

Global Leader in Allogeneic Cellular Medicines for Inflammatory Diseases

Annual General Meeting 2024

November 2024
ASX: MSB; Nasdag: MESO

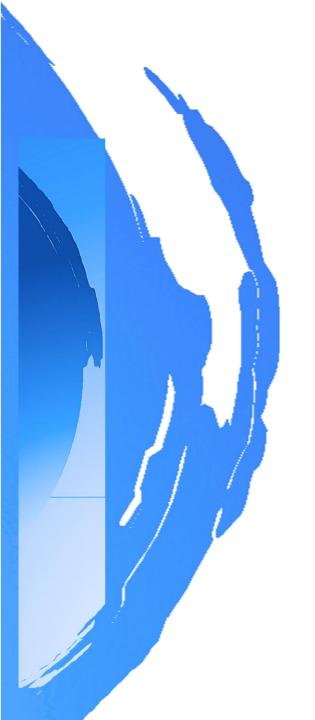


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Mesoblast is committed to bringing to market innovative off-the-shelf allogeneic cellular medicines to treat serious and life-threatening inflammatory illnesses

Our Mission



Corporate Vision

To be the world's leading, most innovative, and highly respected cellular medicines company

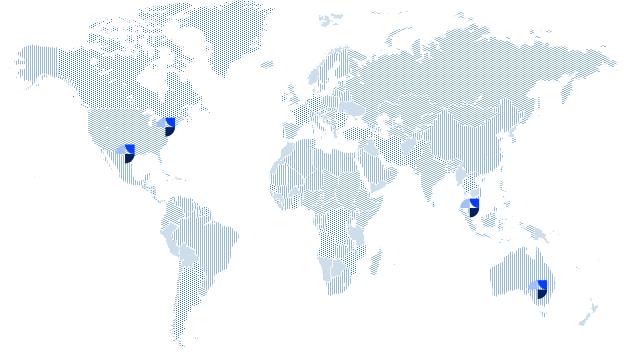
To use our proprietary technologies to develop cellular medicine products that are life-saving and that improve quality of life

To establish an organization that attracts motivated people working towards achieving a common goal

To deliver appropriate returns for our shareholders

Global Leader in allogeneic cellular medicines for inflammatory diseases

- ✓ World leader in developing allogeneic (off-the-shelf) cellular medicines for the treatment of severe and lifethreatening 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 process and facilities



Phase 3 trials in THREE major indications

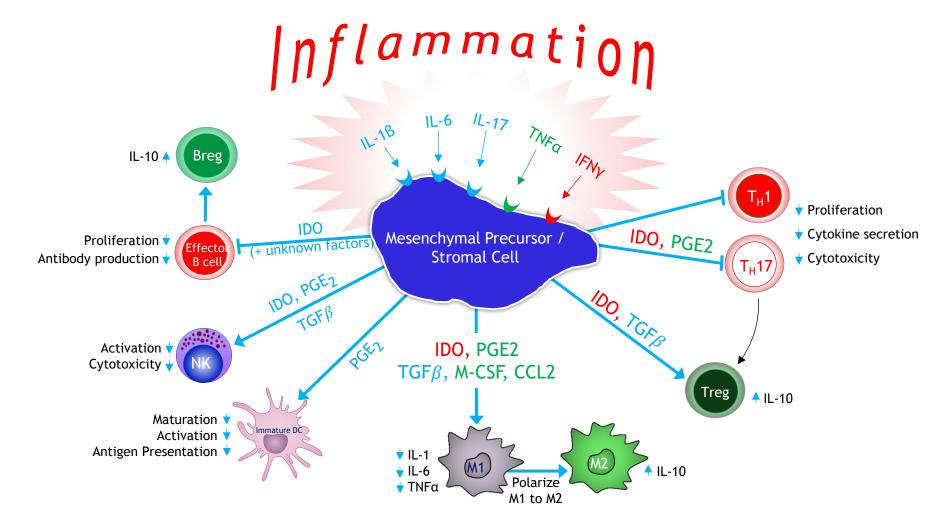
more than
1,100
patents & applications

TWO products
with clinical
data sufficient
for FDA
regulatory
review



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





Commercial-scale Manufacturing Process and Facilities

- 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
- Manufacturing innovations to meet increasing capacity requirements, improve yields and reduce cost of goods
 - Proprietary xeno-free technologies
 - Scaled-up 2D manufacturing
 - □ 3D bioreactors for high volume indications

Manufacturing Remestemcel-L



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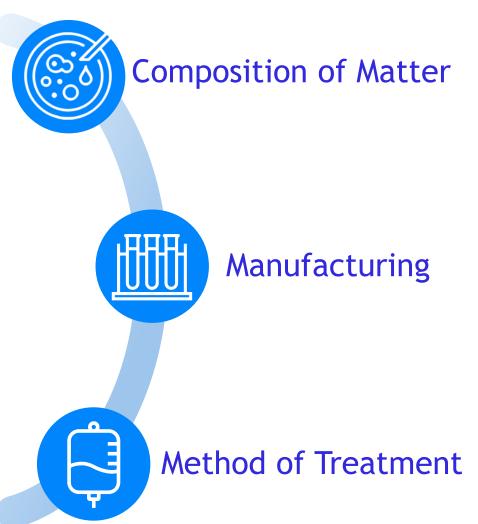
US patent exclusivity for use of mesenchymal precursor / stromal cells for all indications, and for acute GVHD specifically, provides a major commercial barrier against potential competitors

"Composition of matter" and "method of treatment" US patents have been granted for RYONCIL and other mesenchymal precursor / stromal cell products to treat GVHD through to 2032.

Upon FDA approval patent term may be extended up to 5 years to 2037.

Multiple "composition of matter", "method of treatment" and "manufacturing" patent applications have recently been filed and are still undergoing examination.

These applications have the potential to extend coverage through to 2043 for the use of various types of mesenchymal precursor / stromal cells, including bone marrow or iPS derived for the treatment of various indications including GVHD.





Late-Stage Clinical Pipeline based on proprietary allogeneic mesenchymal precursor / stromal cell platform

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

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

SR-aGVHD = Steroid-Refractory
Acute Graft Versus Host
Disease;
IBD = Inflammatory Bowel
Disease; HLHS = Hypoplastic
Left Heart Syndrome
HFrEF = Heart Failure with
Reduced Ejection Fraction;
CLBP = Chronic Low Back Pain;



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.

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

Program

Key Objectives

RYONCIL
Steroid-Refractory AcuteGraft versus Host Disease

Resubmitted BLA for approval in pediatric patients with FDA accepting the submission within two weeks. PDUFA date Jan 7th 2025

Study in adult patients for label extension to follow pediatric approval

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

REVASCOR Heart Failure

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

Preparing for accelerated approval filing



Financials

- Cash balance at September 30, 2024 is US\$51.1 million, with additional US\$60.0 million available from existing financing facilities on FDA approval of RYONCIL.
- Net operating cash spend of US\$10.5 million for the quarter ended September 30, 2024.
- 26% reduction in net operating cash spend for the quarter ended September 30, 2024 versus the comparative quarter in FY2024.
- On September 30, 2024 entered into a convertible note subscription agreement with our largest shareholder for issue, at Mesoblast's sole discretion, up to US\$50.0 million convertible notes on approval of RYONCIL by FDA.

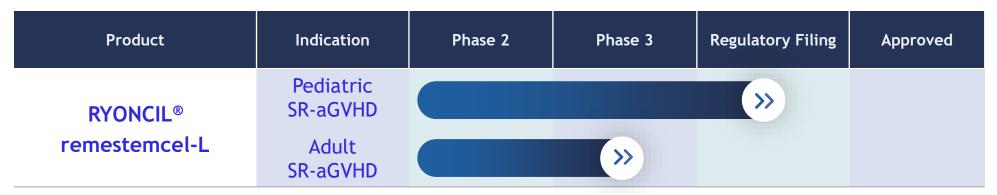


Remestemcel-L

Steroid-Refractory Acute Graft Versus Host Disease (SR-aGVHD)

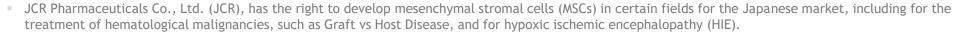


RYONCIL for steroid-refractory acute graft versus host disease (SR-aGVHD)



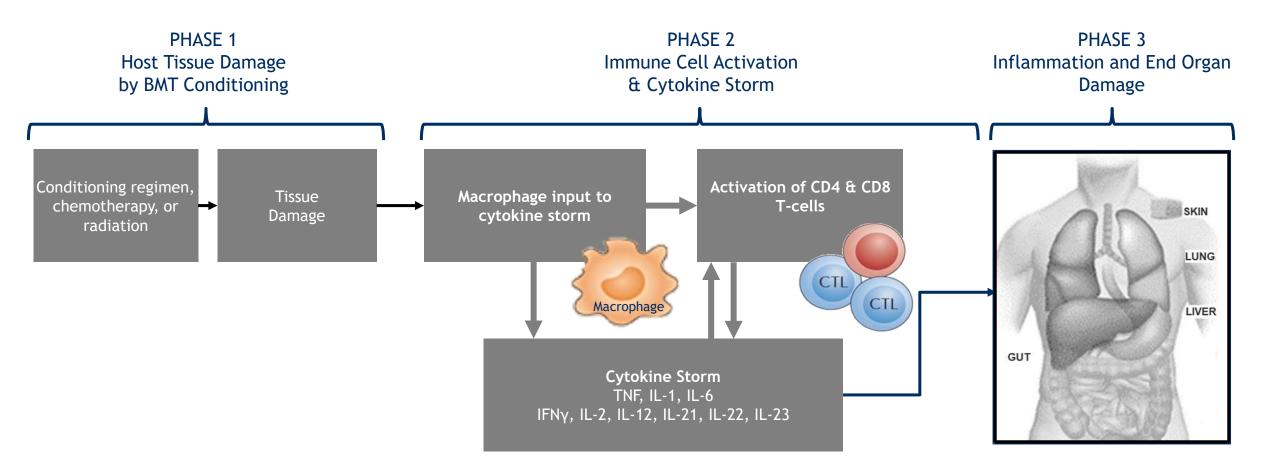
This chart is figurative and does not purport to show individual trial progress within a clinical program

Notes:





Acute Graft Versus Host Disease (aGVHD) is a serious and potentially fatal complication of allogeneic bone marrow transplantation (BMT)





Steroid-Refractory Acute Graft Versus Host Disease (SR-aGVHD) is associated with mortality rates as high as 90%

Treatment Options

- Corticosteroids are first-line therapy for aGVHD
- There is only one approved treatment for disease refractory to steroids and no approved treatment in the US for children under 12 years old
- In Japan, Mesoblast's licensee received the first product approval for SR-aGVHD in both children and adults

Burden of Illness

- Acute GVHD is a lifethreatening complication that occurs in ~50% of patients receiving allogeneic bone marrow transplants (BMTs)¹
- Acute GVHD primarily affects skin, GI tract, and liver
- Steroid-refractory aGVHD is associated with mortality rates as high as 90%^{1,4} and significant extended hospital stay costs²

Market Opportunity

- More than 30,000 allogeneic BMTs performed globally (>20K US/EU) annually, ~20% pediatric^{2,3}
- Approx. 10,000 allogeneic BMTs performed in the US annually
- Approx. 1,500 allogenic BMTs are in children and adolescents in US³



^{1.} Westin, J., Saliba, RM., Lima, M. (2011) Steroid-refractory acute GVHD: predictors and outcomes. Advances in Hematology. 2. Niederwieser D, Baldomero H, Szer J. (2016) Hematopoietic stem cell transplantation activity worldwide in 2012 and a SWOT analysis of the Worldwide Network for Blood and Marrow Transplantation Group including the global survey. 3. HRSA Transplant Activity Report, CIBMTR, 2020 4. 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.



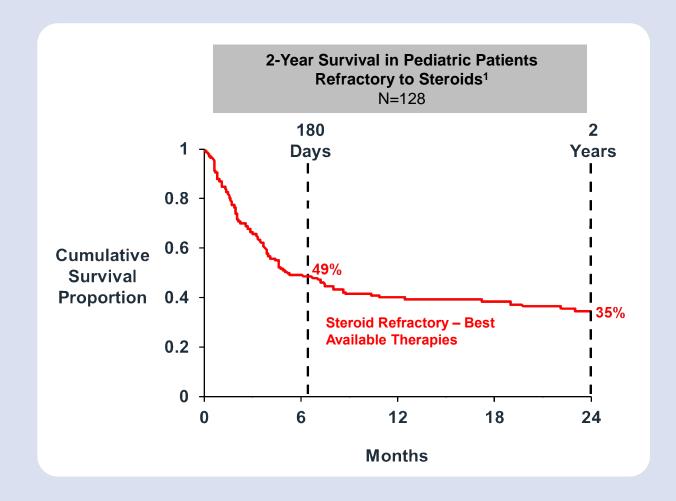
Remestemcel-L for Children with SR-aGVHD

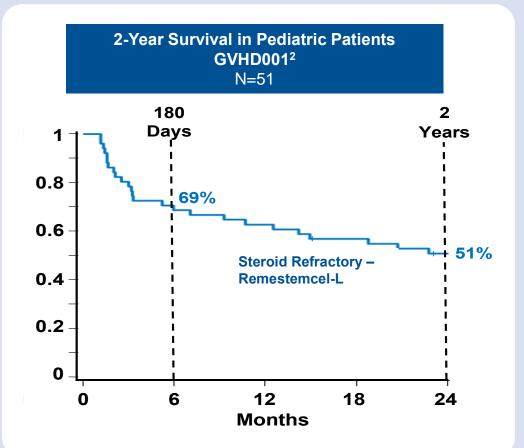
Improved Early Survival Across Three Studies involving more than 300 Treated Children

Day 100 Survival						
Remestemcel-L Protocol	Remestemcel-L	Matched Controls	Matched Control Protocol			
First Line Therapy after Steroids Treatment Setting						
1. Pediatric Subset of Protocol 280: randomized controlled P3, n=27 w/SR-aGVHD	79%	54%	Study Control Arm (n=13)			
2. Study 001 , open-label P3, n=54 ¹ with 89% Grade C/D disease	74%	57%	MAGIC ² cohort, n=30 ³ propensity- controlled subset			
Salvage Therapy Treatment Setting						
3. Expanded Access Protocol (EAP275), n=241	66%	na				



Long term Survival in Pediatric Patients with SR-aGVHD Treated with Remestemcel-L







Extended Survival Data in Children with SR-aGVHD

Remestemcel-L Treatment Resulted in Durable Survival Over 4 Years

Survival Outcomes in Pediatric & Adult SR-aGVHD

(Remestemcel-L data from the Center for International Blood and Marrow Transplant Research (CIBMTR) dbase)

Study	GVHD001	MacMillan et al ¹	Rashidi et al²	REACH2 ³	REACH2 ³	REACH1 ⁴
Treatment	Remestemcel-L	BAT ⁵	BAT ⁵	BAT ⁵	Ruxolitinib	Ruxolitinib
N=	51	128	203	155	154	71
Subjects	Children	Children	Adults	Adults	Adults	Adults
aGVHD Grade	88% Grade C/D	22% Grade 3/4	54% Grade 3/4	63% Grade 3/4	63% Grade 3/4	68% Grade 3/4
Year 1 Survival	63%	40%		44%	49 %	43%
Year 2 Survival	51%	35%	25%	36%	38%	
Year 3 Survival	49%					
Year 4 Survival	49%					

^{1.} MacMillan ML et al. Pediatric acute GVHD: clinical phenotype and response to upfront steroids. Bone Marrow Transplant 2020; 55(1): 165-171



^{2.}Rashidi A et al. Outcomes and predictors of response in steroid-refractory acute graft-versus-host disease: single-center results from a cohort of 203 patients. Biol Blood Bone Marrow Transplant 2019; 25(11):2297-2302.

^{3.}Zeiser R et al. Ruxolitinib for Glucocorticoid-Refractory Acute Graft-versus-Host Disease. N Engl J Med 2020;382:1800-10.

^{4.}Jagasia M et al. Ruxolitinib for the treatment of steroid-refractory acute GVHD (REACH1): a multicenter, open-label phase 2 trial. Blood. 2020 May 14; 135(20): 1739–1749 5.BAT = Best Available Treatment

Potential FDA approval of RYONCIL for pediatric patients with SR-aGVHD

- Mesoblast resubmitted its Biologics License Application (BLA) to FDA for approval of RYONCIL on July 8, 2024 and anticipates a decision prior to or on the FDA's Prescription Drug User Fee Act (PDUFA) goal date of January 7, 2025.
- Mesoblast and FDA continue to be engaged in active and ongoing interactions as part of the review process.
- FDA has already conducted the Pre-License Inspection (PLI) of the manufacturing process for RYONCIL in May 2023 and this did not result in the issuance of any Form 483.
- Inventory has been manufactured and there is an established supply chain to ensure cryopreserved product is available for delivery to meet the needs of each site immediately post approval, with ability to scale up as necessary going forward
- Mesoblast strategy is to first gain pediatric approval for RYONCIL, followed by label extension in the larger adult population.



Pre-Launch Activities For Go to Market Strategy - RYONCIL in Pediatric Patients

- Hiring of select senior positions to build targeted commercial team has commenced
- Key Activities:
 - Market Access initiates payer outreach
 - Medical provides education to payers
 - Corporate leadership initiates engagement with highest volume centers
 - Regional sales directors lead center profiling
- Ongoing KOL engagement with greatest experience using RYONCIL at highest volume centers
- Non-promotional activities including profiling high-volume centers, education on disease awareness & unmet needs, and payer engagement



Post-Launch Activities For Go to Market Strategy - RYONCIL in Pediatric Patients

- Post-launch Staged approach based on centers with highest volume and experience with product.
- Targeted sales force with experience in bone marrow transplant centers 15 highest volume centers account for ~50% of patients.
- **Key Activities:**
 - Initiate commercial onboarding & logistics at centers
 - MSLs engage centers around medical & scientific needs
 - Logistical and reimbursement support offered as needed
 - Center certification for remestemcel-L administration



Label extension strategy for RYONCIL in adult patients with SR-aGVHD

- Continued unmet need in adults with SR-aGVHD who fail ruxolitinib (>40% of treated patients).
- Survival in these patients who fail ruxolitinib remains a dismal 20-30% by 100 days, a patient population with no approved therapies. 1,2
- In contrast, 100-day survival was 73% after RYONCIL treatment was used under expanded access in 25 adults with SR-aGVHD who failed to respond to at least one additional agent, such as ruxolitinib.
- Following approval in pediatric patients, Mesoblast intends to commence a Phase 3 trial of RYONCIL in adults and adolescents with SR-aGVHD who are refractory to a second line agent such as ruxolitinib.
- Mesoblast is collaborating with the Blood and Marrow Transplant Clinical Trials Network (BMT CTN), a NIH-funded body responsible for approximately 80% of all US transplants, to conduct the trial.

^{1.} Jagasia M et al. Ruxolitinib for the treatment of steroid-refractory acute GVHD (REACH1): a multicenter, open-label phase 2 trial. Blood. 2020 May 14; 135(20): 1739-1749.

[.] Abedin S, et al. Ruxolitinib resistance or intolerance in steroid-refractory acute graft versus-host disease — a real-world outcomes analysis. British Journal of Haematology, 2021;195:429-43.



Rexlemestrocel-L for chronic low back pain

Product	Indication	Phase 2	Phase 3	Regulatory Filing	Approved
Rexlemestrocel-L (STRO3+)	CLBP		>>>		

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

Notes



[•] Grünenthal has an exclusive license to develop and commercialize rexlemestrocel-L for chronic low back pain in Europe and Latin America/Caribbean.

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 Treatments

- NSAIDs
- Physical therapy
- Chiropractic treatments
- Acupuncture
- Anticonvulsants (e.g., gabapentin)

Opioid Analgesics

- Weak opioid analgesics (e.g., tramadol)
- Strong opioid analgesics (e.g., oxycodone)

Interventional Therapies

- Epidural steroid injections (offlabel)
- Radio frequency ablation
- Spinal cord stimulation
- Intrathecal pumps

Conservative Treatments

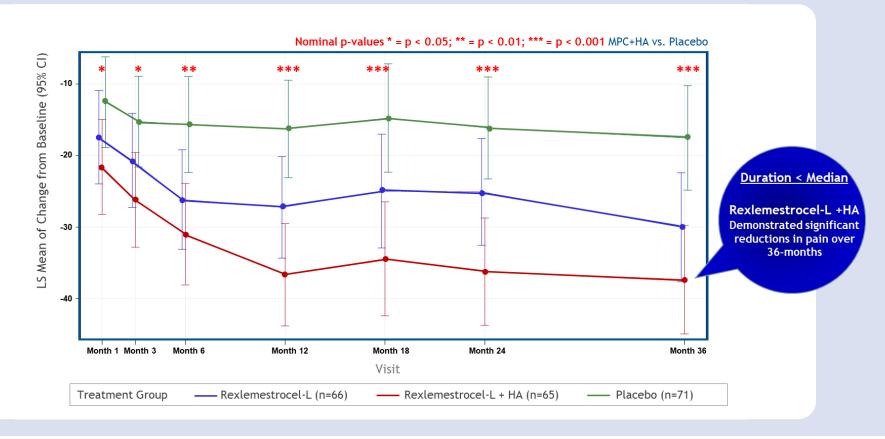
- Spinal fusion
- Disc replacement



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)





Rexlemestrocel-L / CLBP - program summary





Gained alignment with the FDA on the appropriate pivotal Phase 3 study

Seeks to replicate the significant reduction in pain seen at 12 and 24 months in our first Phase 3 trial



Phase 3 Protocol

FDA has agreed with Mesoblast plans for mean pain reduction at 12 months as the primary endpoint of the pivotal trial

Functional improvement and reduction in opioid use as secondary endpoints



Product Manufacturing

Product has been manufactured for use in the second Phase 3 study

Potency assays are in place for product release

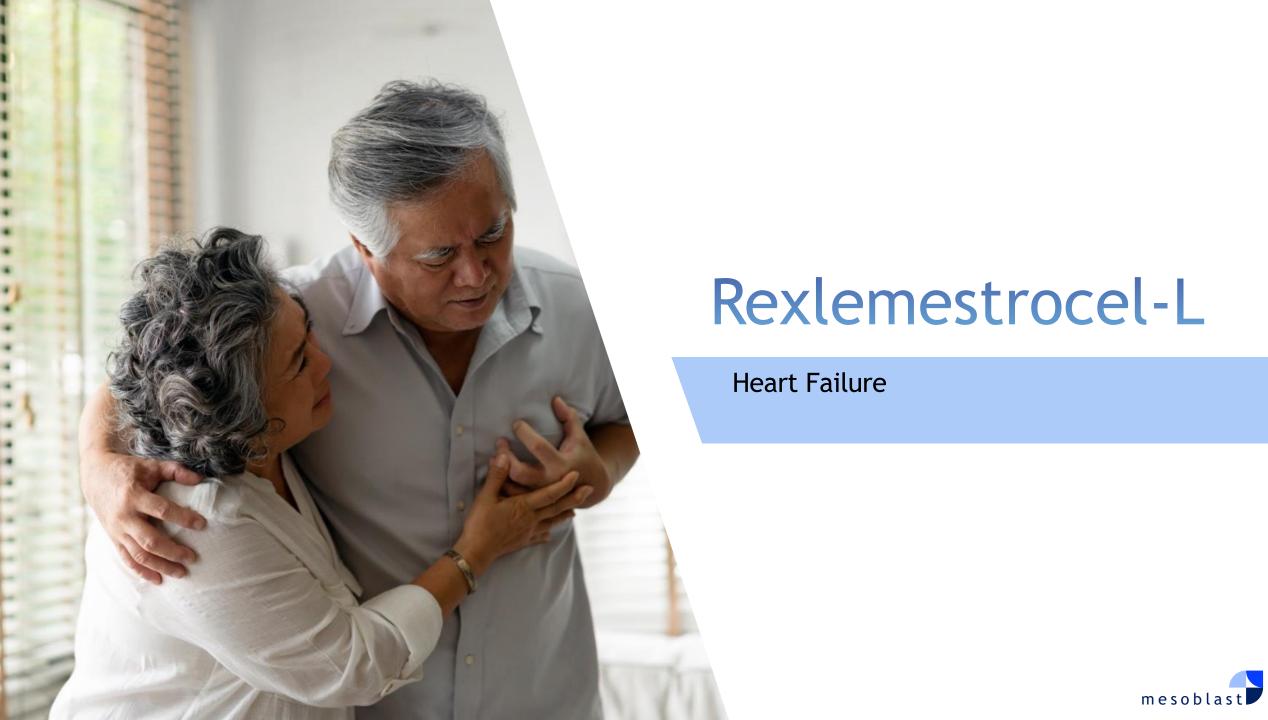


Pivotal P3 Trial

RMAT designation for CLBP received from FDA

Second Phase 3 trial actively enrolling





REVASCOR for pediatric congenital heart disease and adults with ischemic HFrEF



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



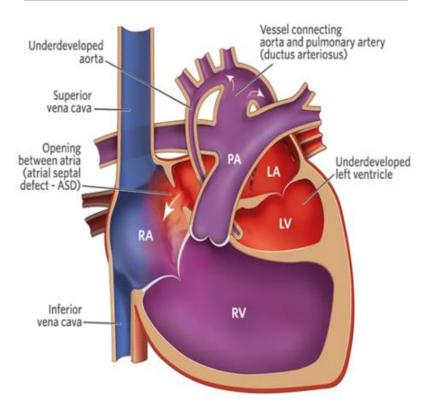
[•] Tasly Pharmaceuticals has exclusive rights for rexlemestrocel-L for the treatment or prevention of chronic heart failure in China.



Pediatric: REVASCOR As treatment for severe congenital heart disease

- REVASCOR has multiple mechanisms-of-action that may be beneficial to children with congenital heart disease including neovascularization, anti-fibrosis, and reduction in inflammation.
- Hypoplastic left heart syndrome (HLHS) is a severe congenital heart disease in which the left ventricle (LV) is underdeveloped and cannot pump oxygenated blood to the rest of the body.
- Current definitive surgical procedure (Fontan) is life-saving, but maintains only a functional right ventricle (RV), resulting in progressive right heart failure, liver congestion, liver fibrosis and cirrhosis
- Creation of permanent two-ventricle circulation with LV pumping blood to the body would avoid the complications of Fontan procedure, but is limited to 30% whose LV is sufficiently large.
- Clinical trial at Boston Children's Hospital evaluated whether REVASCOR could increase LV size and increase the proportion of children capable of receiving permanent two-ventricle surgery.

Anatomy of hypoplastic left heart syndrome





Pediatric: REVASCOR as treatment for severe congenital heart disease

- In the HLHS randomized controlled single-center US trial in 19 patients, a single intramyocardial administration of REVASCOR at the time of staged surgery resulted in significantly increased LV systolic and diastolic volumes over 12 months compared with control.¹
- These changes are indicative of clinically important growth of the small left ventricle, facilitating the ability to have a successful surgical correction, known as full biventricular (BiV) conversion, which allows for a normal two ventricle circulation with the surgically repaired left ventricle taking over circulatory support to the body.
- Without full BiV conversion the right heart chamber is under excessive strain with increased risk of heart failure, liver cirrhosis, and death.
- The study showed 63% (5/8) of the REVASCOR treated HLS children vs 34% (4/11) of the controls went to full BiV conversion at 12 months post LV recruitment surgery. This represents a 75% increase in the rate of the optimal outcome.



Pediatric: FDA awarded Rare Pediatric Disease designation and Orphan Drug designation to REVASCOR for hypoplastic left heart syndrome

- FDA granted Mesoblast's cardiovascular investigational product, REVASCOR, both Rare Pediatric Disease Designation (RPDD) and Orphan Drug Designation (ODD) this year. This followed submission of results from the randomized controlled trial in children with hypoplastic left heart syndrome (HLHS), a potentially life-threatening congenital heart condition.
- RPDD demonstrates that the disease is serious or life-threatening and the manifestations primarily affect individuals aged from birth to 18 years, including age groups often called neonates, infants, children, and adolescents, and that the disease is a rare disease or condition.
- On FDA approval of a BLA for REVASCOR for the treatment of HLHS, Mesoblast may be eligible to receive a Priority Review Voucher (PRV) that can be redeemed for any subsequent marketing application or may be sold or transferred to a third party.
- Mesoblast plans to meet with FDA to discuss whether the randomized controlled study can be used to obtain regulatory approval for REVASCOR in children with this life-threatening condition.



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).



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

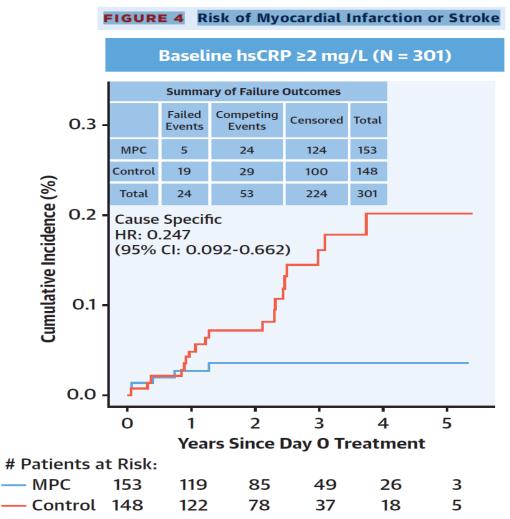


Randomized Trial of Targeted Transendocardial Mesenchymal Precursor Cell Therapy in Patients With Heart Failure



Perin EC, Borow KM, Henry TD, et al. Randomized Trial of Targeted Transendocardial Mesenchymal Precursor Cell Therapy in Patients With Heart Failure. Journal of the American College of Cardiology. 2023;81(9):849-863.

- Randomized, double-blind, controlled, 537 patient Phase 3 trial of rexlemestrocel-L over mean follow-up of 30 months showed:
- Improved LVEF from baseline to 12 months in all patients - maximal benefit seen in patients with active inflammation
- Reduced risk of MI or stroke by 57% in all treated patients, and by 75% in patients with inflammation
- Reduced risk for time-to-first Major Adverse Cardiac Event (MACE), defined as cardiovascular death, MI or stroke, by 28% in all patients, and by 37% in patients with 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.
- At Type B meeting in Q1 2024, FDA informed Mesoblast that the totality of the trial results from these studies may support an accelerated approval pathway for REVASCOR in end-stage ischemic HFrEF patients with LVADs.
- Mesoblast intends to request a pre-BLA meeting with FDA to discuss data presentation, timing and FDA expectations for an accelerated approval filing in ischemic HFrEF patients with end-stage heart failure.





mesoblast

Thank You

