

Global Leader in Allogeneic Cellular Medicines for Inflammatory Diseases

Operational Highlights and Financial Results for the Quarter Ended December 31, 2022

February 2023 ASX: MSB; Nasdaq: MESO



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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 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," "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 a

Our Mission

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

Investment Highlights

Novel Allogeneic
Cell Therapy Platform

Developing off-the-shelf, allogeneic cellular medicines based on proprietary mesenchymal stromal cell (MSC) technology platforms to enable treatment without the need for donor matching or immunosuppression

Remestemcel-L for SR-aGVHD

Remestemcel-L BLA resubmitted to FDA for children with steroid-refractory acute graft versus host disease (SR-aGVHD) January 31, 2023

Rexlemestrocel-L for CLBP

First Phase 3 completed for discogenic chronic low back pain (CLBP). RMAT granted by FDA. Progressing towards initiation of a second pivotal Phase 3 study commencing mid-CY2023

Rexlemestrocel-L for HFrEF

First Phase 3 completed for heart failure with reduced ejection fraction (HFrEF) Class II/III patients. RMAT granted by FDA for end-stage HFrEF patients with an LVAD

Finances

Annualized revenue of US\$7.6 million from royalties on sales MSC products; US\$67.6 million in cash plus up to an additional US\$40 million from existing financing facilities, subject to certain milestones. Potential for commercial partnering and royalty sharing transactions



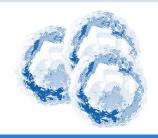
Late-Stage Clinical Pipeline

Based on the Proprietary Allogeneic Mesenchymal Stromal Cell Platforms

Product	Indication	Phase 2	Phase 3	Regulatory Filing	Approved	Status/Next Steps
Remestemcel-L	SR-aGVHD			>>>		BLA resubmitted Jan 2023
Rexlemestrocel-L	CLBP		>>>			 RMAT granted Planning to start pivotal Phase 3 trial mid-CY2023
Rexlemestrocel-L	HFrEF		>>>			 RMAT granted for End- Stage/LVAD FDA meeting planned for H1 CY2023
Remestemcel-L	ARDS and other applications		>>			Clinical collaborations, investigator studies

Mesoblast's Proprietary Stromal Cell Technology

Based on mesenchymal lineage adult stromal cells (MLCs/SCs)



Mesenchymal Lineage

MLCs are **derived** from healthy bone marrow, **present** around blood vessels and **responsive** to signals associated with tissue damage / inflammation



Defined Stromal Cells

Biologically-defined, optimized for results: Remestemcel-L: based on mesenchymal stromal cells (MSCs)

Rexlemestrocel-L: based on mesenchymal precursor cells (MPCs)



Allogenic Properties

Expanded without differentiation

No expression of cell surface co-stimulatory

molecules





Scalable Production

Scalable "off-the-shelf" cellular platforms

Validated potency assay to ensure batch-to-batch consistency and reproducibility





Financial Results

for the Period Ended December 31, 2022



Financial Highlights

Royalty Revenue

Revenue from royalties on sales of TEMCELL® HS Inj.¹ sold in Japan by our licensee were US\$1.9 million for the quarter ended December 31, 2022. On a constant currency basis, sales for the quarter ended December 31, 2022, were US\$2.1 million², compared with US\$2.3 million for the quarter ended December 31, 2021.

Cash Burn

Net cash usage for operating activities in the second quarter FY2023 was US\$16.5 million; this represented a 9% reduction (US\$1.7 million) on the second quarter FY2022, and a 46% reduction (US\$14.1 million) on the second quarter FY2021.

Cash Reserves

At December 31, 2022, cash-on-hand was US\$67.6 million. Up to an additional US\$40.0 million may be drawn from existing financing facilities subject to achieving certain milestones.

- 1. TEMCELL® HS Inj. is a registered trademark of JCR Pharmaceuticals Co. Ltd.
- TEMCELL sales by our Licensee are recorded in Japanese Yen before being translated into USD for the purposes of calculating the royalty paid to Mesoblast. Results have been adjusted for the movement of the USD to Japanese Yen exchange rate from 1USD:116.02 Yen for the 3 months ended December 31, 2021 to 1USD:133.70 Yen for the 3 months ended December 31, 2022.



Reduction in Expenditure on R&D, Improved Loss Before Tax

P&L for the quarter ended (US\$m)	Dec 31, 2022	Dec 31, 2021
Total Revenue	2.1	2.4
Research and development	(7.7)	(10.2)
Manufacturing	(7.9)	(6.6)
Management & administration	(6.4)	(7.8)
Revaluation of contingent consideration	1.5	(0.4)
Revaluation of warrant liability	(0.3)	2.2
Other operating income & expenses	0.3	(0.2)
Finance costs	(6.2)	(5.4)
Loss before tax	(24.6)	(26.0)
Income tax benefit	0.1	0.1
Loss after tax	(24.5)	(25.9)

Revenue: Revenue predominately from royalties on sales of TEMCELL® HS Inj.¹ sold in Japan by our licensee.

Reduction in R&D Expenditure: reduced by US\$2.5 million (25%), down to US\$7.7 million for the quarter ended December 31, 2022. R&D expenses primarily supported preparations for the remestemcel-L BLA re-submission and preparations for pivotal studies for rexlemestrocel-L, as clinical trial activities for our product candidates are reduced since clinical trial recruitment and data analysis are now complete.

Continued Investment in Manufacturing: continued manufacturing activities to support the potential commercial launch for SR-aGVHD. On FDA approval US\$30.4 million of remestemcel-L pre-launch inventory will be recognized on the balance sheet.

Finance Costs include US\$5.0 million of non-cash expenditure for the quarter ended December 31, 2022 comprising accruing interest and borrowing costs.





Remestemcel-L

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



Remestemcel-L: Steroid-Refractory Acute Graft Versus Host Disease (SR-aGVHD) 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 has received the only 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%^{1,5} and significant extended hospital stay costs²

Market Opportunity

- More than 30,000 allogeneic BMTs performed globally (>20K US/EU) annually, ~20% pediatric^{3,4}
- Approx. 1,500 allogeneic BMTs in children and adolescents in US⁴



^{1.} Westin, J., Saliba, RM., Lima, M. (2011) Steroid-refractory acute GVHD: predictors and outcomes. Advances in Hematology. 2. Anthem-HealthCore/Mesoblast claims analysis (2016). Data on file 3. 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. 4. HRSA Transplant Activity Report, CIBMTR, 2019 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.

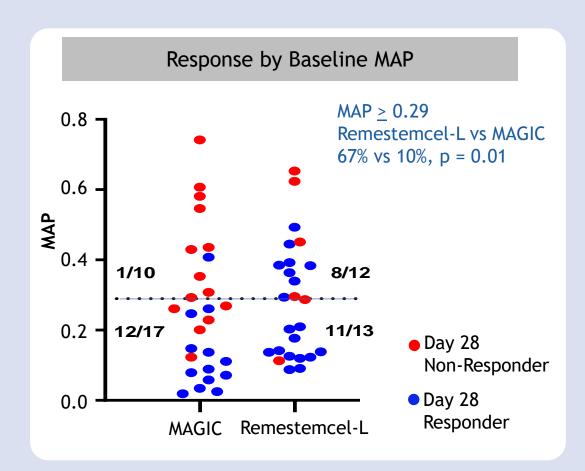


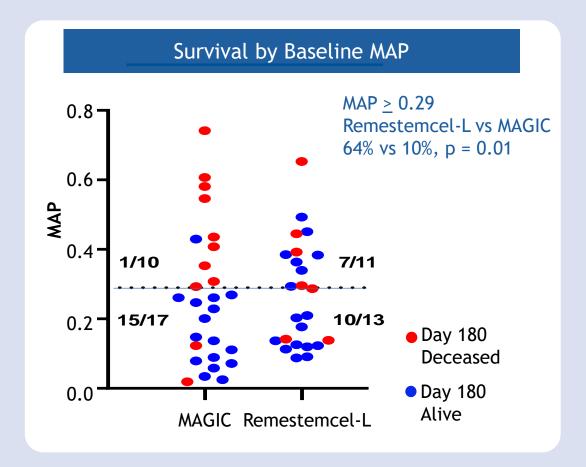
BLA Resubmission Contains New Data on Product Potency and Clinical Outcomes in Pediatric Patients with SR-aGVHD

- New data showing remestemcel-L's treatment benefit in high-risk disease activity and on survival in propensity-matched studies of children in the Phase 3 trial and controls stratified by validated biomarkers for high-risk disease
- New long-term survival data for children enrolled in the Phase 3 trial showing durability of treatment effect through at least four years
- New analyses of data from Phase 3 trial and the Expanded Access Program showing that the validated potency assay reflects the primary mechanism of action of remestemcel-L in children with SR-aGVHD, correlates with the product's in vivo bioactivity, and predicts overall survival outcomes
- New data showing that the validated potency assay has low variability and can adequately demonstrate manufacturing consistency and reproducibility



Use of Validated Biomarker for Assessment of Treatment Effect in Severe SR-aGVHD Remestemcel-L Results in Significantly Greater Day 28 Overall Responses and Day 180 Survival in Highest-Risk Patients (Baseline MAP ≥ 0.29)

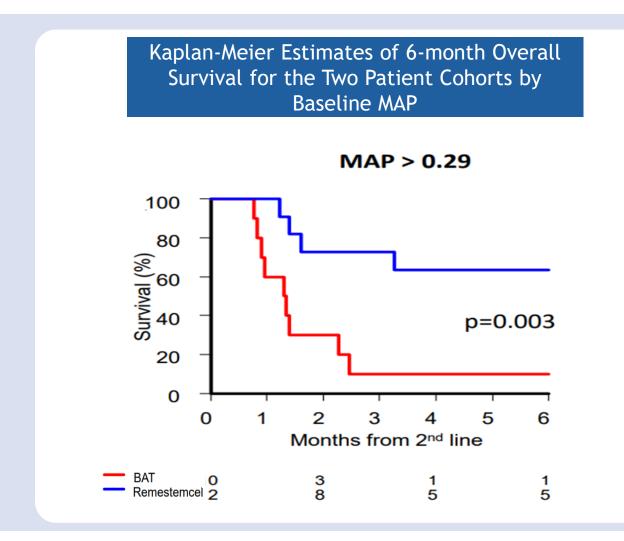






Remestemcel-L Treatment Outcomes

Significantly Greater Survival in Steroid-Refractory Patients with Baseline MAP ≥ 0.29



Abbreviations:

MAP: MAGIC algorithm probability;

BAT: best available therapy.



Remestemcel-L for SR-aGVHD

Improved Early Survival in Children Across Three Studies

Day 100 Survival						
Remestemcel-L Protocol	Remestemcel-L	Matched Controls	Matched Control Protocol			
First Line Therapy after Steroids Treatment Setting						
Pediatric Subset of Protocol 280: randomized controlled P3, n=27 w/SR-aGVHD	79%	54%	Study Control Arm (n=13)			
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						
Expanded Access Protocol (EAP275), n=241	66%	na				
EAP275 , n=51 Grade D subset	51%	31%	CIBMTR dbase, n=3274 propensity controlled subset			



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	Zeiser et al 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



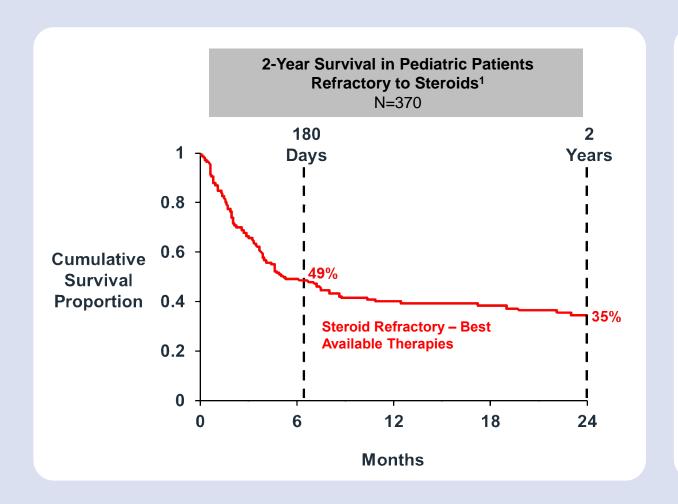
^{2.}Rashidi A et al. Outcomes and predictors of response in steroid-refractory acute graft-versus-host disease: single-center results from a cohort of 203 patients. Biol Blood Bone Marrow Transplant 2019; 25(11):2297-2302.

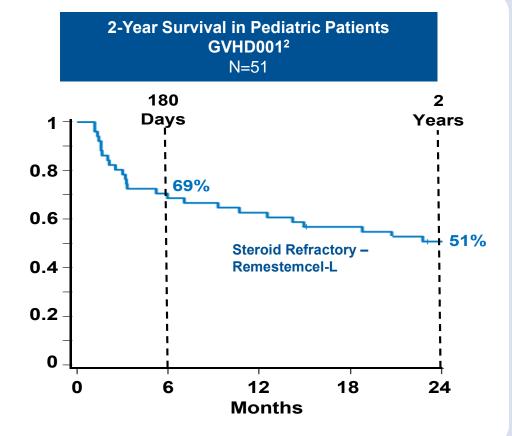
 $^{3.} Zeiser\ R\ et\ al.\ Ruxolitinib\ for\ Glucocorticoid-Refractory\ Acute\ Graft-versus-Host\ Disease.\ N\ Engl\ J\ Med\ 2020; 382: 1800-10.$

^{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

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

Presented at the 2023 Tandem Meeting of ASTCT and CIBMTR









Chronic Low Back Pain Due to Degenerative Disc Disease (CLBP) Impacts 7M+

Rexlemestrocel-L represents a potential new paradigm for the treatment of CLBP

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 the Potential to be First-Line Treatment for Patients with 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



Regenerative Medicine Advanced Therapy (RMAT) Designation Granted by FDA for Rexlemestrocel-L in the treatment of CLBP

RMAT designation provides all the benefits of Breakthrough and Fast Track designations, including rolling review and eligibility for priority review on filing of a Biologics License Application (BLA)

Results from the trial showed that:

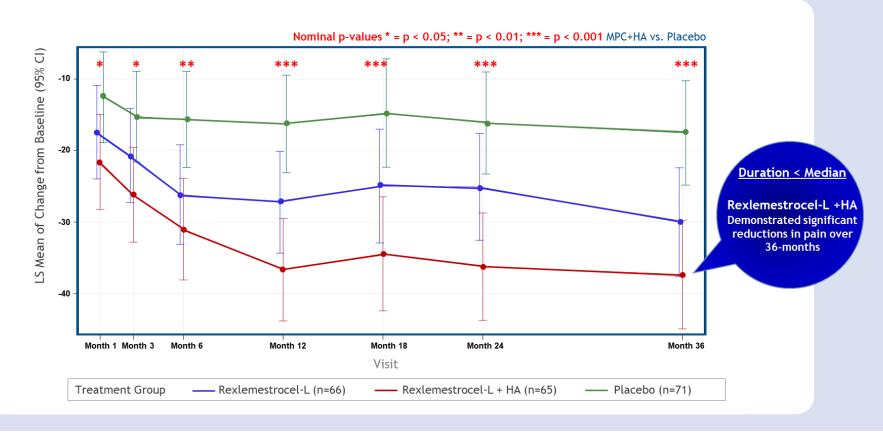
- A single injection of rexlemestrocel-L+HA into the lumbar disc resulted in significant reduction in pain compared with saline control at 12 and 24 months across all subjects (n=404)
- Pain reduction through 36 months was seen in the subset of patients using opioids at baseline (n=168) with the rexlemestrocel-L+HA group having substantially greater reduction at all time points compared with saline controls
- Among patients on opioids at baseline, despite instructions to maintain existing therapies throughout the trial, at 36 months 28% who received rexlemestrocel-L+HA were not taking an opioid compared with 8% of saline treated controls



Phase 3 Trial Outcomes based on a Single Injection of Rexlemestrocel-L + HA Results in 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



Regulatory Alignment

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 a primary endpoint of the next pivotal trial

Mean functional improvement and reduction in opioid use as secondary endpoints



In Prep for US/EU Submissions

The planned Phase 3
Program will include 80%
of subjects in the US and
20% from the EU, to
support regulatory
submissions to FDA and
EMA

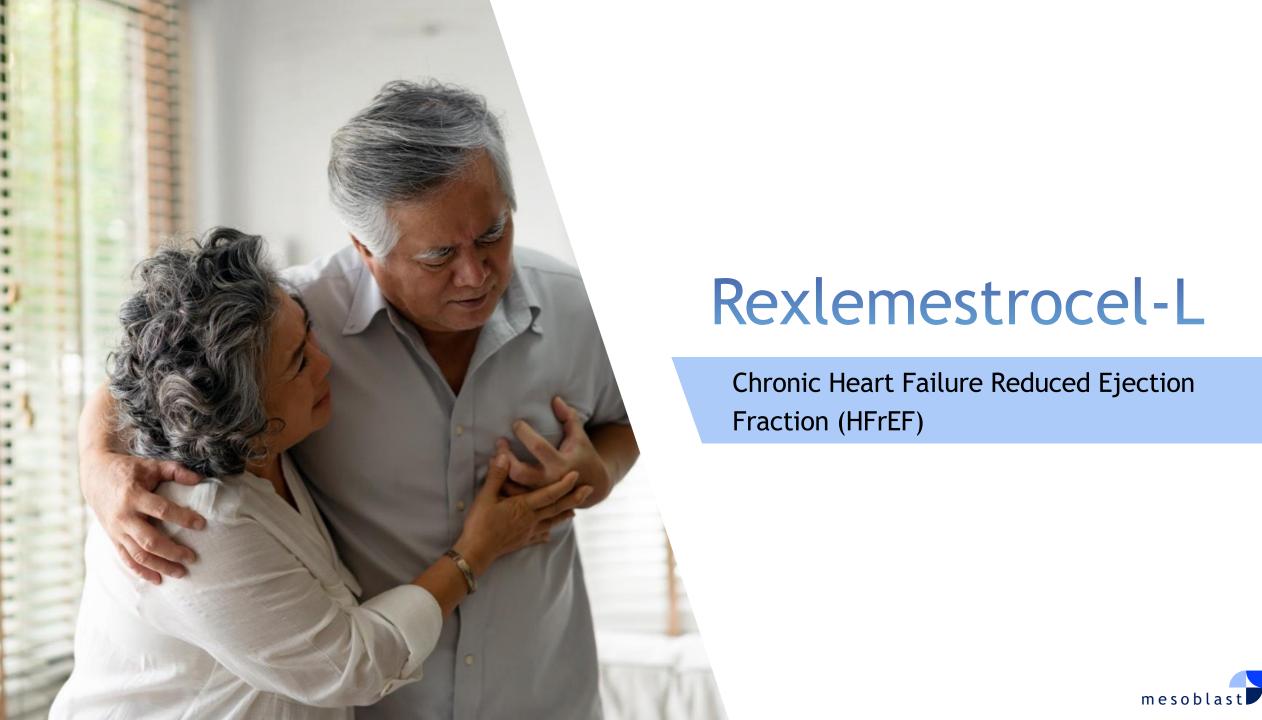


Commence Pivotal P3 Mid-CY2023

RMAT designation for CLBP received from FDA February 2023

Commencement of pivotal trial by mid-CY2023





Chronic Heart Failure (CHF): Rising Incidence and High Mortality

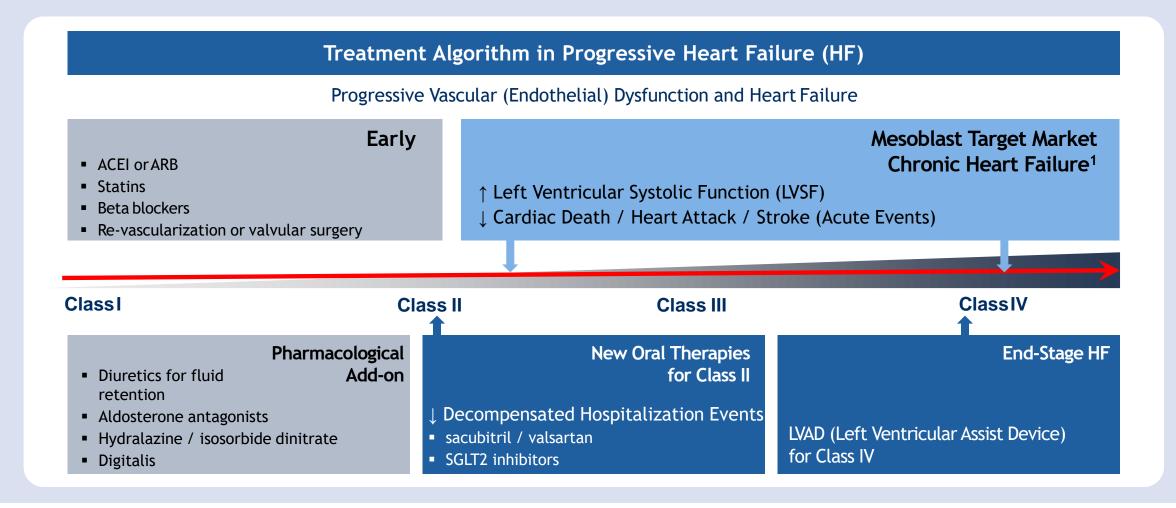
New therapies reduce recurrent hospitalization but do not materially improve mortality or major ischemic event rates

- Cardiovascular disease 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)



Patients Experience Progressive Vascular Dysfunction and Heart Failure

Rexlemestrocel-L has the potential to improve endothelial dysfunction in patients from Class II thru IV





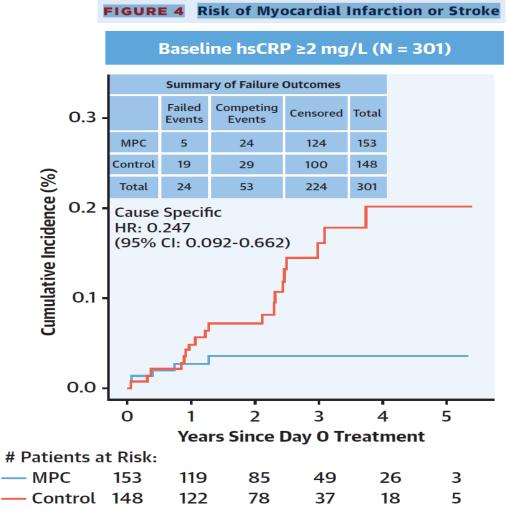
Randomized Trial of Targeted Transendocardial Mesenchymal Precursor Cell Therapy in Patients With Heart Failure



Emerson C. Perin, MD, PHD,a Kenneth M. Borow, MD,b Timothy D. Henry, MD,c Farrell O. Mendelsohn, MD,d Leslie W. Miller, MD,e Elizabeth Swiggum, MD,f Eric D. Adler, MD,g David H. Chang, MD,h R. David Fish, MD,a Alain Bouchard, MD,d Margaret Jenkins, BSc (Hons),f Alex Yaroshinsky, PHD,f Jack Hayes, MA,k Olga Rutman, PHD,k Christopher W. James, PA,k Eric Rose, MD,f Silviu Itescu, MD,f Barry Greenberg, MDm

Randomized, double-blind, controlled, 537 patient Phase 3 trial of rexlemestrocel-L over mean followup 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



Rexlemestrocel-L / HFrEF

Defining the Regulatory Path to FDA Approval



Significant Need

Cardiovascular disease remains the leading cause of death in the US

CHF is a progressive disease with a high mortality approaching 50% at 5 years, and at least 75% after an initial hospitalization



Promising Data

Recent data from the DREAM-HF P3 trial showed improved LVEF at 12 months, preceding long-term reduction in MACE events across all treated patients

LVEF is a potential early surrogate endpoint



Targeting Inflammation

Effects on LVEF and MACE outcomes are enhanced in patients with active inflammation

Trial results from class II to end-stage HFrEF now support a MOA by which rexlemestrocel-L reverses inflammation-related endothelial dysfunction



H1 CY2023 FDA Meeting

Mesoblast plans to meet with the FDA in H1 CY2023 under its RMAT designation to discuss the potential pathway to approval







