

Global Leader in Allogeneic Cellular Medicines for Inflammatory Diseases

Financial Results and Operational Update for the Full Year Ended June 30, 2025

August 2025
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 have based 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 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

Mesoblast is committed to bringing to market innovative off-the-shelf allogeneic cellular medicines to treat serious and life-threatening inflammatory illnesses

Our Mission

Global leader in allogeneic cellular medicines for inflammatory diseases

- ✓ World leader in developing allogeneic (off-theshelf) cellular medicines for the treatment of severe and life-threatening inflammatory conditions
- ✓ Locations in Australia, the United States and Singapore
- ✓ Listed on the ASX (MSB) and NASDAQ (MESO)
- ✓ Developing product candidates for distinct indications based on its remestemcel-L and rexlemestrocel-L stromal cell technology platforms
- ✓ Extensive global intellectual property portfolio with protection extending through to at least 2041 in all major markets
- ▼ FDA-inspected commercial scale manufacturing
- ✓ US commercial organization

ONE product FDA approved



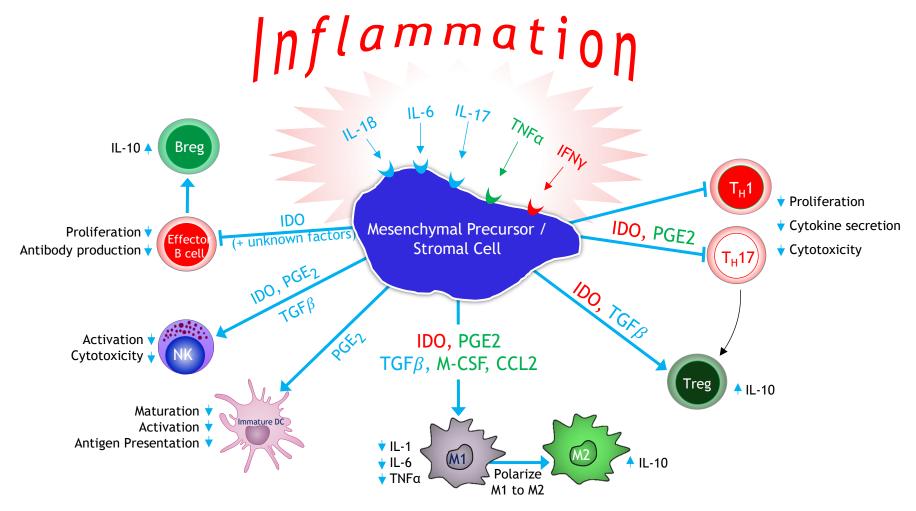
more than
1,100
patents & applications

Phase 3 trials in **TWO** major indications



Platform technology: shared mechanism of action across our products

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





Mesoblast allogeneic Mesenchymal Stromal Cell portfolio

Product	Indication	Phase 2	Phase 3	Regulatory Filing	Approved
RYONCIL®	Pediatric SR-aGvHD				
remestemcel-L	Adult SR-aGvHD		>>		
RYONCIL® remestemcel-L	IBD / UC & Crohn's		>>		
REVASCOR® rexlemestrocel-L (STRO3+)	Adult HFrEF Class II/III		>>		
	Adult HFrEF End-stage		>		
	Pediatric HLHS		>>>		
Rexlemestrocel-L (STRO3+)	CLBP		>>>		

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

- JCR Pharmaceuticals Co., Ltd. (JCR), has the right to develop mesenchymal stromal cells (MSCs) in certain fields for the Japanese market, including for the treatment of hematological malignancies, such as Graft vs Host Disease, and for hypoxic ischemic encephalopathy (HIE).
- Grünenthal has an exclusive license to develop and commercialize rexlemestrocel-L for chronic low back pain in Europe and Latin America/Caribbean.
- Tasly Pharmaceuticals has exclusive rights for rexlemestrocel-L for the treatment or prevention of chronic heart failure in China.

mesobla

Addressable annual market opportunity for product portfolio



First mesenchymal stromal cell (MSC) therapy approved by FDA

- Steroid-refractory acute GvHD for children & adults ~US\$1 billion
- Biologic-refractory inflammatory bowel disease >US\$5 billion
- Heart failure with reduced ejection fraction (HFrEF) >US\$10 billion
- Chronic low back pain (CLBP) >US\$10 billion
- Additional potential multi-billion-dollar opportunities from existing and future product pipeline based on existing technology platforms



Successful commercial launch of Ryoncil®

- In December 2024, Ryoncil® became the first and only FDA approved MSC product in the US.
- Ryoncil® became commercially available for purchase on March 28, 2025, within one quarter of receiving FDA approval for treatment of SR-aGvHD in children.
- Since launching we have onboarded 32 US transplant centers.
- Aim to have onboarded by the end of this quarter the top 45 centers that account for 80% of pediatric bone marrow transplants in the US.
- Coverage for Ryoncil® continues to expand with over 250 million US lives insured by commercial and government payers.





Financial Results

for the Period Ended June 30, 2025



Financial highlights for the year ended June 30, 2025

- Revenue from cell therapy products was US\$17.2 million, up 191% on prior year.
- Revenue growth driven by successful launch of Ryoncil® in the final quarter, with US\$13.2m gross sales and US\$11.3m in reported net sales after 14.6% gross to net adjustment.
- Net operating cash spend was US\$50.0 million, a 3% increase on prior year, inclusive of costs related to commercial team build and product launch.
- Cash on hand at June 30, 2025, was US\$162 million (A\$247 million)¹.



Total Revenues from cell therapy products up 191% on prior year

P&L for the full year ended	June	June
US\$ million	2025	2024
Revenue:		
Product sales, net	11.3	-
Royalty revenue	5.9	5.9
Total revenues	17.2	5.9
Cost of revenues	(5.1)	-
R&D expenses	(34.8)	(39.7)
Selling, general and administration	(39.3)	(25.0)
Reval. of contingent consideration	(14.9)	(9.7)
Reval. of warrant liability	(5.0)	8.0
Other op. income and expenses	3.1	2.6
Finance costs	(23.0)	(23.0)
Loss before income tax	(101.8)	(88.1)
Income tax benefit/(expense)	(0.3)	0.2
Loss after income tax	(102.1)	(88.0)

Cost of Revenues

- Related to product sales were \$1.2m, 10% of net product sales (gross margin of 90%).
- Additionally, \$3.9m of expenses related to non-cash amortization of the intangible value of the prior MSC asset acquisition.

Selling, General & Admin expenses were \$39.3m for FY2025 an increase of \$14.3m on FY2024 for the commercial team build and product launch.

Revaluation of Contingent Consideration: we recognized a loss of \$14.9m in FY2025 reflecting a non-cash revaluation of potential future third party payments.

Revaluation of Warrant Liability: As a result of FDA approval of Ryoncil® and the consequential share price appreciation, we recognized a warrant remeasurement loss of \$5.0m in FY2025 compared to a gain of \$0.8m for FY2024.

Figures have been rounded.





Opportunity to address critical unmet need in children 2 months and older, including adolescents & teenagers with SR-aGVHD

>30,000 allogeneic BMTs performed globally (>20K US/EU) annually, ~20% pediatric^{2,3}

Corticosteroids are first-line therapy for aGvHD

RYONCIL is the only approved therapy for SR-aGvHD in children 2 months and older

~1,500

Children & adolescents undergo allogeneic BMT in US annually

~50%

Incidence of acute GvHD

~375pts
Per year with SR-aGvHD

Approx. 10,000 allogeneic BMTs performed in the US annually

Acute GvHD occurs in ~50% of patients¹
with approx. half failing to respond to steroids

SR-aGvHD has high mortality^{1,4} and significant extended hospital stay costs²



Ryoncil® delivered high overall response rates at Day 28, a measure that predicts survival in aGvHD

MSB-GVHD001^{1,2}

(n=54)
Single-arm, multi-center
Phase 3

Overall Response Rate at Day 28 95% CI 56.4, 82.0

70%

SR-GvHD severity³ at baseline

in GVHD001:

Grade B: 11%

Grade C: 43%

Grade D: 46%

RYONCIL treatment was not discontinued or interrupted in any patient for any laboratory abnormality, and the full course was completed without interruption in more than 85% of patients

Full Prescribing Information at www.ryoncil.com

1.NCT02336230; 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 https://doi.org/10.1016/j.bbmt.2020.01.018; 3. International Blood and Marrow Transplantation Registry Severity Index Criteria (IBMTR)



Ryoncil® long-term survival free from aGvHD

Long-term followup of Ryoncil by the Center for International Blood and Marrow Transplant Research (CIBMTR)

Children from GVHD001

N = 51

88% Grade C/D

Year 2 Survival:

51%

Year 4 Survival:

49%

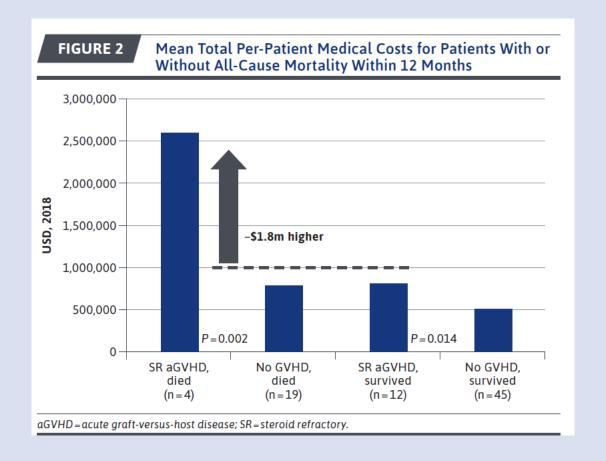
Only 14% (N=7) died due to aGvHD through 4 years



High cost of treating child who dies from SR-aGvHD

The cost of treating a child who dies of SR-aGVHD within 12 months of transplant is:

- Approximately \$2.5M
- \$1.8M higher than for those with SR aGvHD who remain alive¹





Value of Ryoncil® in treating pediatric patients with SR-aGvHD

Total benefits of patient outcomes using Ryoncil® range \$3.2m to \$4.1m (comprising long-term survival benefit, cost-offset, and cost-savings)

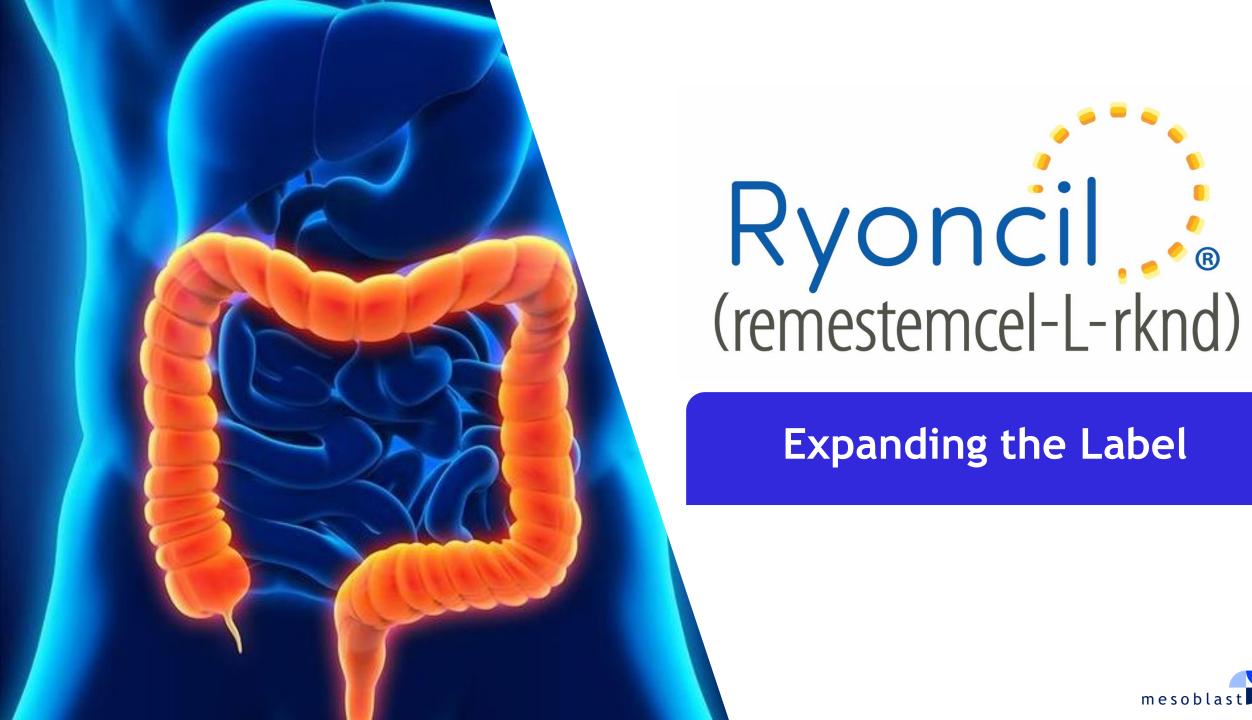
Benefits based on health economic models for lifetime ultra rare disease and highimpact short-term therapies, including Quality of Life Years (QALYs) gained





Label extension strategy for Ryoncil® in adult patients with SR-aGvHD

- Most of the sites already onboarded for use of Ryoncil® in children with SR-aGvHD also perform adult bone marrow transplants. We have an active compassionate care program to provide Ryoncil® to adults with SR-aGvHD who have failed other therapies
- Adults with severe SR-aGvHD have a high rate of non-responsiveness to second-line agents such as ruxolitinib. Survival in those with SR-aGvHD who have failed at least one additional agent, such as ruxolitinib, remains as low as 20-30% by 100 days.^{1,2}
- In contrast, among 25 patients aged 12 and older with SR-aGvHD who failed ruxolitinib or other second-line agents, Day-100 survival was 76% after Ryoncil® treatment was used under expanded access.
- Mesoblast recently met with FDA to discuss a pivotal trial for Ryoncil® in adults with severe SR-aGvHD and intends conduct a pivotal study of Ryoncil® on top of approved second-line therapy in patients with severe SR-aGvHD.
- This trial will be conducted with the NIH-funded Bone Marrow Transplant Clinical Trials Network (BMT-CTN), the objective being to extend the product's label from children to adults with SR-aGvHD, a population approximately three times the size of the pediatric SR-aGvHD population.

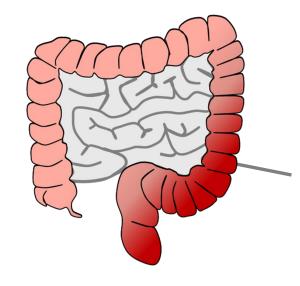


Inflammatory Bowel Diseases (IBD): Ulcerative Colitis (UC) & Crohn's Disease (CD)

Population

More than 3 million people in the US alone have inflammatory bowel disease¹

Approximately 38,000 new cases of ulcerative colitis and 33,000 new cases of Crohn's disease and diagnosed every year³⁻⁵



Ulcerative
Colitis
Affects the
colon causing
inflammation
of the inner
lining of the
bowel

Unmet Need

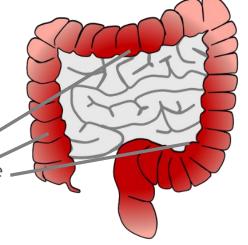
Approximately 30% of patients are unresponsive to anti-TNF α agents and other biologics

Up to 80% of patients with medically-refractory CD and 20% of patients with medically-refractory UC eventually require surgical treatment of their disease¹⁻⁵

Early and durable remission remains major objective for new therapies to avoid surgery

Crohn's Disease

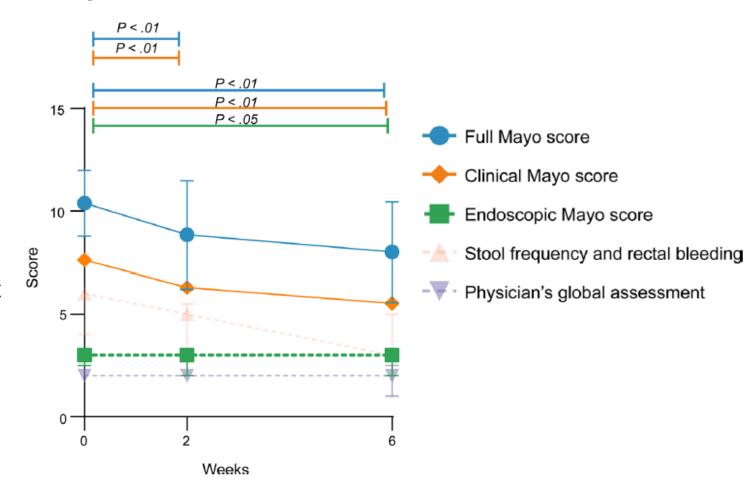
Can present
anywhere along the
GI tract - usually in
lower part of small
bowel and upper
colon. Can penetrate
through intestinal
layers from inner to
outer





Local administration of mesenchymal stromal cells is safe and improves outcomes in ulcerative proctitis

- Ulcerative proctitis (UP) occurs in all patients with ulcerative colitis (UC) and isolated to the rectum in 30%.
- 13 adult patients with biologicrefractory UP received local administration into the rectal mucosa of 20-80 million allogeneic bone marrow-derived MSCs by endoscopic injection.¹
- After 6 weeks mean clinical and endoscopic scores significantly improved.



^{1.} Ouboter, LF, et al. Local administration of mesenchymal stromal cells is safe and modulates the immune compartment in ulcerative proctitis JCI Insight 2023;8(9):e167402 https://doi.org/10.1172/jci.insight.167402.

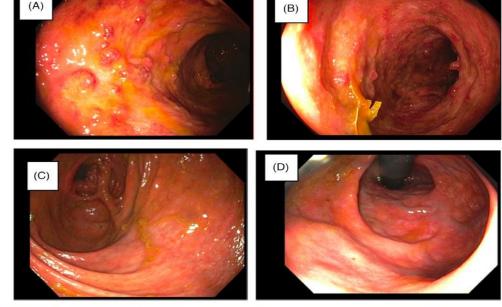


Local administration of Ryoncil[®] improves outcomes in patients with biologic-refractory extensive colitis

In 12 patient pilot study of biologic-refractory inflammatory colitis local administration of Ryoncil® resulted in clinical and endoscopic response and remission by 6 weeks.^{1,2}

- In Crohn's colitis this was accompanied by reduced faecal calprotectin levels consistent with rapid mucosal healing and disease remission.
- In addition, a monthly course of intravenous remestemcel-L has been shown to induce early remission in CD adults following failure of a first biologic.
- Mesoblast plans to initiate a pivotal study of Ryoncil® for early remission in patients with medically-refractory inflammatory colitis.

FIGURE 3 Colonoscopy: pretreatment colonoscopy with MSCs showing a Mayo score of 2 and pancolitis (A, B) as compared with the colonoscopy 3 months after MSC treatment showing a Mayo score of 0 to 1 throughout (C, D).



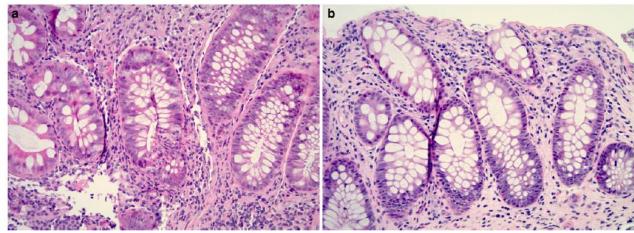


Fig. 2 Histological resolution of active Crohn's disease in the rectum 6 months after delivery of mesenchymal stem cells

a At baseline, rectal biopsy showed increased lamina propria mononuclear inflammatory cells and foci of cryptitis (Global Histological Disease Activity Score (GHAS 4). b Six months after the delivery of mesenchymal stem cell product there is complete resolution of mucosal disease with no evidence of epithelial injury, decreased lamina propria mononuclear inflammatory cells, and an absence of active neutrophilic inflammation (GHAS 0). Formalin-fixed, paraffin-embedded rectal biopsies were stained with haematoxylin and eosin according to standard protocols (original magnification ×10).

Lightner A, et al. Abstracts of the 17th Congress of ECCO - European Crohn's and Colitis Organisation. Poster P428.

^{22 2.} Lightner A, et al. Abstracts of the 17th Congress of ECCO - European Crohn's and Colitis Organisation. Poster P407.



Chronic low back pain due to degenerative disc disease (CLBP) impacts 7M+

Burden of Illness

- Back pain causes more disability than any other condition¹
- Inflicts substantial direct and indirect costs on the healthcare system, including excessive use of opioids in this patient population

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 CLBP²
- Durable improvement in pain has potential to reduce opioid use and prevent 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 2-4





^{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.Decision Resources: Chronic Pain December 2015., 3. LEK & NCI opinion leader interviews, and secondary analysis., 4. Navigant: Commercial Assessment for a Proprietary Cell-Based Therapy for DDD in the U.S. and the EU3 - August 2014.

Patients with CLBP refractory to standard treatment have minimal options

Rexlemestrocel-L has potential to be first-line treatment for patients with moderate to severe CLBP, refractory to conservative treatment

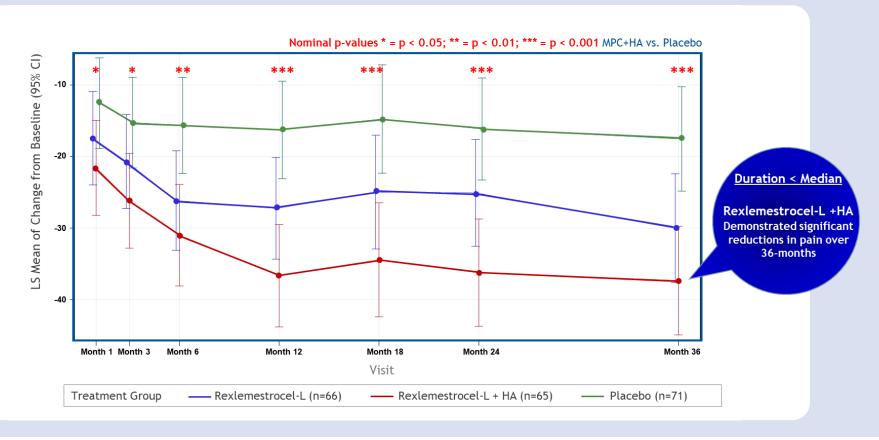
Rexlemestrocel-L targeting moderate-to-severe CLBP Conservative Opioid Interventional Surgical **Analgesics Treatments Therapies** NSAIDs Weak opioid Epidural steroid Spinal fusion injections (offanalgesics Physical therapy Disc replacement (e.g., tramadol) label) Chiropractic Strong opioid Radio frequency treatments analgesics ablation Acupuncture (e.g., oxycodone) Spinal cord Anticonvulsants stimulation (e.g., gabapentin) Intrathecal pumps



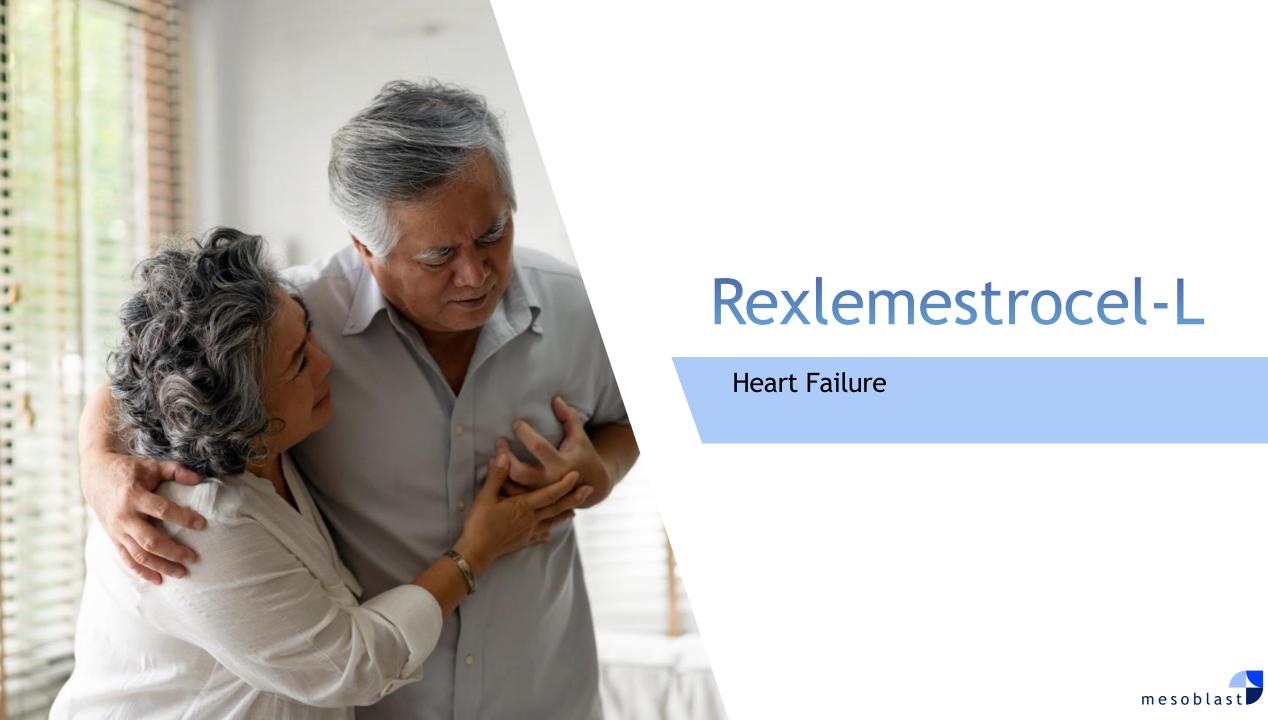
Phase 3 trial outcomes based on a single injection of rexlemestrocel-L + HA showed more than three years of pain reduction

Greatest pain reduction was observed in the pre-specified population of subjects with CLBP duration shorter than the baseline study median of 68 months (n=202) with significantly greater reduction (nominal p-value < 0.05) at all time points analyzed over 36 months compared with saline controls

LS Mean VAS Change in Low Back Pain from Baseline - Duration CLBP < 68 Month Median Baseline Duration (n=202)







Adult: Heart failure with low ejection fraction (HFrEF) and underlying ischemia is increasing in prevalence and associated with high risk of mortality, heart attacks and strokes

- Heart failure affects 6.5 million patients in the US alone, with prevalence increasing. 1
- Chronic heart failure (CHF) is a progressive disease with a high mortality that approaches 50% at 5 years^{1,2} and at least 75% after an initial hospitalization.³
- Heart failure with low ejection fraction (HFrEF) is associated with greater mortality, occurs in approximately 50% of all patients.
- Over 60% of HFrEF patients have underlying ischemia and these are at highest risk of recurrent major adverse cardiac events involving large vessels (heart attacks / strokes).

Target market: approximately one million patients with ischemic HFrEF and inflammation in the U.S.



REVASCOR has the potential to improve endothelial dysfunction in HFrEF patients across the spectrum of disease from mild-moderate to end-stage patients with a left ventricular assist device (LVAD)

Mesoblast's Programs for REVASCOR (150 million MPCs)

DREAM HF-1 Trial 537 Patients

LVAD MPC Studies
159 Patients

Guideline Directed Medical Therapies (GDMT)

Continuum of Cardiovascular Disease Risk

DEATH

NYHA Class I

Traditional Early Therapies for HFrEF

- Statins
- Beta blockers
- · Re-vascularization or valvular surgery
- RAAS antagonists
- Diuretics for fluid retention
- · Hydralazine / isosorbide dinitrate
- Digitalis

NYHA Class II

Recent New Oral Therapies for Decompensated HFrEF Hospitalizations and Fluid Overload

- sacubitril / valsartan
- SGLT2 inhibitors
- Vericiguat

NYHA Class IIB/IIIA

NYHA Class IIB or IIIA
Persistent HFrEF Patients

- Cardioverter Defibrillator (ICD) +/-
- CRT-D or Wearable Cardioverter Defibrillator if Indicated

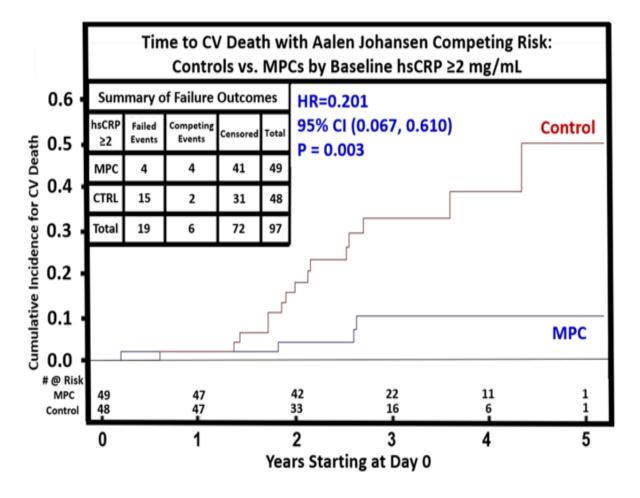
NYHA Class IIIB/IV

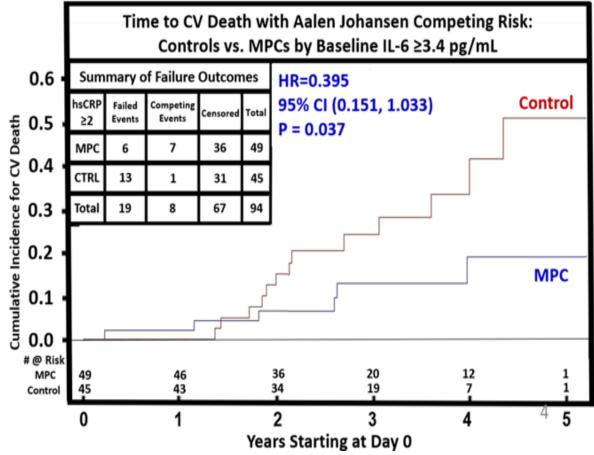
NYHA Class IIIB/IV Pts with end-stage HFrEF

- Optimal medical management
- LVAD implantation
- Heart transplant
- Artificial Heart



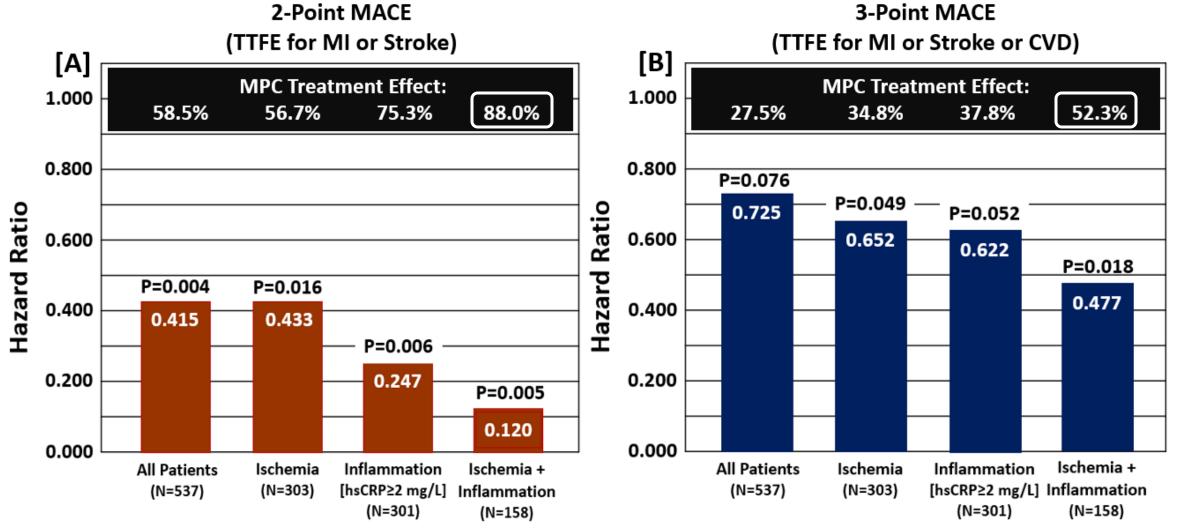
MPCs Compared to Controls Reduce CV Mortality by 60-80% in Patients with HFrEF and Baseline Inflammation (hsCRP >2mg/ml or IL-6 >3.4pg/ml)







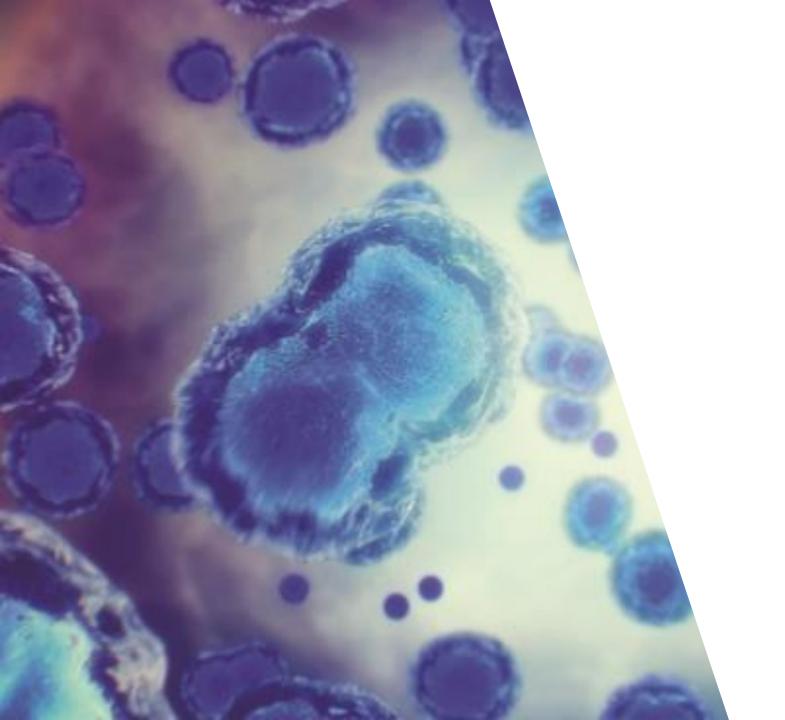
MPCs Compared to Controls had the Greatest Beneficial Treatment Effect on 2-Point MACE and 3-Point MACE in the Sub-group of Chronic HFrEF Patients with Baseline Ischemia plus Inflammation



Pathway to accelerated approval for Revascor® in adults with HFrEF

- → DREAM-HF Trial over a mean follow-up of 30 months showed significant reduction in 3-Point MACE in ischemic HFrEF patients (n=158).
- LVAD-MPC Study #2, over 12 months of follow-up, showed significant increase in proportion of LVAD recipients with ischemic HFrEF etiology successfully weaned (n=70), with significant reduction in hospitalizations and mortality.
- FDA informed Mesoblast following a Type B meeting in Q1 2024, that the totality of the trial results from these studies could support accelerated approval under the existing Regenerative Medicine Advanced Therapy (RMAT) designation for end-stage HFrEF patients with a left ventricular assist device (LVAD),
- Mesoblast and FDA met recently in June 2025 and aligned on items required for filing a biologics license application (BLA) for REVASCOR regarding chemistry, manufacturing & controls (CMC), potency assays for commercial product release, and proposed design and primary endpoint for the confirmatory trial post-approval.





Key Corporate Milestones



Mesoblast expects to substantially advance its multiple product pipeline toward FDA approvals over the next six to twelve months

Program

Key Objectives

RYONCIL®
Pediatric & Adult
Inflammatory Diseases

Commence registration trial for label expansion in adults with severe SR-aGvHD.

Commence registration trial for label expansion in inflammatory colitis.

2 REVASCOR® Chronic Heart Failure

Heart failure in adults with low ejection fraction heart failure (HFrEF), and children with congenital heart disease

Preparing for accelerated approval filing

Rexlemestrocel-L Chronic Low Back Pain CLBP Phase 3 trial actively enrolling at multiple sites across the U.S.

The 300-patient randomized, placebo-controlled trial has a 12-month primary endpoint of pain reduction





mesoblast

Thank You

