

### Global Leader in Allogeneic Cellular Medicines for Inflammatory Diseases

Financial Results and Operational Update for the Year Ended June 30, 2023

August 2023 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 pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements oth stores than statements of historical facts contained in this presentation are forward-looking statements. We have based these forward-looking statements and future events, "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 of Mesoblast's intellectual property, the timeline for Mesoblast's adult stern cell technologies; expectations regarding the strength of Mesoblast's intellectual property, the timeline for Mesoblast's and potential future expites and statements concerning Mesoblast's and potential future expites and statements should not be read as a guarantee of future performance or achievements to be materially and efficiency in business that may cause our exits, 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, need for future experts or or out regulatory approvals or cearance; government regulation; the need for future expite, and potential products; uncertainty of clinical trial results or regulatory approvals or clearance; government regulation; the need for future expite, an

### **Our Mission**

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



### Late-Stage Clinical Pipeline

#### Based on the Proprietary Allogeneic Mesenchymal Stromal Cell Platform

Product	Indication	Phase 2	Phase 3	Regulatory Filing	Approved
Remestemcel-L	Pediatric SR-aGVHD			>>>	
Remestemcel-L	Adult SR-aGVHD		<b>&gt;&gt;</b>		
Rexlemestrocel-L	CLBP		>>>		
Rexlemestrocel-L	HFrEF		<b>&gt;&gt;</b>		

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

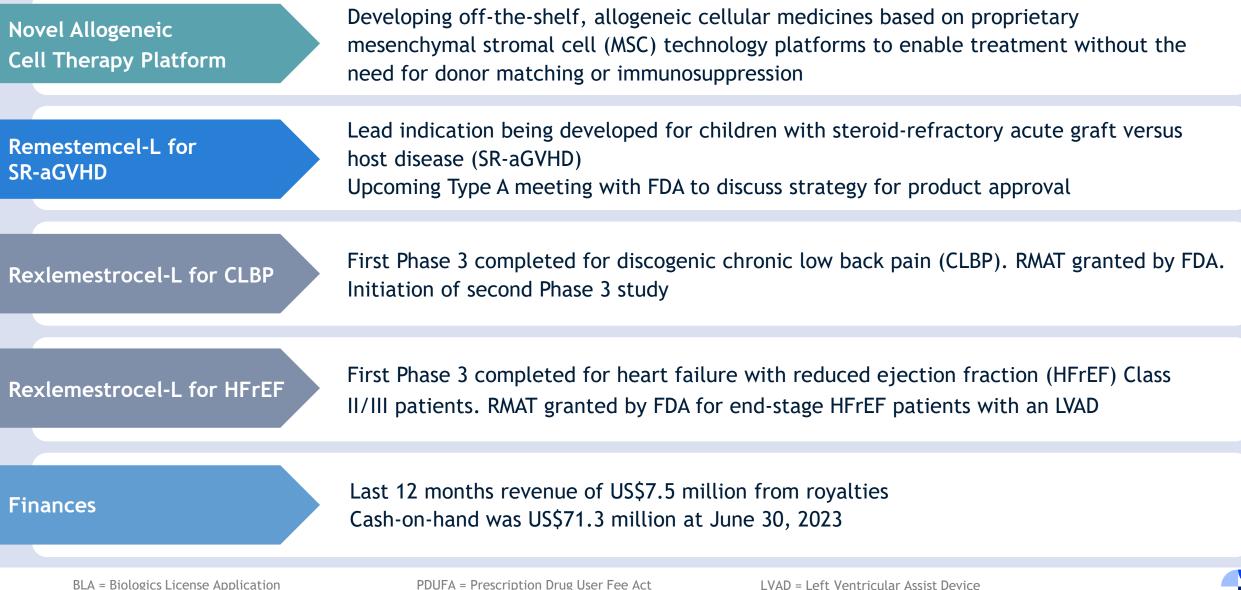
Notes:

- 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.



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#### **Investment Highlights**



FDA = United States Food and Drug Administration

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RMAT = Regenerative Medicine Advanced Therapy

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### Regulatory Status for Remestemcel-L in Pediatric Patients with SR-aGVHD

#### Type A FDA Meeting Scheduled for mid-September

- During the six-month BLA review we made substantial progress towards bringing this cutting-edge product to market with completion of a comprehensive FDA inspection of our manufacturing process
- In August 2023 FDA provided a complete response to Biologics License Application (BLA) resubmission for remestemcel-L for the treatment of pediatric SR-aGVHD.
- FDA provided a complete response requiring Mesoblast to demonstrate that product used in the phase 3 trial is similar to product intended for commercial release, as measured by a standardized potency assay
- FDA indicates that an additional clinical trial would be needed to establish this link if the company is not able to do so via additional potency assay work
- Type A meeting with FDA scheduled to be held mid-September
- Mesoblast proposes providing FDA with additional potency assay data to provide link between Phase 3 product and commercial inventory
- Mesoblast proposes providing FDA with new clinical trial data in adults, which could also support the pediatric indication

#### Regulatory Status for Remestemcel-L in Patients with SR-aGVHD

#### **Generating New Clinical Data in Adults**

- In line with our overall commercial strategy to progress to adult patient populations, which make up approximately 5-fold larger numbers than children, Mesoblast intends to conduct a targeted, controlled study in adults with high mortality risk
- Survival in adults with SR-aGVHD who have failed at least one additional agent, such as ruxolitinib, remains as low as 20-30% by 100 days<sup>1,2</sup>
- In contrast, 100-day survival was 63% after remestemcel-L treatment was used under expanded access in 71 patients aged 12 and older with SR-aGVHD who failed to respond to at least one additional agent, such as ruxolitinib
- Mesoblast is in discussions with world-leading investigators at the Blood and Marrow Clinical Trials Network (BM CTN), a body responsible for 80% of all US transplants, to conduct the new clinical trial
- The costs of this targeted study are expected to be covered by the planned spending reductions as outlined in the financial section

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

2. 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.





# **Financial Results**

for the Period Ended June 30, 2023

Manufacturing Remestemcel-L



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### Financial Highlights for the Year

Royalty Revenue	Revenue from royalties were US\$7.5 million for the year ended June 30, 2023. On a constant currency basis, royalties on sales of TEMCELL® HS Inj. <sup>1</sup> in Japan by our licensee were US\$8.1 <sup>2</sup> million for the year ended June 30, 2023, compared with US\$8.7 million for the year ended June 30, 2022.
Cash Burn	Net cash usage for operating activities in FY2023 was US\$63.3 million; this represented a 37% reduction compared with FY2021 and a 4% reduction compared with FY2022.
Cash Reserves	At June 30, 2023, cash-on-hand was US\$71.3 million, with up to an additional US\$40.0 million from our existing financing facilities subject to both certain milestones and the extension of availability.

1. TEMCELL<sup>®</sup> HS Inj. is a registered trademark of JCR Pharmaceuticals Co. Ltd.

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2. 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:122.14 Yen for the year ended June 30, 2022 to 1USD:139.76 Yen for the year ended June 30, 2023.



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

P&L for the quarter ended (US\$m)	June 30, 2023	June 30, 2022
Total Revenue	7.5	10.2
Research and development	(27.2)	(32.8)
Manufacturing	(27.7)	(30.8)
Management & administration	(25.4)	(27.2)
Revaluation of contingent consideration	8.8	0.9
Revaluation of warrant liability	(2.2)	5.9
Other operating income & expenses	4.2	(0.5)
Finance costs	(20.1)	(17.3)
Loss before tax	(82.1)	(91.6)
Income tax benefit	0.2	0.2
Loss after tax	(81.9)	(91.4)

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

Reduction in R&D Expenditure: reduced by US\$5.6 million (17%), down to US\$27.2 million for the year ended June 30, 2023. R&D expenses primarily supported preparations for the remestemcel-L BLA re-submission and preparations for pivotal studies for rexlemestrocel-L.

**Reduction in Manufacturing Expenditure:** reduced by US\$3.0 million (10%), down to US\$27.7 million for the year ended June 30, 2023. During the year ended June 30, 2023, we continued pre-launch manufacturing activities.

**Finance Costs** include US\$15.2 million of non-cash expenditure for the year ended June 30, 2023 comprising accruing interest and borrowing costs.

Figures have been rounded.



### Cost Containment Plan for Next 12 Months

#### Reduction in Spend on Operational Activities And Payroll

- Net operating cash usage in FY2023 was a 37% reduction compared with FY2021 and 4% reduction compared with FY2022
- Further targeted 23% reduction (US\$15 million) from US\$63.3 million in FY2023 to US\$48.3 million in projected FY2024 annual net operating cash spend through reduced spend across research, sales & marketing, commercial inventory, and payroll, which will be partially offset by investment in our Phase 3 programs for SR-aGVHD and CLBP
  - 40% annualized reduction in payroll by February 2024 which includes base salaries, STI payments and contractor fees
    - CEO and CMO have deferred their entire FY23 short-term incentives (STI), have voluntarily reduced their base salaries for FY24 by 30% to preserve cash and will instead receive long-term non-cash incentives (LTIs) to further align with shareholders
    - FY23 short-term incentives (STI) have been entirely deferred for all employees
    - Management are eligible to receive LTIs in lieu of a 30% reduction in salary
- Non-Executive Directors have voluntarily deferred 100% of the cash payment of their fees and agreed to receive 50% of the value of their compensation in long-term non-cash incentives (LTI)
- Shift from quarterly to half yearly reporting of Financial Statements from FY2024 with continued quarterly Appendix 4C cash and operational reports, in-line with ASX-listed entities





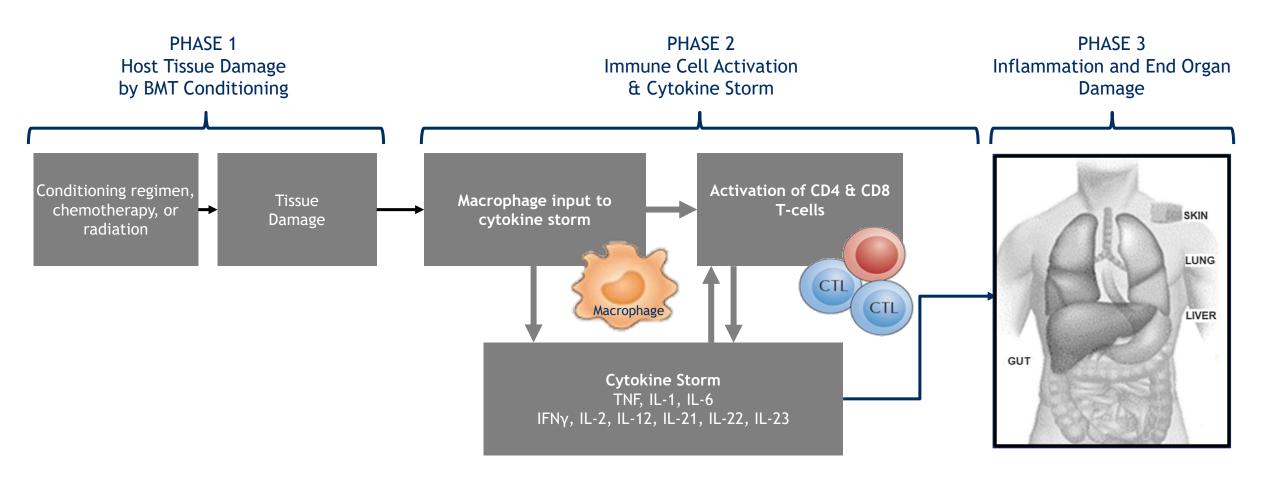
## Remestemcel-L

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



#### Acute Graft Versus Host Disease (aGVHD)

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





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

Treatment Options	Burden of Illness	Market Opportunity	
<ul> <li>Corticosteroids are first-line therapy for aGVHD</li> <li>There is only one approved treatment for disease refractory to steroids and no approved treatment in the US for children under 12 years old</li> <li>In Japan, Mesoblast's licensee has received the only product approval for SR-aGVHD in both children and adults</li> </ul>	<ul> <li>Acute GVHD is a life- threatening complication that occurs in ~50% of patients receiving allogeneic bone marrow transplants (BMTs)<sup>1</sup></li> <li>Acute GVHD primarily affects skin, GI tract, and liver</li> <li>Steroid-refractory aGVHD is associated with mortality rates as high as 90%<sup>1,5</sup> and significant extended hospital stay costs<sup>2</sup></li> </ul>	<ul> <li>More than 30,000 allogeneic BMTs performed globally (&gt;20K US/EU) annually, ~20% pediatric<sup>3,4</sup></li> <li>Approx. 9,000 -10,000 allogeneic BMTs performed in the US annually</li> <li>Approx. 1,500 allogenic BMTs are in children and adolescents in US<sup>4</sup></li> </ul>	
Data on file 3. Niederwieser D, Baldomero H, Szer J. ( Blood and Marrow Transplantation Group including the	2016) Hematopoietic stem cell transplantation activity we global survey. 4. HRSA Transplant Activity Report, CIBM	n Hematology. 2. Anthem-HealthCore/Mesoblast claims ana orldwide in 2012 and a SWOT analysis of the Worldwide Net R, 2020 5. Axt L, Naumann A, Toennies J (2019) Retrospecti eic hematopoietic cell transplantation. Bone Marrow Trans	work for ve single

### 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					
<b>Pediatric Subset of Protocol 280:</b> randomized controlled P3, n=27 w/SR-aGVHD	<b>79</b> %	54%	Study Control Arm (n=13)		
<b>Study 001</b> , open-label P3, n=54 <sup>1</sup> with 89% Grade C/D disease	74%	57%	MAGIC <sup>2</sup> cohort, n=30 <sup>3</sup> propensity- controlled subset		
Salvage Therapy Treatment Setting					
Expanded Access Protocol (EAP275), n=241	66%	na			
EAP275, n=51 Grade D subset	51%	31%	<b>CIBMTR dbase</b> , n=327 <sup>4</sup> propensity controlled subset		

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1. GVHD001 had 55 randomized patients, however one patient dropped out before receiving any dose of remestemcel-L; 2. 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 the mean of the mea

therapy; 3. Two subjects in the MAGIC cohort had follow-up <100 days; these subjects are excluded from the respective survival analyses; 4. Data on file

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#### 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 <u>Blood and Marrow Transplant Research (CIBMTR) dbase</u>)

Study	GVHD001	MacMillan et al <sup>1</sup>	Rashidi et al <sup>2</sup>	REACH2 <sup>3</sup>	REACH2 <sup>3</sup>	<b>REACH1</b> <sup>4</sup>
Treatment	Remestemcel-L	BAT <sup>5</sup>	BAT <sup>5</sup>	BAT <sup>5</sup>	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%	<b>49</b> %	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

16 5.BAT = Best Available Treatment



#### Remestemcel-L for Adults with SR-aGVHD

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- Commercial strategy is to progress to adults who have failed steroids and a first-line agent, including ruxolitinib
- Market opportunity approximately five times larger than pediatric
- Approximately 45% of ruxolitinib patients are non-responders<sup>1</sup>
- Survival in adults with SR-aGVHD who have failed at least one additional agent, such as ruxolitinib, is 20-30% by 100 days<sup>1,2</sup>
- In contrast, 100-day survival was 63% after remestemcel-L treatment was used under compassionate care in 71 patients aged 12 and older with SR-aGVHD who failed to respond to at least one additional agent, such as ruxolitinib
- Mesoblast is in discussions with world-leading investigators at the Blood and Marrow Clinical Trials Network (BM CTN), a body responsible for 80% of all US transplants, to conduct the new clinical trial
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## Rexlemestrocel-L

Chronic Low Back Pain due to Degenerative Disc Disease (CLBP)

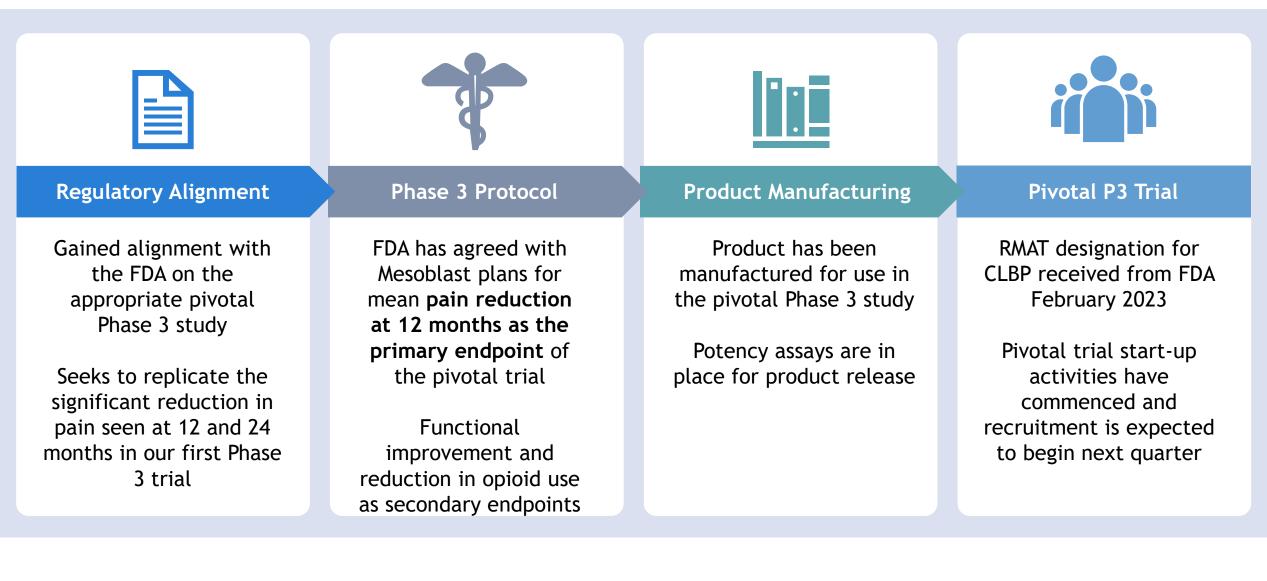


#### Chronic Low Back Pain Due to Degenerative Disc Disease (CLBP) Impacts 7M+ Rexlemestrocel-L represents a potential new paradigm for the treatment of CLBP

Burden of Illness	Treatment Options	Market Opportunity
<ul> <li>Back pain causes more disability than any other condition<sup>1</sup></li> <li>Inflicts substantial direct and indirect costs on the healthcare system,<sup>1</sup> including excessive use of opioids in this patient population</li> </ul>	<ul> <li>Minimal treatment options for patients with chronic low back pain (CLBP) who fail conservative therapy include opioids and surgery</li> <li>50% of opioid prescriptions are for CLBP<sup>2</sup></li> <li>Durable improvement in pain has potential to reduce opioid use and prevent surgical intervention</li> </ul>	• 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 <sup>2-4</sup>
on global ageing and adult health (SAGE). PloS One. 2		dults in low-and middle-income countries. Results from the WHO Study n December 2015., 3. LEK & NCI opinion leader interviews, and .S. and the EU3 - August 2014.

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#### **Rexlemestrocel-L / CLBP - Program Summary**





# 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)

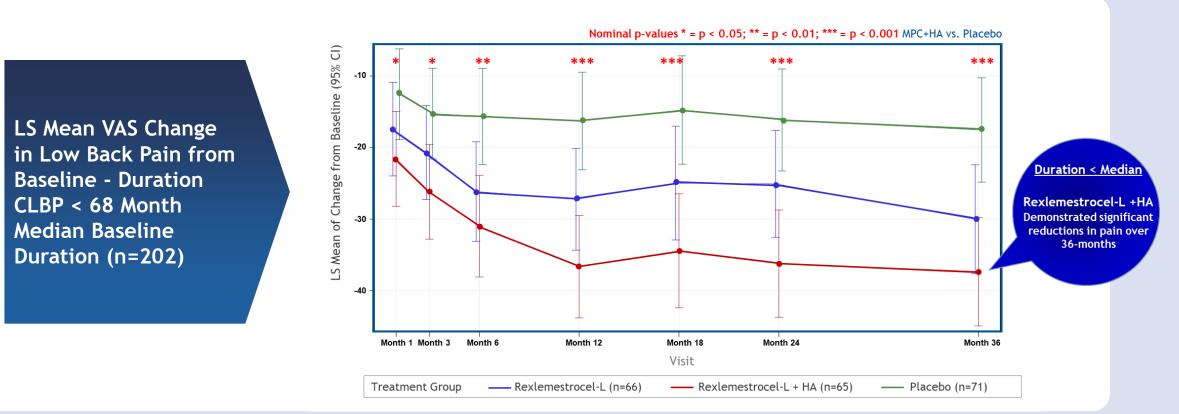
Results from the trial showed that:

- 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



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VAS=Visual Analog Score; HA=Hyaluronic Acid

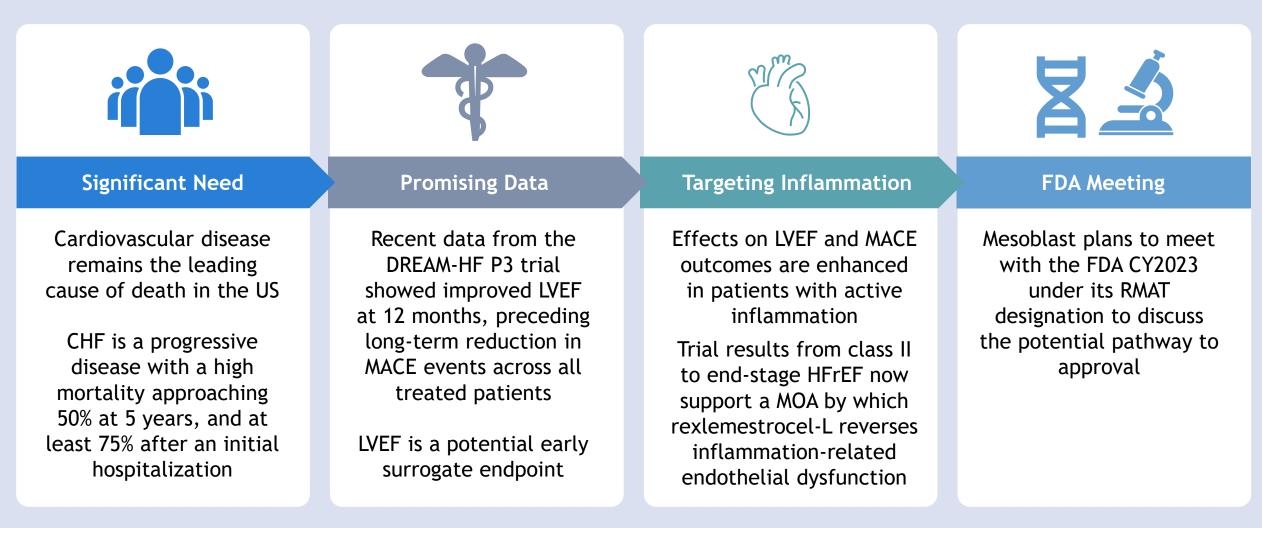


## Rexlemestrocel-L

Chronic Heart Failure Reduced Ejection Fraction (HFrEF)



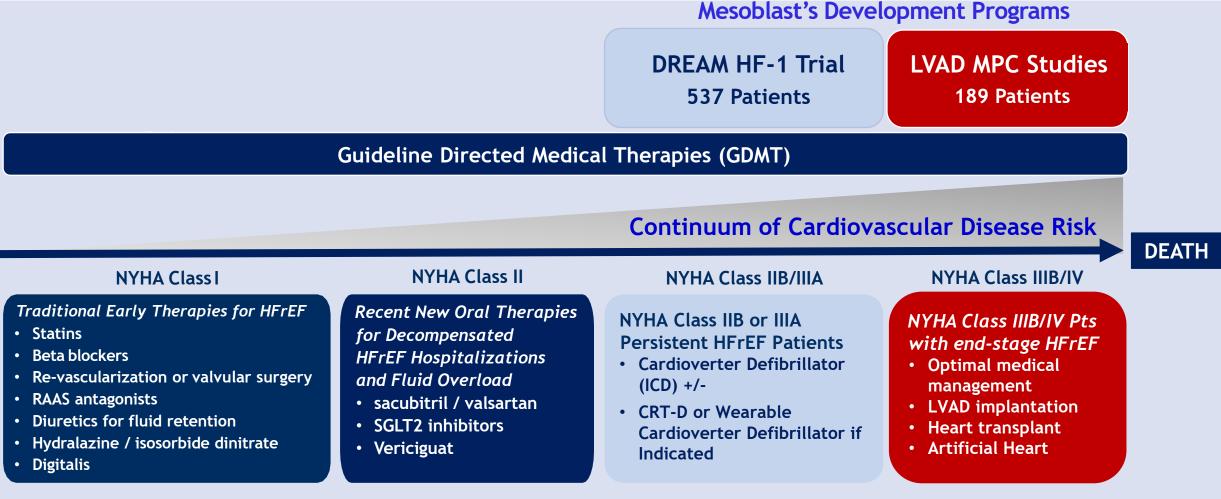
#### Rexlemestrocel-L / HFrEF - Program Summary Defining the Regulatory Path to FDA Approval





#### Patients Experience Progressive Vascular Dysfunction and Heart Failure

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





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



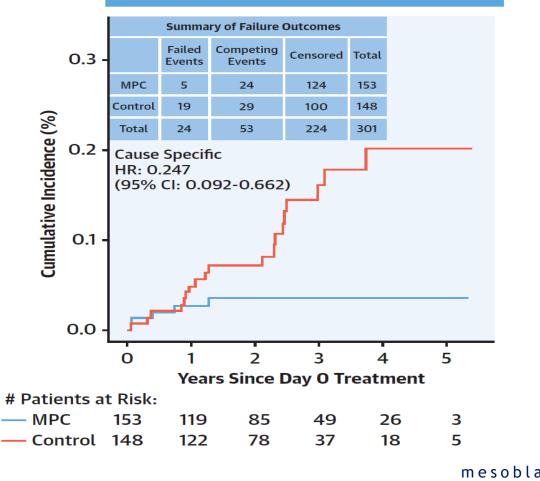
Emerson C. Perin, MD, PHD,a Kenneth M. Borow, MD,b Timothy D. Henry, MD,c Farrell O. Mendelsohn, MD,d Leslie W. Miller, MD,e Elizabeth Swiggum, MD,f Eric D. Adler, MD,g David H. Chang, MD,h R. David Fish, MD,a Alain Bouchard, MD,d Margaret Jenkins, BSc (HONS), Alex Yaroshinsky, PHD, Jack Hayes, MA,k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

#### FIGURE 4 Risk of Myocardial Infarction or Stroke

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

#### Baseline hsCRP ≥2 mg/L (N = 301)



### Rexlemestrocel-L - Two Pivotal Studies in Chronic Heart Failure (CHF)

Mesoblast's Development Programs Assess the Impact of Intra-cardiac Administration of Rexlemestrocel-L Across the Continuum of Disease from Mild/Moderate to End-stage Severity

MPC Study Design	LVAD-MPC Study #2	DREAM-HF Trial			
Treated Patients	159	537			
Study Design	Prospective, randomized, Multi-center, double-blinded, single dose, sham-controlled, parallel group efficacy & safety studies of allogeneic mesenchymal precursor cells (MPCs)				
Pathologies of ↑ed Importance	LV Systolic Function, Inflammation, Mortality, Major Morbidities				
Product	Mesenchymal Precursor Cells with defined Cardiac Potency (Rexlemestrocel-L)				
Cell Preparation, Manufacturing, Central Storage and Shipping	Same facilities and vendors in both studies				
Physical Location Used for Cell Administration at the Study Site	Operating room Cardiac catheterization laboratory				
Patient Analysis Population	End-stage chronic HFrEF candidate for LVAD implant (NYHA Class IIIB or IV), ischemic or non-ischemic etiology (N=159: MPC=106, CTRL=53)	Chronic HFrEF (Late NYHA Class II or IIIA), ischemic or non-ischemic etiology (N=537: MPC=265, CTRL=272)			
Cell Dose in MPC	150 million cells administered as 15-20 individual injections during a single procedure				
Route of Cell Administration	Epicardial injection Transendocardial injection				
Target of Cell Administration	Mid-wall of left ventricle				





### Thank You

