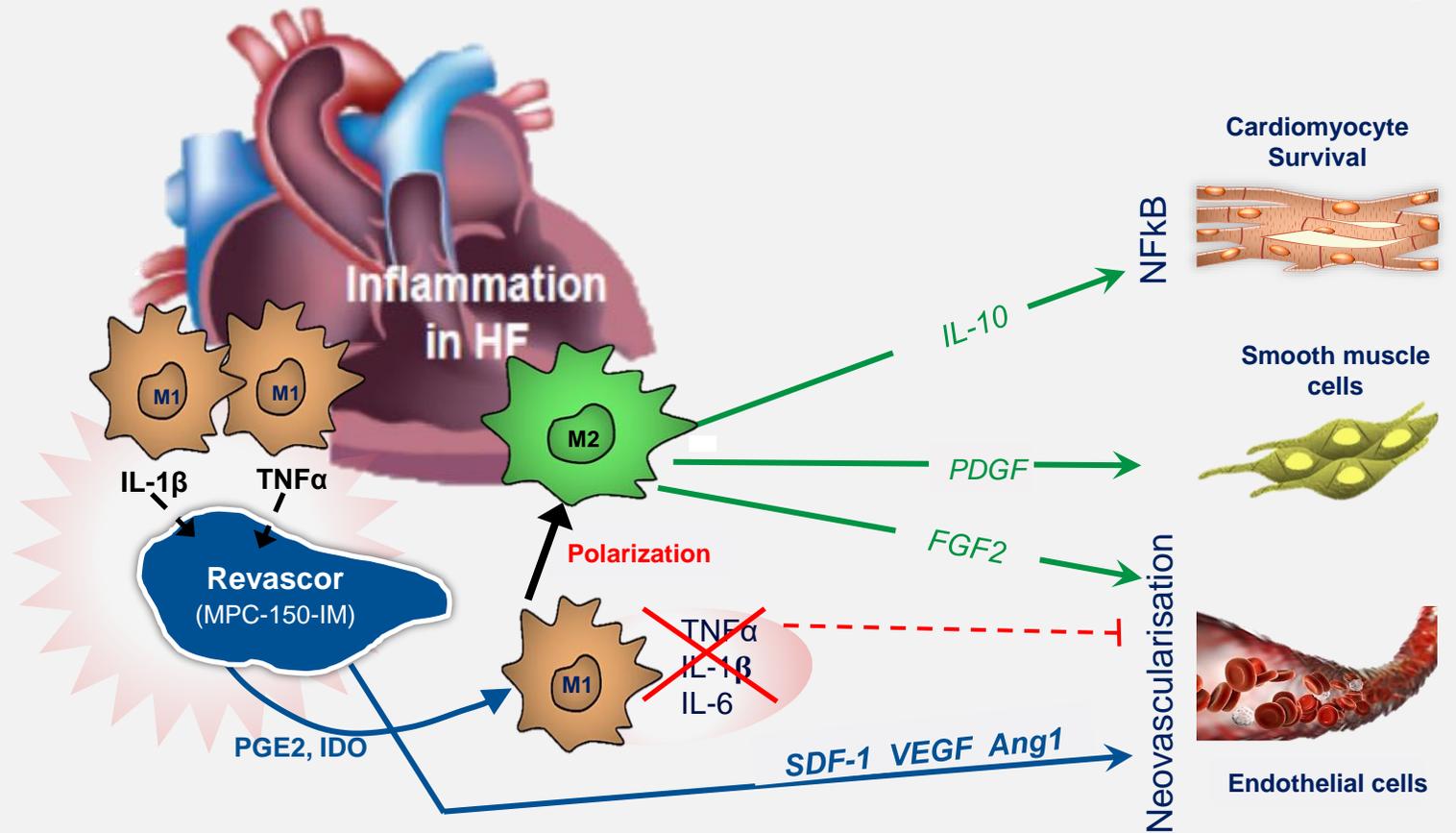
New therapies for chronic heart failure reduce recurrent hospitalizations due to cardiac decompensation, however they do not materially improve cardiac mortality or major ischemic events (heart attacks/strokes)

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

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

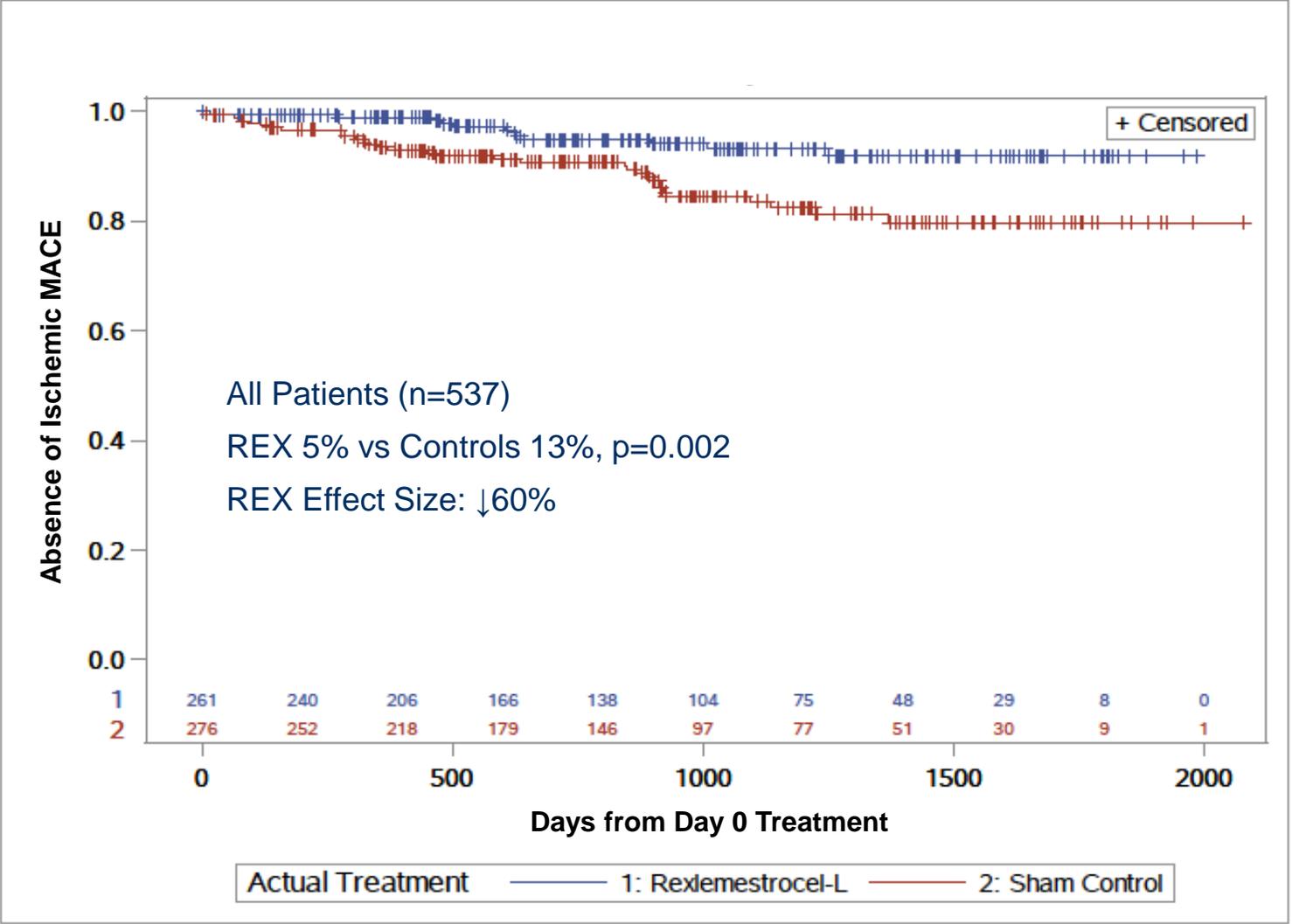
Mesenchymal precursor cells (MPC) key mechanisms of action thought to beneficially impact the heart and the systemic vasculature:

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

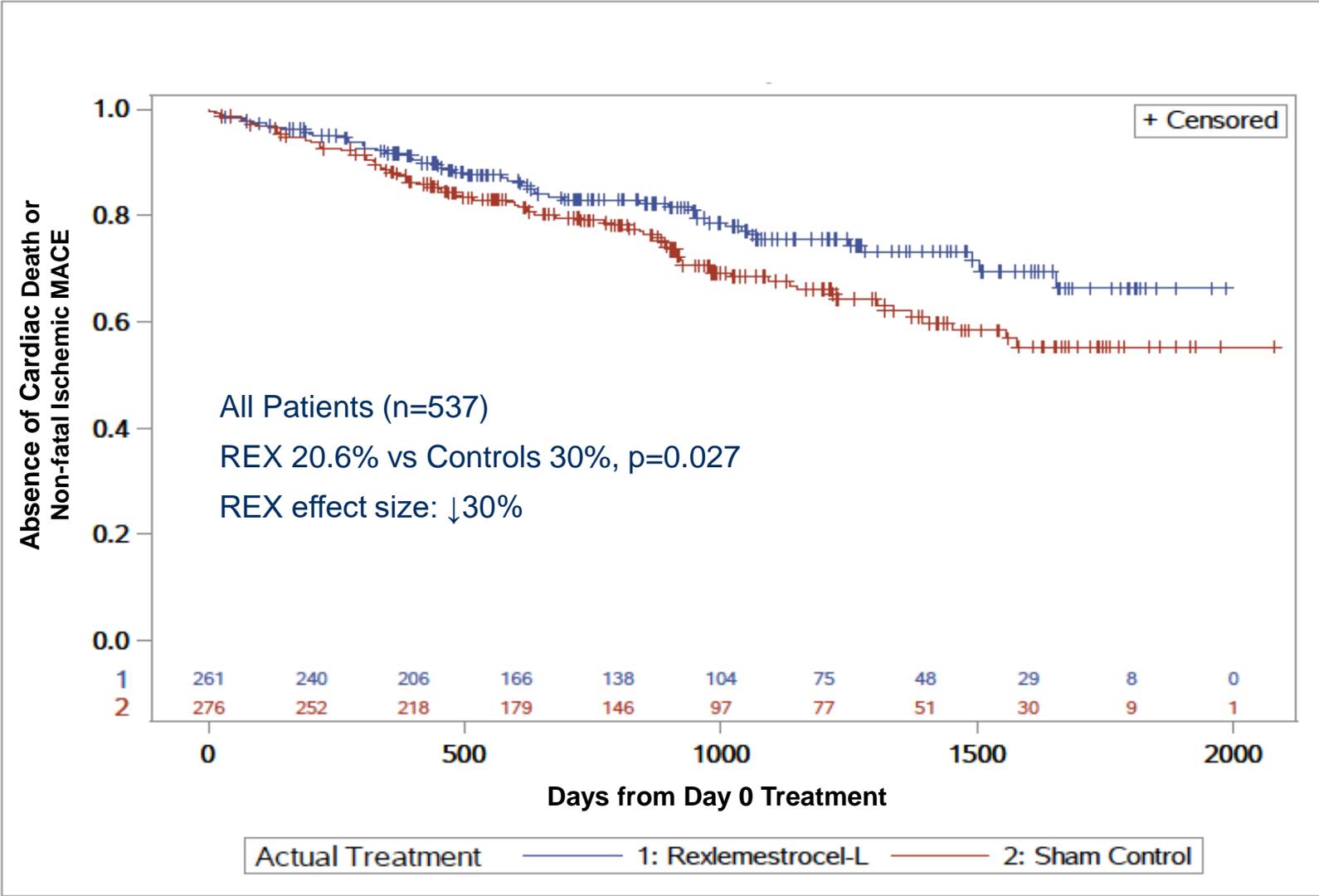


Borow KM, Yaroshinsky A, Greenberg B, Perin E. Phase 3 DREAM-HF Trial of Mesenchymal Precursor Cells in Chronic Heart Failure: A Review of Biological Plausibility and Implementation of Flexible Clinical Trial Design. *Circ Res.* 2019;125:265-281

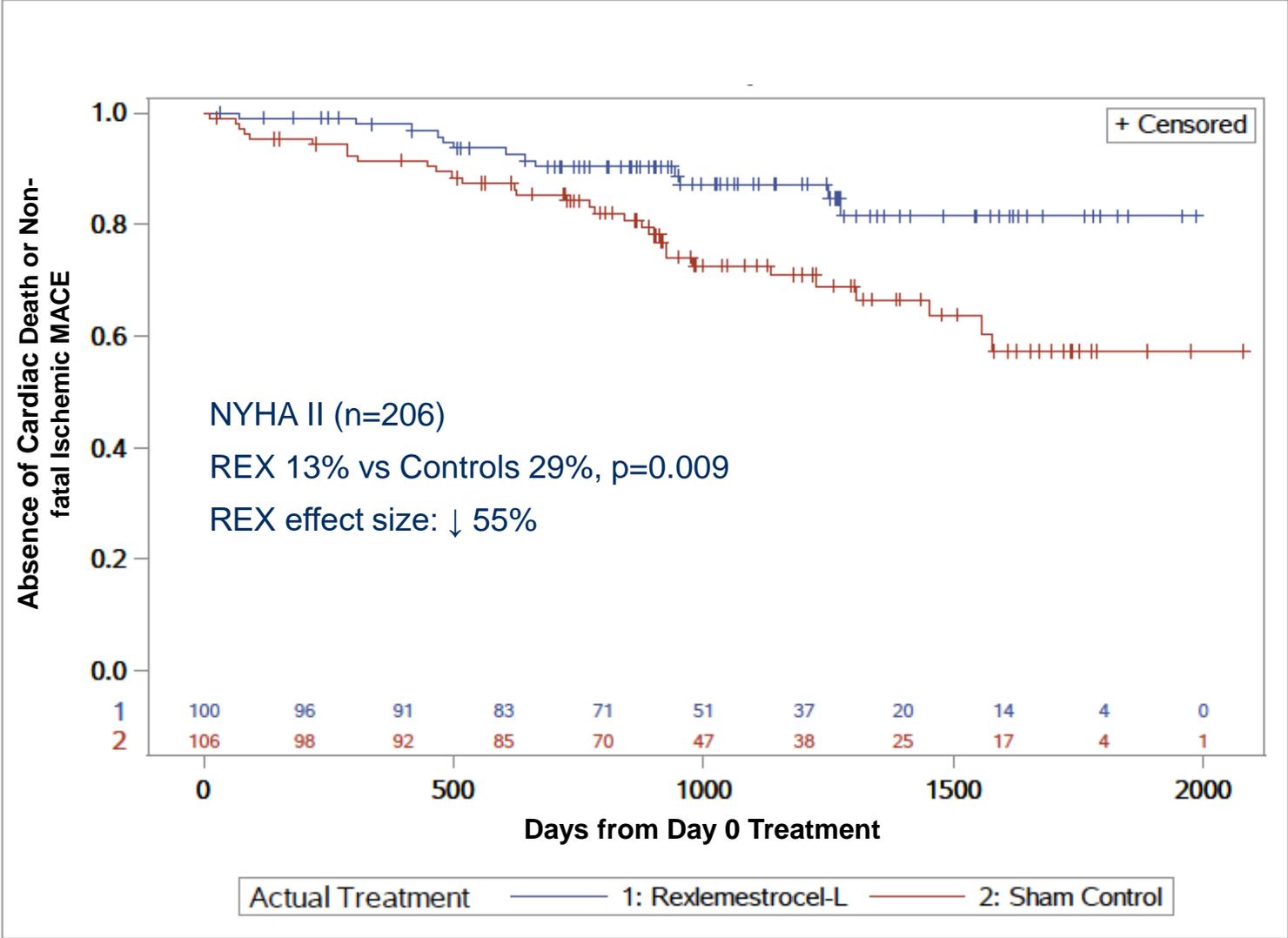
# Ischemic MACE: Rexamestrocel-L Significantly Reduced Incidence of MI & Stroke by 60% Relative to Controls (n=537 Patients)



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



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

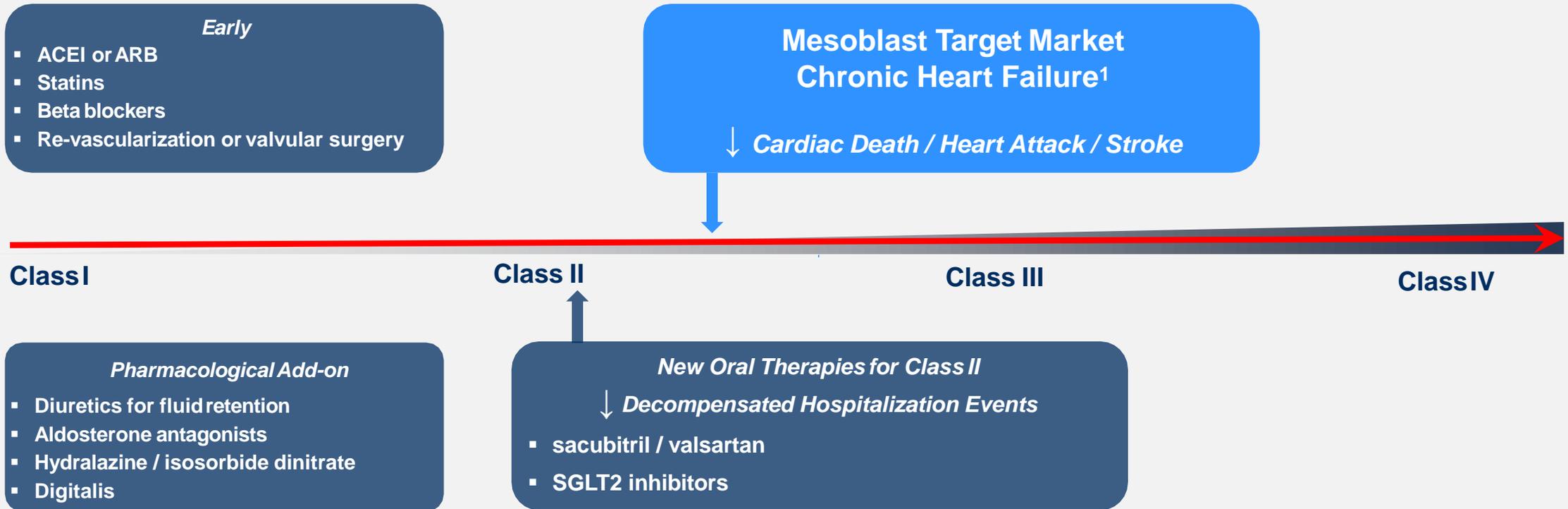


# Rexlemestrocel-L for Chronic Heart Failure



## Treatment Algorithm in Progressive Heart Failure

### Progressive Vascular (Endothelial) Dysfunction and Heart Failure



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



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

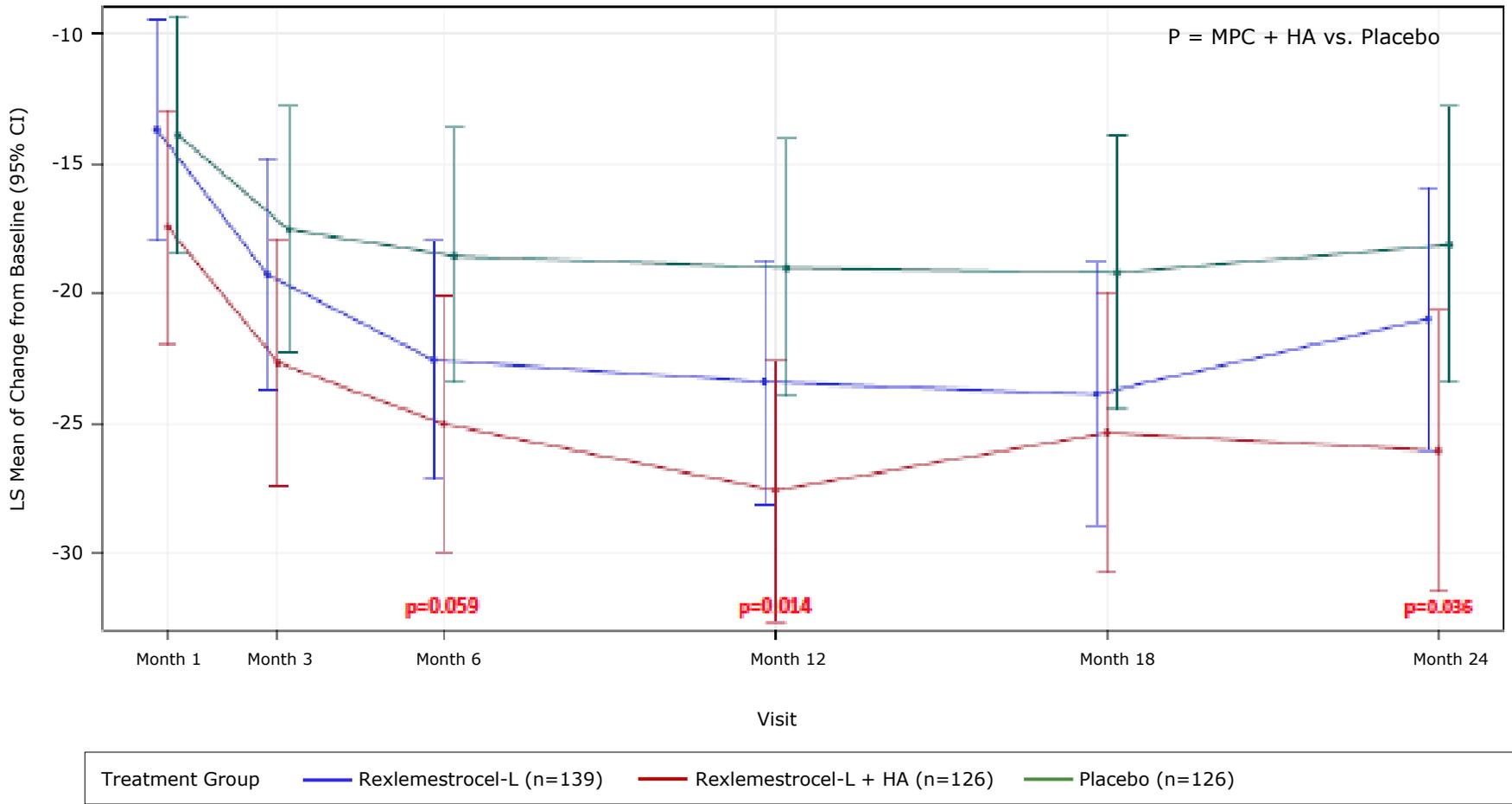
# Single Injection of Rexlemestrocel-L + HA in Phase 3 Trial Results in at Least 2 Years of Pain Reduction with Opioid Sparing Activity in Patients with CLBP



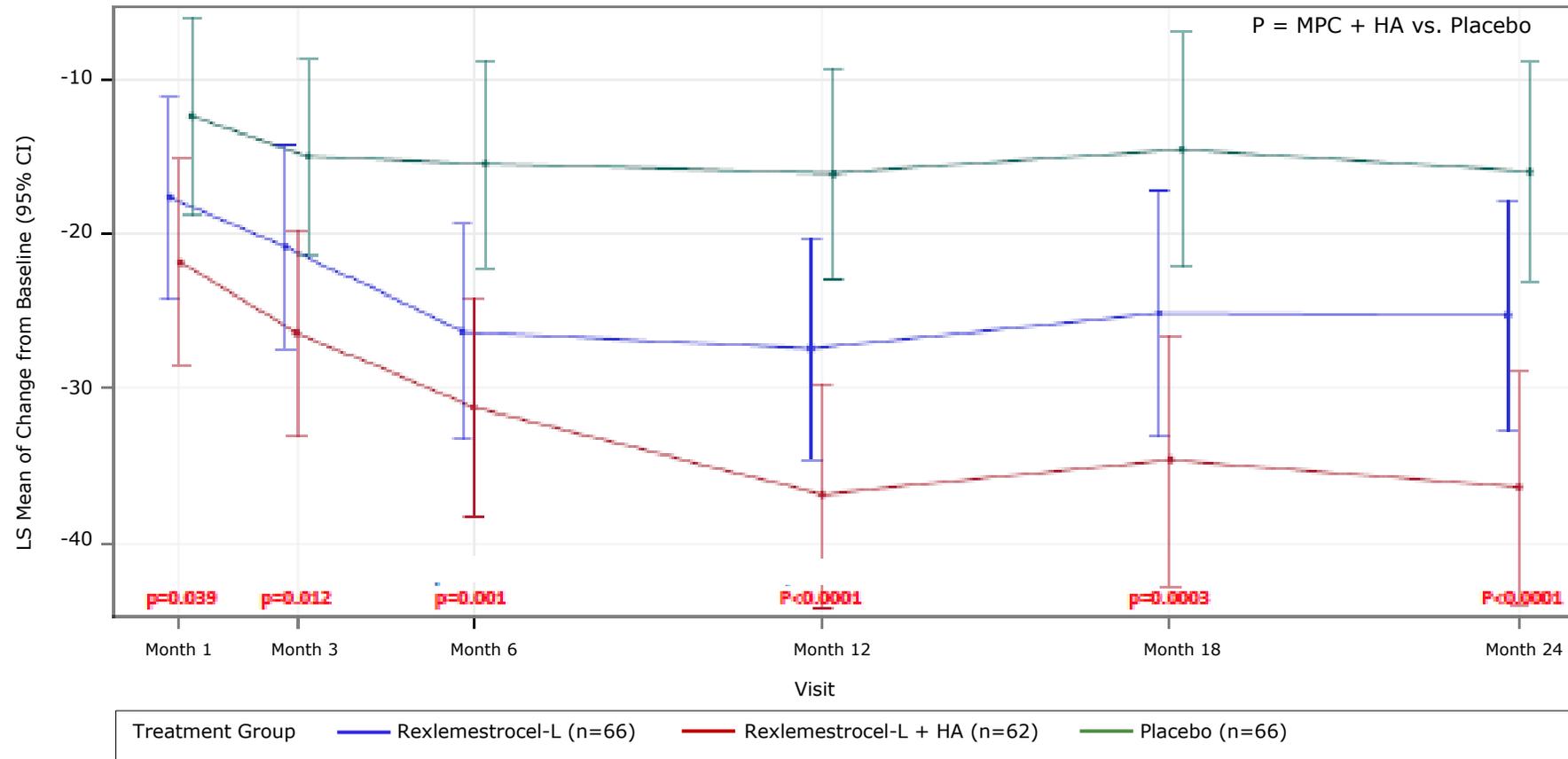
- Achievement of significant and durable reductions in CLBP through 24 months across the entire evaluable study population (n=391) compared with saline controls
- Greatest pain reduction observed in the pre-specified population with CLBP of shorter duration than the study median of 68 months (n=194), significantly greater reduction at all time points (1, 3, 6, 12, 18 and 24 months) compared with saline controls
- Significantly greater pain reduction in the pre-specified patient subset of opioid users (n=168) at all time-points compared with saline controls and by 24 months there was a 40% reduction in opioid use

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

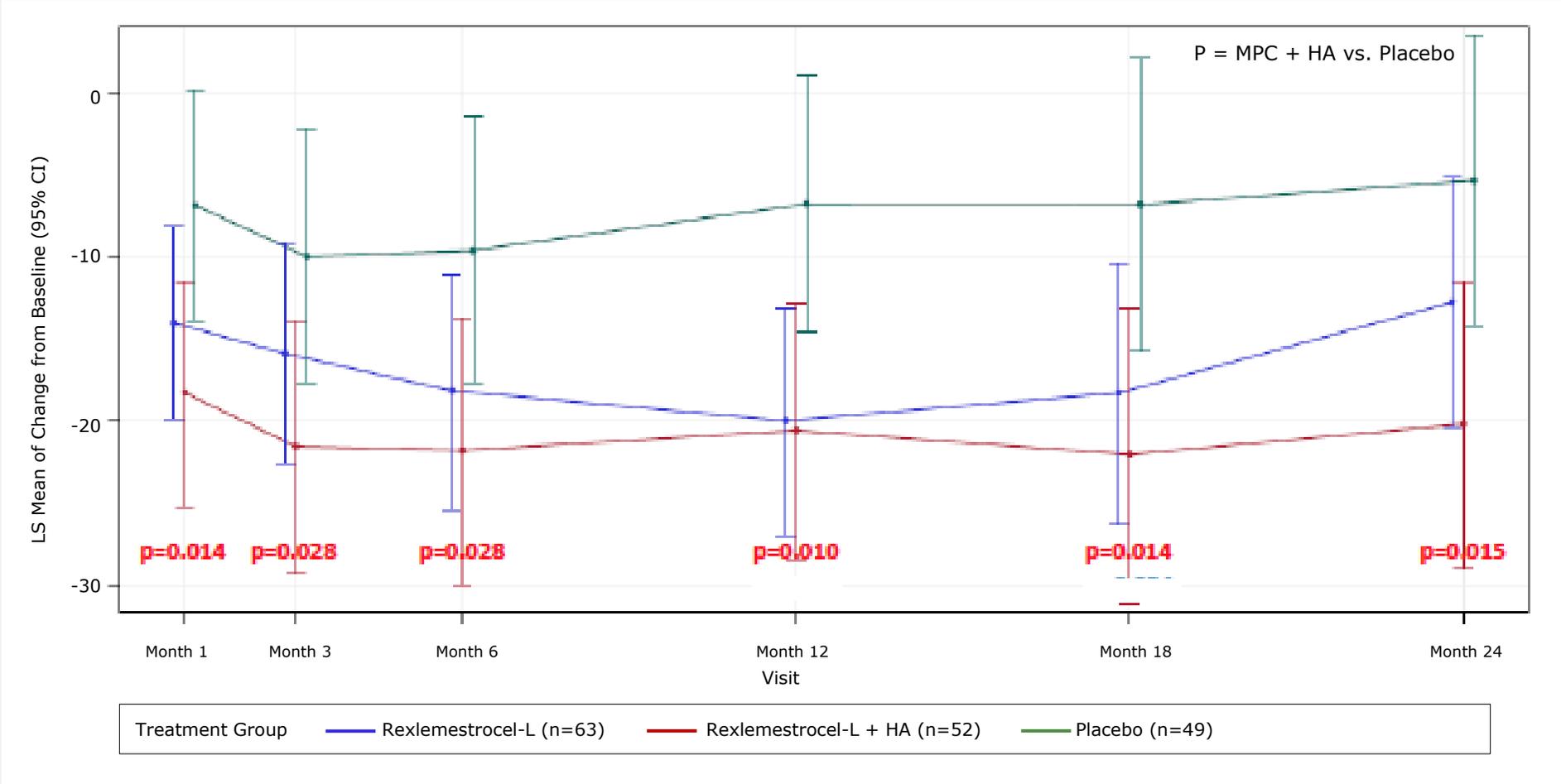
# LS Mean VAS Low Back Pain Change from Baseline VAS of 60.4 - Entire Study (n=391)



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



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



# Key initiatives and Upcoming Milestones for the Next Two Quarters

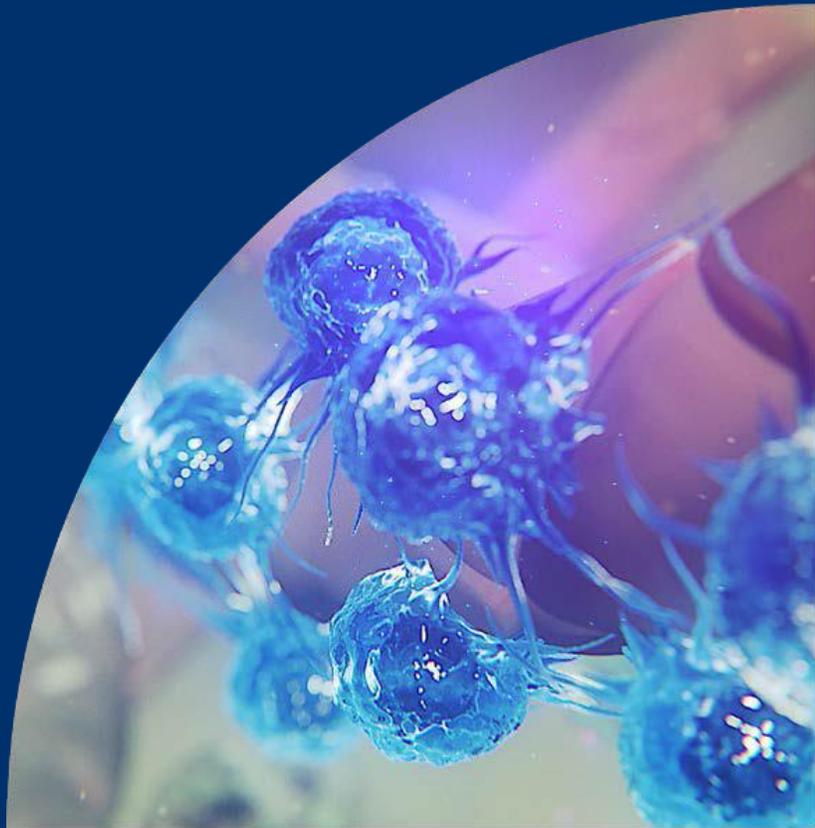


## Remestemcel-L

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

## Rexlemestrocel-L

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



**mesoblast**  
the regenerative medicine company



ASX

Nasdaq