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# Global Leader in Allogeneic Cellular Medicines for Inflammatory Diseases

## Capital Raising Presentation

1 for 4 Accelerated Non-Renounceable Entitlement Offer
together with an Institutional Placement

4 December 2023

ASX: MSB; Nasdaq: MESO

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(a) eligible institutional shareholders of Mesoblast (**Institutional Entitlement Offer**); and
(b) eligible retail shareholders of Mesoblast (**Retail Entitlement Offer**),
(collectively, **Entitlement Offer**), under section 708AA of the Corporations Act 2001 (Cth) (**Corporations Act**), as notionally modified by ASIC Corporations (Non-Traditional Rights Issues) Legislative Instrument 2016/84 and ASIC Corporations (Disregarding Technical Relief) Instrument 2016/73.

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**Financial data**

All dollar values are expressed in Australian dollars ($ or AUD) unless stated otherwise. All references starting with "FY" refer to the financial year for Mesoblast ended 30 June. For example, "FY 23" refers to the financial year ended 30 June 2023.

Investors should note that this Presentation contains pro forma financial information. The pro forma historical financial information provided in this presentation is for illustrative purposes only and is not represented as being indicative of Mesoblast's views on its, nor anyone else's, future financial condition and/or performance. The pro forma historical financial information has been prepared by Mesoblast in accordance with the measurement and recognition requirements, but not the disclosure requirements, of applicable accounting standards and other mandatory reporting requirements in Australia.

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# Offer Summary

| | |
|---|---|
| Structure and size ("The Offer") | 1 for 4 pro-rata accelerated non-renounceable Entitlement Offer together with a Placement to raise up to A$97.0 million before costs through issuing approximately 323.4 million new shares (39.7% of current issued capital) |
| Offer price | Offer Price of A$0.30 per New Share under the Placement and the Entitlement Offer ("Offer Price"), which represents:<br>▪ 25.9% discount to the last traded price of A$0.405 on ASX on 30 November 2023<br>▪ 20.0% discount to TERP[1] of A$0.375 |
| Placement | An institutional placement of up to approximately 120 million new fully paid ordinary shares at an offer price of A$0.30 per share to raise up to approximately A$36 million to be conducted on 4 December 2023 |
| Entitlement Offer | An Entitlement Offer of up to approximately 203 million new fully paid ordinary shares to be issued to existing eligible shareholders at an offer price of A$0.30 per share to raise up to approximately A$61 million<br>▪ The Retail Entitlement Offer will open on 9:00am (Sydney time) 8 December 2023 and close on 5:00pm (Sydney time) 19 December 2023<br>▪ eligible retail shareholders may also apply for additional New Shares in excess of their Entitlement under the Retail Entitlement Offer |
| Founder / CEO Commitment | Mesoblast Chief Executive and Founder Silviu Itescu, intends to take up a majority of his Entitlement |
| Ranking | New Shares issued will rank equally with existing fully paid ordinary shares in Mesoblast from the time of issue |
| Record Date | 7.00pm (AEDT) 6 December 2023 |
| Allocation Policy | The Directors reserve the right to issue the shortfall at their discretion. The allocation policy of Mesoblast in such event is to allocate shortfall to existing Institutional Securityholders or new Institutional Investors as the Directors determine in their sole and absolute discretion. |

1 The Theoretical Ex-Rights Price ("TERP") is the theoretical price at which Mesoblast shares should trade at immediately after the ex-date for the Offer, and is calculated based on the maximum size of the Entitlement Offer together with the Placement. The TERP is a theoretical calculation only and the actual price at which Mesoblast shares trade immediately after the ex-date for the Offer will depend on many factors and may not equal the TERP. TERP is calculated by reference to Mesoblast's closing price of A$0.405 on 30 November 2023.

# Financials and Use of Proceeds

- Cash balance at September 30, 2023 was US$53.2 million, with net operating cash spend of US$14.2 million for the quarter.
- Management and the Board have put in place a plan that focuses on preservation of cash by implementing significant cost containment strategies and enacting substantial payroll reductions.
- Net operating cash usage over the past two years reduced by 37% to US$63.3 million in FY2023. We have implemented a cost containment plan to achieve a further targeted 23% reduction (US$15 million) in projected FY2024 annual net operating cash spend compared with FY2023, which will be partially offset by investment in our Phase 3 programs for adults with steroid-refractory acute graft versus host disease (SR-aGVHD) and chronic low back pain (CLBP).
- Proceeds from the Offer and existing cash reserves will be used to fund the adult Phase 3 registration trials for SR-aGVHD and for CLBP, and general corporate purposes.

# Sources and Uses of Funds

| Sources of funds | US$ million[1] |
|---|---|
| The Offer (net of offer costs) | 61.6 |
| Existing cash as at September 30, 2023 | 53.2 |
| **Total** | **114.8** |

| Uses of funds[2] | US$ million |
|---|---|
| Proceeds from The Offer to fund Adult Phase 3 registration trials for steroid-refractory acute graft versus host disease (SR-aGVHD) and for chronic low back pain (CLBP) and general corporate purposes | 61.6 |
| **Total** | **61.6** |

(1) A$92.3 million translated at 0.6672 AUD:USD exchange rate published by the Financial Times on close of business on 1 December 2023 net of offer costs of A$4.7m.
(2) Assumes total A$97.0 million offer size

# Pro Forma Balance Sheet

US$m

| | 30 June 2023[1] (audited) | 30 June 2023[2] Pro forma |
|---|---|---|
| Cash and cash equivalents | 71.3 | 132.9 |
| Other assets | 598.1 | 598.1 |
| **Total Assets** | **669.4** | 731.0 |
| | | |
| Current liabilities | 42.0 | 42.0 |
| Non-current liabilities | 125.6 | 125.6 |
| **Total Liabilities** | **167.6** | 167.6 |
| | | |
| Issued Capital | 1,249.1 | 1,310.7 |
| Reserves | 73.5 | 73.5 |
| Accumulated Losses | (820.8) | (820.8) |
| **Total Equity** | **501.8** | 563.4 |

(1) Extracted from the audited financial statements for the year ended 30 June 2023 (as disclosed in the Form 20-F announced on the ASX on 31 August 2023 and available at Mesoblast.com).

(2) Cash and cash equivalents and issued capital adjusted for the US$61.6m equity raise (A$92.3m translated at 0.6672 AUD:USD exchange rate published by the Financial Times on close of business 1 December 2023) net of offer costs of US$3.1m.

# Indicative Offer Timetable

| Event | Date |
|---|---|
| Announcement of the Offer | 4 December 2023 |
| Placement and Institutional Entitlement Offer opens | 4 December 2023 |
| Placement and Institutional Entitlement Offer closes | 4 December 2023 |
| Trading halt lifted and Mesoblast shares recommence trading on ASX | 5 December 2023 |
| Record Date for determining entitlement to subscribe for New Shares | 7.00pm (AEDT)[1] 6 December 2023 |
| Retail Entitlement Offer opens | 9.00am (AEDT)[1] 8 December 2023 |
| Retail Entitlement Offer Booklet despatched to Eligible Retail Shareholders | 8 December 2023 |
| Settlement of applications in the Placement and Institutional Entitlement Offer | 11 December 2023 |
| Allotment and normal trading of New Shares issued under the Placement & Institutional Entitlement Offer | 12 December 2023 |
| Retail Entitlement Offer closes | 5.00pm (AEDT)[1] 19 December 2023 |
| Settlement of Retail Entitlement Offer | 27 December 2023 |
| Allotment of New Shares issued under the Retail Entitlement Offer | 28 December 2023 |
| Quotation of New shares under the Retail Entitlement Offer | 29 December 2023 |
| Despatch of holding statements in respect of New Shares issued under the Retail Entitlement Offer | 29 December 2023 |

*All dates and times are indicative and subject to change without notice*
[1] *Australian Eastern Daylight Time*





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# Our Mission

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

# Corporate Vision

*To be 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*

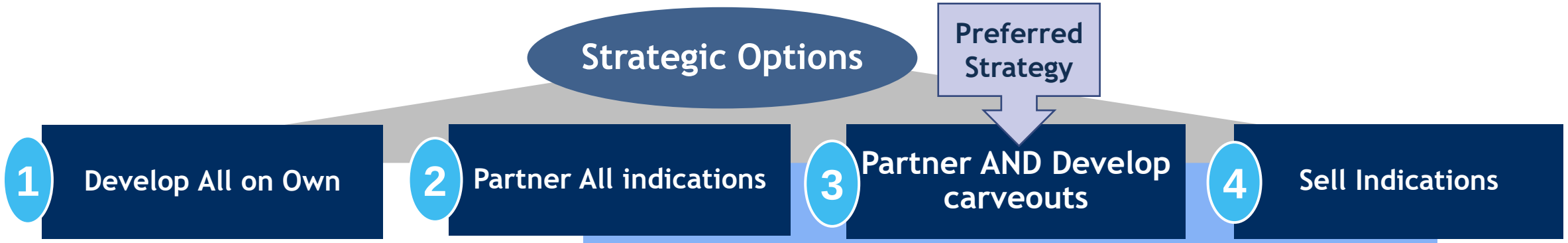
*To deliver appropriate returns for our shareholders*

# 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 *Pediatric* SR-aGVHD** | Single-arm pivotal Phase 3 trial completed; primary endpoint successfully met<br>Long-term data shows durability of survival benefit >4 years<br>Additional potency assay data to be presented to FDA |
| **Remestemcel-L for *Adult* SR-aGVHD** | Market size for adult population approx. 5-fold larger than pediatric<br>The pivotal trial is expected to be conducted by BMT CTN, a body responsible for approximately 80% of all US transplants, at a fraction of the cost of a traditional CRO |
| **Rexlemestrocel-L for CLBP** | First randomized controlled Phase 3 trial completed, RMAT granted by FDA for discogenic pain<br>Agreement on 12-month pain reduction endpoint for FDA approval, confirmatory trial needed<br>Start-up activities for this trial significantly advanced with investigators, trial sites & CRO |
| **Rexlemestrocel-L for Heart Disease** | 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.<br>Randomized controlled trial in pediatric congenital heart disease patients published |

SR-aGVHD = Steroid-Refractory Graft v Host Disease
FDA = United States Food and Drug Administration
BMT CTN = Bone Marrow Transplant Clinical Trials Network
RMAT = Regenerative Medicine Advanced Therapy
LVAD = Left Ventricular Assist Device
CRO = Contract Research Organization

# Corporate Level Strategic Options Evaluated and Set




- ✓ Potential immediate financial rewards through partnership
- ✓ Diminished development and commercial costs if partner large indications
- ✓ Invest in smaller or orphan indications with lower development and commercialization costs
- ✓ Attain high level of shareholder value by demonstrating range capabilities



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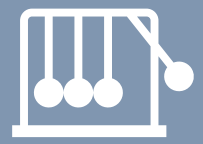
# Tactical Execution Of Corporate Strategy

**Intellectual Capital**

Our **Patents** & our **People**

**Manufacturing Strategy** for Product Delineation and Life-Cycle



Advancing our **Clinical Pipeline**

Securing a **Robust Financial Base**

Go to market **Direct** versus **Partnership**

Building a **Strong Brand**



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# Setting Key Strategic Priorities for 2024

**1 Seeking first regulatory approval in the US**

- Additional potency assay data, provide to FDA
- Commence adult SR-aGVHD Phase 3 trial
- Continue to seek pediatric SR-aGVHD approval and launch

**2 Further advancement of MPC therapies**

- Enrollment of CLBP second Phase 3 trial
- FDA regulatory discussions re HFrEF in adults and congenital heart disease in children

**3 Optimize manufacturing/CMC**

- Manufacturing key to product delineation, pricing strategies, and partnering
- Optimize separate potency assays for each product
- 3D manufacturing to support commercial requirements and reduction in COGS

**4 Strengthen financial position overall**

- Obtain global scale partnership(s), to fund clinical programs and enterprise build
- Obtain and maintain 2 years of cash flow position at minimum
- Monetize assets inc royalty streams and 3rd generation products (cell + gene)

**5 Culture, structure, governance and talent**

- Attract, retain and develop key talent across the enterprise
- Align and build when needed the capabilities to support the plan

FDA = United States Food and Drug Administration
SR-aGVHD = Steroid-Refractory Acute Graft v Host Disease
HFrRF = Heart Failure with Reduced Ejection Fraction
CLBP = Chronic Low Back Pain
MPC = Mesenchymal Precursor Cells
CMC = Chemistry, Manufacturing, Controls





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# Global Intellectual Property (IP) Estate

## Provides Substantial Competitive Advantage

- Extensive patent portfolio with protection extending through 2040
- Over 1,100 patents and patent applications (82 patent families) across all major jurisdictions
- Covers composition of matter, manufacturing, and therapeutic applications of mesenchymal lineage cells
- Provides strong global protection in areas of our core commercial focus against cell-based competitor products
- Outside our core areas, may grant rights to third parties requiring access to our patent portfolio to commercialize their products
- Track record of managing intellectual property
  - Royalty agreement and income received from JCR Pharmaceuticals in Japan for treatment of aGVHD
  - Patent license granted to TiGenix, S.A.U., a wholly owned subsidiary of Takeda, on its worldwide sales of its product Alofisel® for the treatment of complex perianal fistulas in Crohn's disease

**Markets**
Global coverage including U.S., Europe, China, and Japan

**Therapeutic Areas**
Core commercial and non-core indications

**Sources**
Allogeneic / Autologous (Bone Marrow, Adipose, Dental Pulp, Placental), Pluripotent (iPS)

# 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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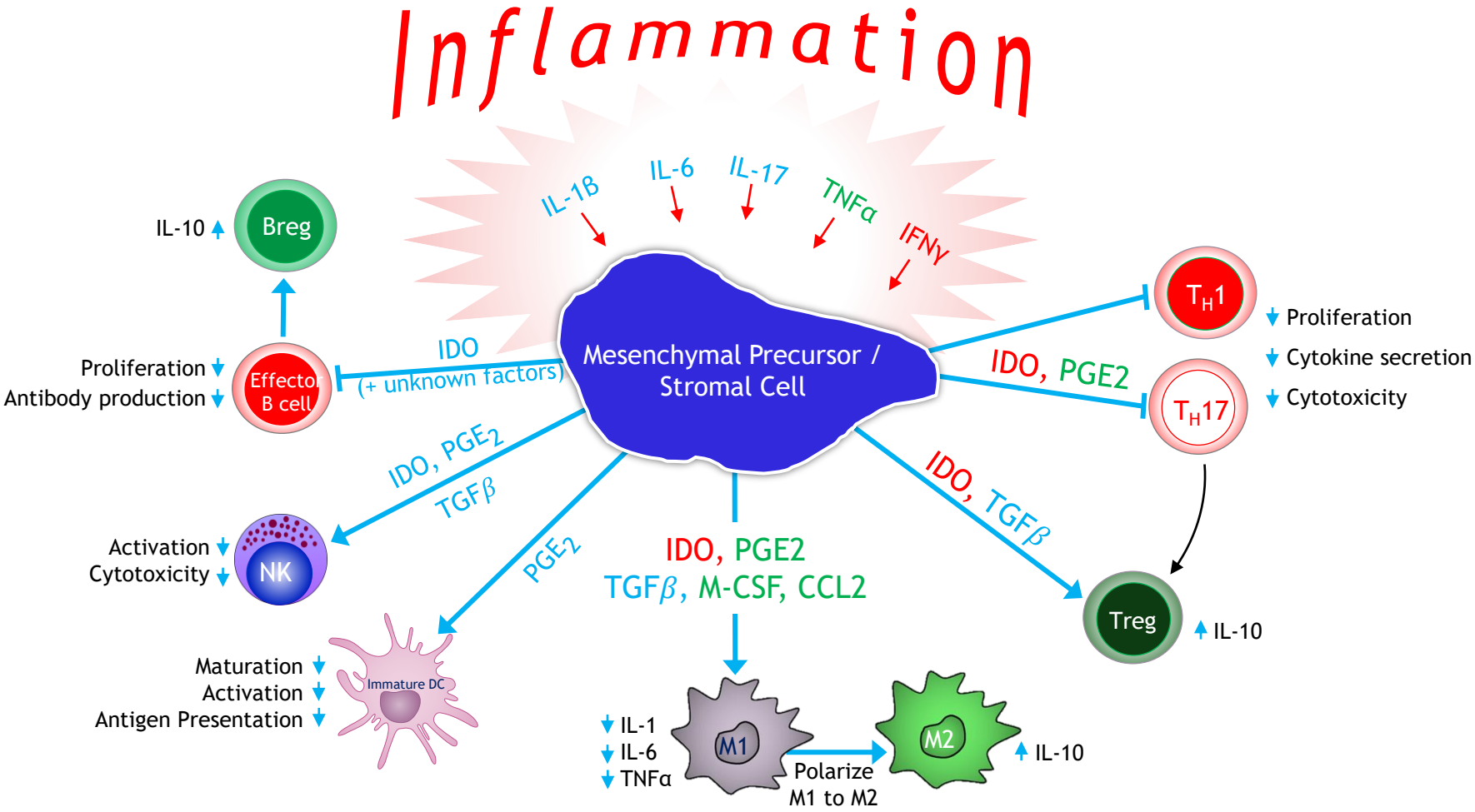
# Platform Technology – Shared Mechanism of Action Across Our Products

## 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

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# 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 Crohn's | | | | |
| **Rexlemestrocel-L** | CLBP | | | | |
| **Rexlemestrocel-L** | HFrEF | | | | |

SR-aGVHD = Steroid-Refractory Acute Graft Versus Host Disease; CLBP = Chronic Low Back Pain; HFrEF = Heart Failure with Reduced Ejection Fraction

*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.

# Clinical Program Milestones - Next 12 Months

| | | Target Date | Status |
|---|---|---|---|
| **RYONCIL Adult & Pediatric SR-aGVHD (remestemcel-L)** | • Currently finalizing additional potency assay data on commercial inventory to provide to FDA | Q1 CY2024 | In progress |
| | • Planned meeting with the FDA regarding potency assay data for the pediatric BLA | Q1 CY2024 | Planned |
| | • Completion and submission to FDA of protocol for adult SR-aGVHD Phase 3 trial in partnership with BMT CTN | Q1 CY2024 | In progress |
| | • Commence patient enrollment for adult SR-aGVHD trial | Q2 CY2024 | Planned |
| **Inflammatory Pain (rexlemestrocel-L)** | • CLBP Phase 3 trial start-up activities with investigators, trial sites & contract research organization (CRO) | Q4 CY2023 | In progress |
| | • Phase 3 CLBP patient screening/enrollment initiates and completes | Q1-Q4 CY2024 | Planned |
| **REVASCOR Adult & Pediatric Heart Disease (rexlemestrocel-L)** | • Meet with the FDA under RMAT to discuss the potential pathway to approval in adults with HFrEF based on LVAD and DREAM-HF trials | Q1 CY2024 | In progress |
| | • Meeting with FDA on congenital heart disease pathway to approval in pediatric patients based on results of randomized, controlled trial | Q1 CY2024 | Planned |



SR-aGVHD = Steroid-Refractory Graft v Host Disease
FDA = United States Food and Drug Administration
BMT CTN = Bone Marrow Transplant Clinical Trials Network
RMAT = Regenerative Medicine Advanced Therapy
LVAD = Left Ventricular Assist Device
HFrRF = Heart Failure with Reduced Ejection Fraction

# Pathway to Approval for RYONCIL in Pediatric Patients with SR-aGVHD

- During the Biologics License Application (BLA) review Mesoblast made substantial progress towards bringing this cutting-edge product to market with a completed FDA inspection of our manufacturing process.
- In August FDA provided a complete response requiring Mesoblast to provide additional potency assay data confirming that product used in the Phase 3 trial is similar to product intended for commercial release, as measured by a standardized potency assay.
- At the Type A meeting in September, Mesoblast presented clinical data indicating that treatment with the improved RYONCIL product version of remestemcel-L, manufactured using the current process inspected by FDA, resulted in consistently high survival rates in children with SR-aGVHD.
- Similarly high survival rates were seen whether using product made for the Phase 3 clinical trial MSB-GVHD001 between 2015-2018 or made with the validated manufacturing process proposed for commercial release and used under Emergency Investigational New Drug (EIND) protocol through 2023.
- Mesoblast believes that the totality of these clinical studies, together with additional potency assay data currently being generated using the IL-2R alpha inhibition potency assay in place during the pediatric Phase 3 trial, will both support approval for the pediatric indication and provide a link between the RYONCIL product that was used in the pediatric Phase 3 trial and available commercial inventory.

# Pathway to Approval for RYONCIL in Adult Patients with SR-aGVHD

- 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, a patient population with no approved therapies.[1,2]
- 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.
- In its September 2023 draft guidance to industry for development of agents to treat aGVHD, the FDA stated that a marketing application in a population with refractory aGVHD where there are no approved therapies might be supported by positive results from a single-arm trial.[3]
- Mesoblast intends to commence a Phase 3 trial of RYONCIL in adults and adolescents, a market approx. 5-fold larger than pediatric, who are refractory to both corticosteroids and a second line agent such as ruxolitinib, for whom there are no approved therapies.
- The trial is expected to be conducted by the Blood and Marrow Transplant Clinical Trials Network (BMT CTN), a body responsible for approximately 80% of all US transplants, at a fraction of the cost of a traditional contract research organization (CRO).


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.
3. US FDA. Graft-versus-Host Diseases: Developing Drugs, Biological Products, and Certain Devices for Prevention or Treatment Guidance for Industry. Draft Guidance. Sep 2023

# Financial Highlights

- Revenue from royalties, predominantly on sales of TEMCELL® HS Inj.[1] sold in Japan by our licensee, were US$7.5 million for the year ended June 30, 2023.
- Cash balance at September 30, 2023 was US$53.2 million, with net operating cash spend of US$14.2 million for the quarter.
- Management and the Board have put in place a plan that focuses on preservation of cash by implementing significant cost containment strategies and enacting substantial payroll reductions.
- Net operating cash usage over the past two years reduced by 37% to US$63.3 million in FY2023. We have implemented a cost containment plan to achieve a further targeted 23% reduction (US$15 million) in projected FY2024 annual net operating cash spend compared with FY2023, which will be partially offset by investment in our Phase 3 programs for adults with SR-aGVHD and CLBP.
- These activities to preserve cash are complemented by initiatives currently underway to increase cash inflows which would by design enable us to prudently invest in our Phase 3 programs. In this regard, we are working on corporate initiatives to strengthen our balance sheet, including royalty monetization and strategic partnerships to both access existing commercial distribution channels and supplement costs of development.

1. TEMCELL® HS Inj. is a registered trademark of JCR Pharmaceuticals Co. Ltd.

# Rexlemestrocel-L

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



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# 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

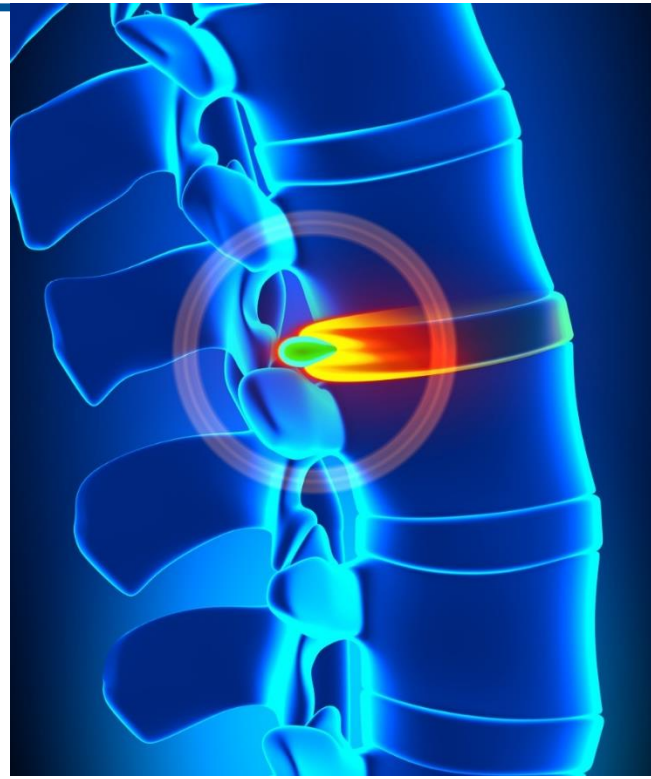
- Back pain causes more disability than any other condition[1]
- Inflicts substantial direct and indirect costs on the healthcare system,[1] including excessive use of opioids in this patient population

### 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 CLBP[2]
- Durable improvement in pain has potential to reduce opioid use and may 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.





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# Rexlemestrocel-L / CLBP – Program Summary

## 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 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 pivotal Phase 3 study

Potency assays are in place for product release

## Pivotal P3 Trial

RMAT designation for CLBP received from FDA this year

Start-up activities for this trial significantly advanced with investigators, trial sites & CRO

# 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

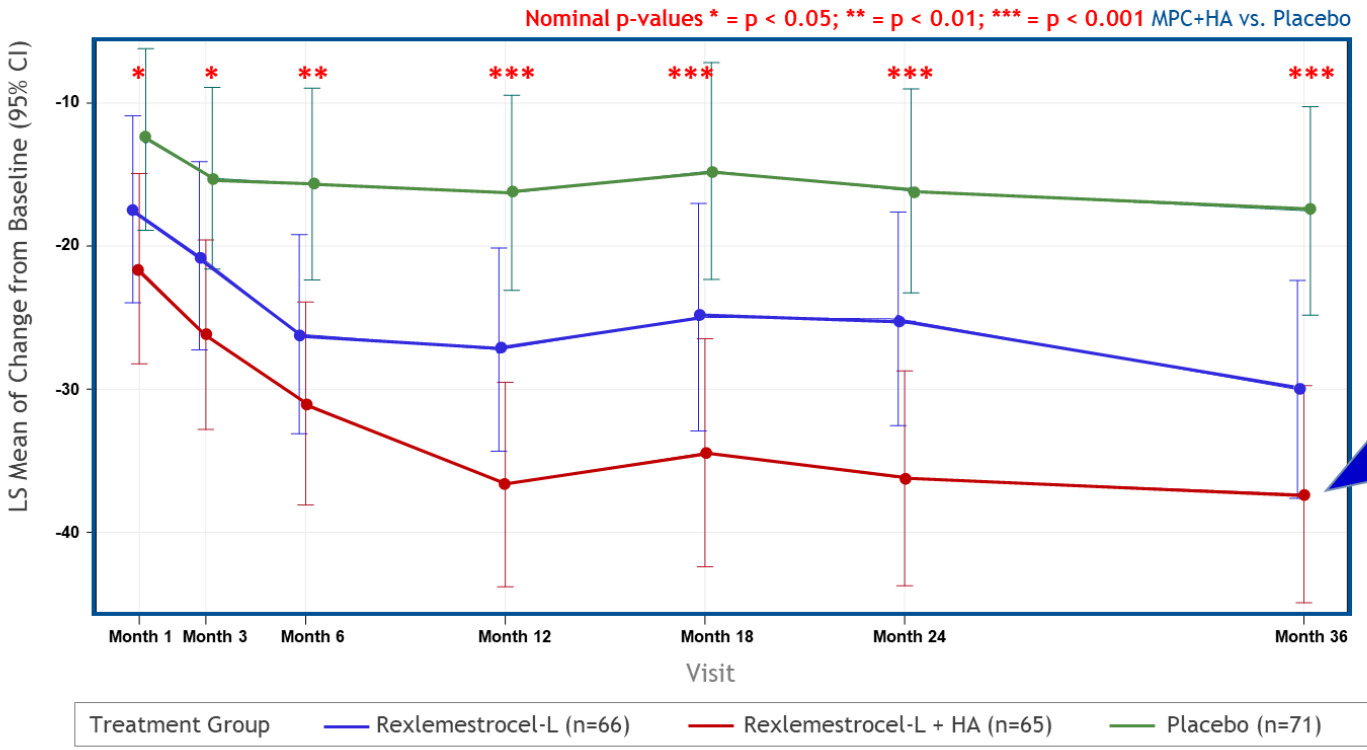
  - Among patients on opioids at baseline, despite instructions to maintain existing therapies throughout the trial, at 36 months 28% who received rexlemestrocel-L+HA were not taking an opioid compared with 8% of saline treated controls

# 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)**




**Duration < Median**

**Rexlemestrocel-L +HA** Demonstrated significant reductions in pain over 36-months

VAS=Visual Analog Score; HA=Hyaluronic Acid





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# Rexlemestrocel-L

## Chronic Heart Failure Reduced Ejection Fraction (HFrEF)



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# Rexlemestrocel-L / HFrEF - Program Summary

## 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

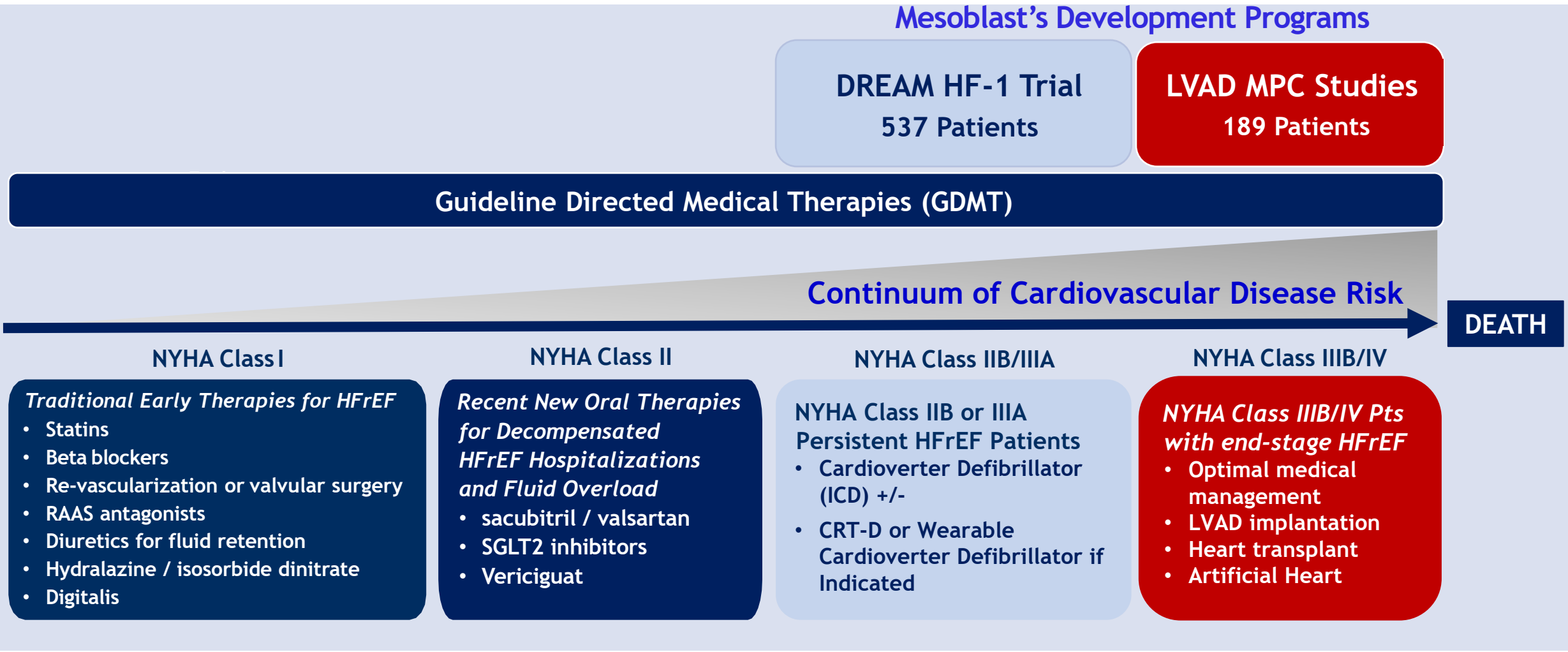
Trial results from class II to end-stage HFrEF now support a MOA by which rexlemestrocel-L reverses inflammation-related endothelial dysfunction

### FDA Meeting

Mesoblast plans to meet with the FDA under its RMAT designation to discuss the potential pathway to 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





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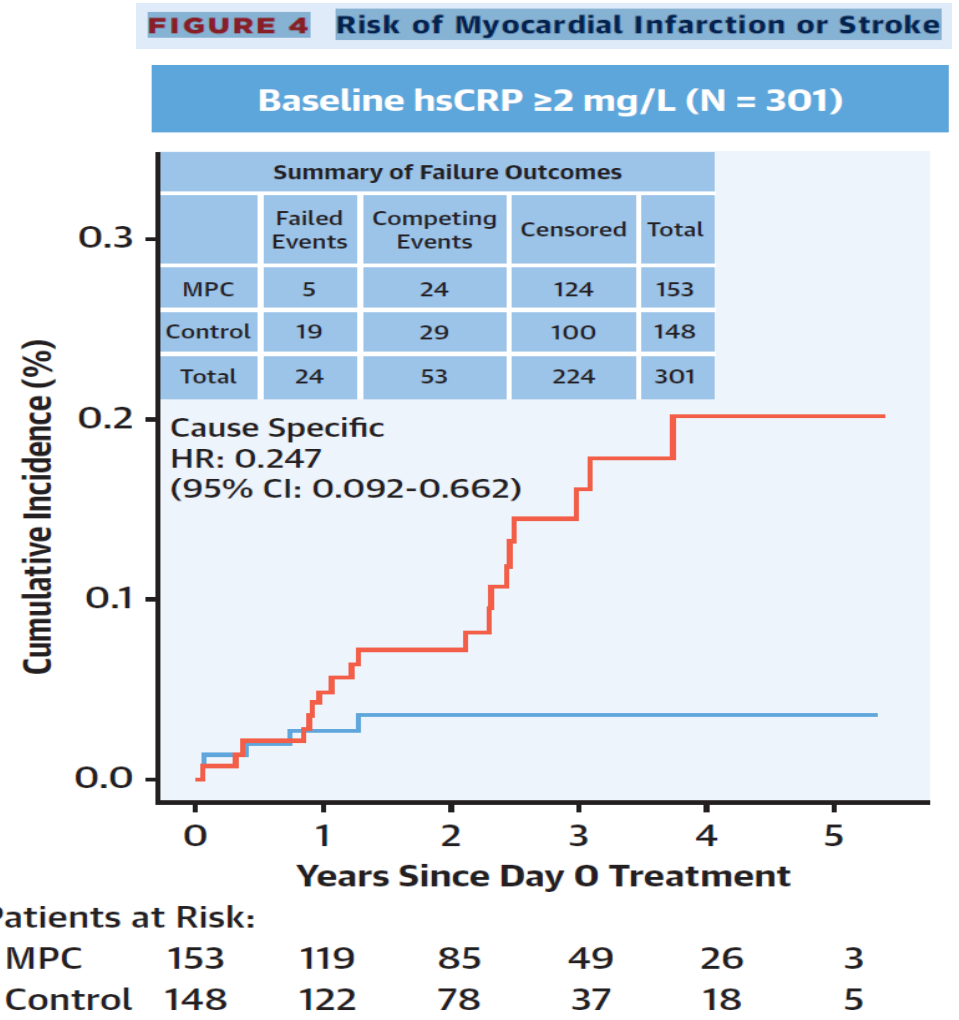
# Randomized Trial of Targeted Transendocardial Mesenchymal Precursor Cell Therapy in Patients With Heart Failure

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





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# 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 | |

# REVASCOR As Treatment For Severe Congenital Heart Disease

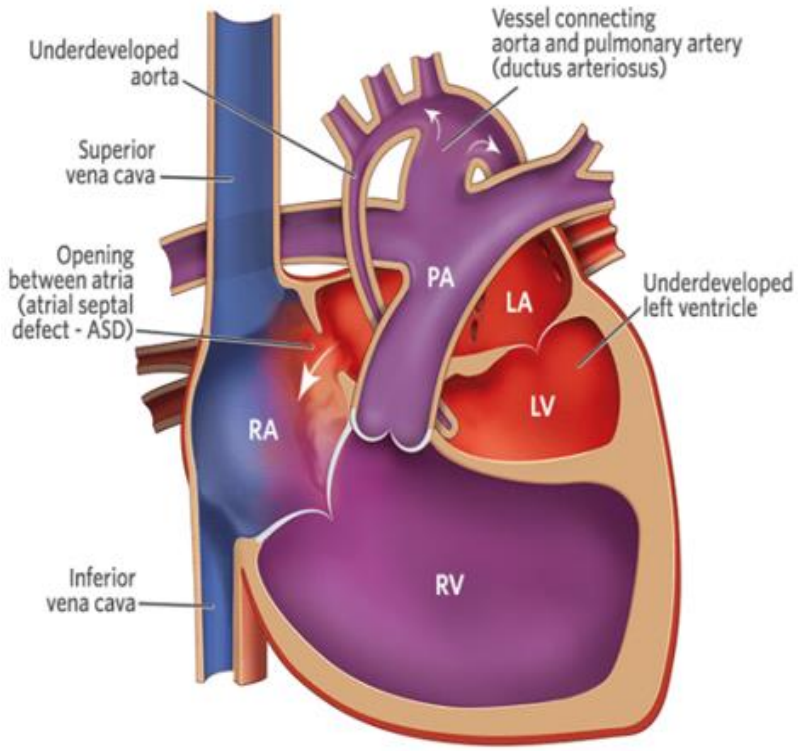
## Filed with FDA For Orphan Drug And Pediatric Rare Disease Designations

- Hypoplastic left heart syndrome (HLHS) is a severe congenital heart disease in which the left side of the heart does not fully develop and effective pumping of oxygenated blood by the left ventricle to the rest of the body is reduced.

- Without immediate surgery after birth, the prognosis is dismal with HLHS overall being responsible for 25% to 40% of all neonatal cardiac mortality.[1]

- In the longer term, surgery that creates a two-ventricle series circulation with the left ventricle (LV) pumping blood to the body and the right ventricle pumping blood to the lungs is the ideal anatomic repair. Unfortunately, achievement of this objective is limited by the inability in most patients for the left ventricle to grow sufficiently to support the circulation to the body.

**Anatomy of hypoplastic left heart syndrome**




- REVASCOR has multiple mechanisms-of-action that may be beneficial to children with HLHS including neovascularization, anti-fibrosis, anti-apoptosis, immunomodulation, reduction in inflammation, and reversal of endothelial dysfunction.



1. Kritzmire, S. M, et al. (2022). Hypoplastic left heart syndrome. https://www.ncbi.nlm.nih.gov/books/NBK554576/#

# REVASCOR As Treatment For Severe Congenital Heart Disease

## Filed with FDA For Orphan Drug And Pediatric Rare Disease Designations

- 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 that can help facilitate a subsequent surgical correction allowing for a normal two ventricle circulation.

- Improvement in left ventricular functional outcomes with REVASCOR may encourage more widespread use of surgical procedures to create a functioning left ventricle in children with HLHS resulting in reduction in long-term morbidity and mortality compared with other medical and/or surgical approaches.

- An orphan drug designation (ODD) qualifies sponsors for incentives including tax credits for qualified clinical trials, exemption from user fees, and the potential for seven years of market exclusivity after approval.

- A rare pediatric disease designation (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.

1. Wittenberg RE, Gauvreau K, Leighton J, Moleon-Shea M, Borow KM, Marx GR, Emani SM, Prospective randomized controlled trial of the safety and feasibility of a novel mesenchymal precursor cell therapy in hypoplastic left heart syndrome, JTCVS Open (2023), doi: https://doi.org/10.1016/j.xjon.2023.09.031.

# Remestemcel-L

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



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# Acute Graft Versus Host Disease (aGVHD)

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

PHASE 1
Host Tissue Damage
by BMT Conditioning

PHASE 2
Immune Cell Activation
& Cytokine Storm

PHASE 3
Inflammation and End Organ
Damage

Conditioning regimen, chemotherapy, or radiation

Tissue Damage

Macrophage input to cytokine storm

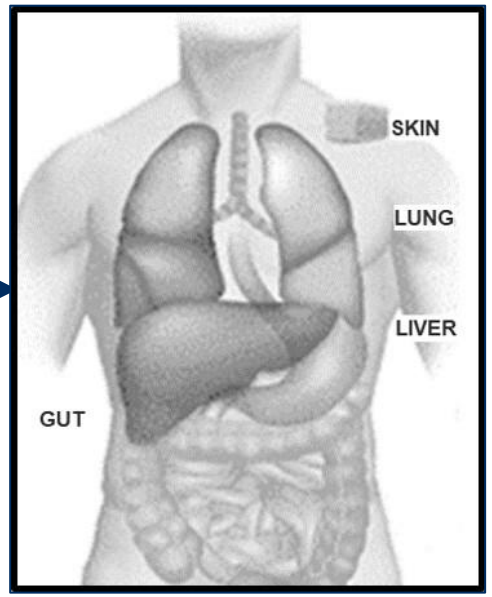
Activation of CD4 & CD8 T-cells

Macrophage

CTL

CTL

Cytokine Storm
TNF, IL-1, IL-6
IFNγ, IL-2, IL-12, IL-21, IL-22, IL-23




Modified from Blazar et al., Nature Reviews Immunology 12: 443 - 458





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# Remestemcel-L: Steroid-Refractory Acute Graft Versus Host Disease (SR-aGVHD)

## SR-aGVHD is associated with mortality rates as high as 90%

### Treatment Options

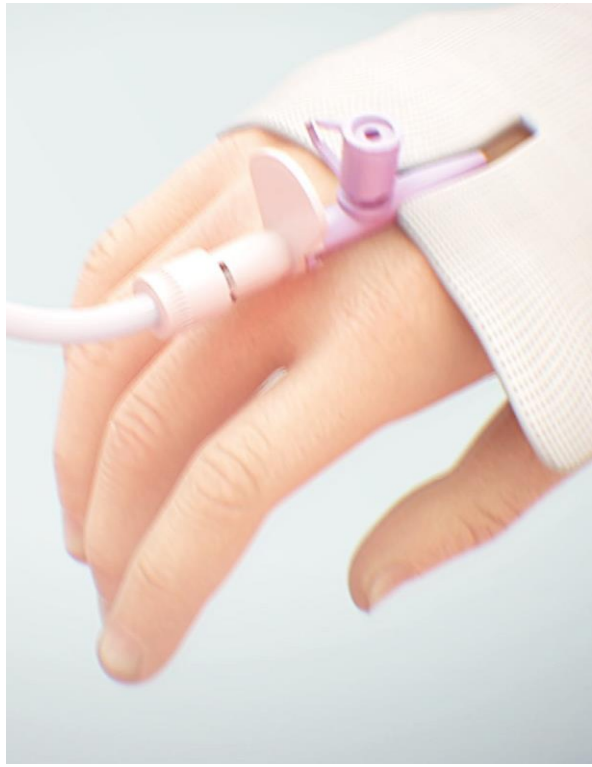
- Corticosteroids are first-line therapy for aGVHD
- There is only one approved treatment for disease refractory to steroids and no approved treatment in the US for children under 12 years old
- In Japan, Mesoblast's licensee received the first product approval for SR-aGVHD in both children and adults

### Burden of Illness

- Acute GVHD is a life-threatening 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 costs[2]

### Market Opportunity

- More than 30,000 allogeneic BMTs performed globally (>20K US/EU) annually, ~20% pediatric[2,3]
- Approx. 9,000 -10,000 allogeneic BMTs performed in the US annually
- Approx. 1,500 allogenic BMTs are in children and adolescents in US[3]



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.





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# 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** | | | |
| **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=327[4] propensity controlled subset |

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 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 Blood and Marrow Transplant Research (CIBMTR) dbase)

| Study | GVHD001 | MacMillan et al[1] | Rashidi et al[2] | 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.






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# Pathway to Approval for RYONCIL in Pediatric Patients with SR-aGVHD

- During the Biologics License Application (BLA) review we made substantial progress towards bringing this cutting-edge product to market with a completed FDA inspection of our manufacturing process.

- In August the FDA provided a complete response requiring Mesoblast to provide additional potency assay data confirming that product used in the Phase 3 trial is similar to product intended for commercial release, as measured by a standardized potency assay.

- At the Type A meeting in September, Mesoblast presented clinical data indicating that treatment with the improved RYONCIL product version of remestemcel-L, manufactured using the current process inspected by FDA, resulted in consistently high survival rates in children with SR-aGVHD.

- Similarly high survival rates were seen whether using product made for the Phase 3 clinical trial MSB-GVHD001 between 2015-2018 or made with the validated manufacturing process proposed for commercial release and used under Emergency Investigational New Drug (EIND) protocol through 2023.

- Mesoblast believes that the totality of these clinical studies, together with additional potency assay data currently being generated using the IL-2R alpha inhibition potency assay in place during the pediatric Phase 3 trial, will both support approval for the pediatric indication and provide a link between the RYONCIL product that was used in the pediatric Phase 3 trial and available commercial inventory.

# RYONCIL for Adults with SR-aGVHD

- 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 [1]
- Survival in adults with SR-aGVHD who have failed at least one additional agent, such as ruxolitinib, is 20-30% by 100 days [1,2]
- 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
- In its September 2023 draft guidance to industry for development of agents to treat aGVHD, the FDA stated that a marketing application in a population with refractory aGVHD where there are no approved therapies might be supported by positive results from a single-arm trial.[3]
- The Blood and Marrow Transplant Clinical Trials Network (BMT CTN), a body responsible for approximately 80% of all US transplants, is expected to conduct the pivotal trial of RYONCIL in this adult population at a fraction of the cost of a traditional contract research organization (CRO)


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.
3. US FDA. Graft-versus-Host Diseases: Developing Drugs, Biological Products, and Certain Devices for Prevention or Treatment Guidance for Industry. Draft Guidance. Sep 2023

# Key Risk Factors





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# Key Risks (1 of 5)

| Risk type | Outline |
|---|---|
| **FINANCIAL POSITION AND CAPITAL REQUIREMENTS** | The Company has incurred operating losses since its inception and anticipates that it will continue to incur substantial operating losses for the foreseeable future. It is currently unclear whether the Company will ever achieve or sustain profitability. The Company has incurred net losses during most of its fiscal periods since inception. The Company's net loss for the year ended June 30, 2023 was $81.9 million. As of June 30, 2023, the Company has an accumulated deficit of $820.8 million since inception. Losses have resulted principally from costs incurred in clinical development and manufacturing activities. These risks may arise or be exacerbated as a result of the following:<br>▪ the Company has never generated revenue from product sales;<br>▪ the Company's ability to generate future revenues from product sales depends heavily on completing research, preclinical and clinical development, seeking and obtaining regulatory and marketing approvals for product candidates, seeking and obtaining regulatory and marketing approvals for product candidates, seeking and obtaining regulatory and marketing approvals for product candidates and obtaining and sustaining an adequate level of reimbursement from payors;<br>▪ substantial additional financing (in addition to the funds proposed to be raised under the Offer and irrespective of the degree of take up of the offer), is required and failure to obtain the necessary capital or establish and maintain strategic partnerships to provide funding support could force the Company to delay, limit, reduce or terminate product development or commercialization efforts. The Company may seek to raise further funds through financing, strategic partnerships, royalty monetization, product specific financing or other means. Failure to obtain sufficient financing for the Company's activities and future projects may result in delay and indefinite postponement of operations and further development programmes. There can be no assurance that additional finance will be available when needed or, if available, the terms of the financing might not be favourable to the Company;<br>▪ the terms of loan facilities with funds associated with Oaktree Capital Management, L.P. and NovaQuest Capital Management, L.L.C. restrict operations;<br>▪ risks associated with currency fluctuations, and changes in foreign currency exchange rates. Specifically, as Shares offered under the Entitlement Offer will have an application price denominated in Australian dollars, whereas the Company's functional currency for reporting purposes is denominated in US dollars, fluctuations in the conversion rate between these two currencies may materially affect the total amount (denominated in US dollars) raised by the Company, particularly where the value of the Australian dollar depreciates against the US dollar, which would depress the total funds raised;<br>▪ unfavourable global economic or political conditions which adversely affect business, financial condition or results of operations;<br>▪ potential failure to demonstrate safety and efficacy to the satisfaction of applicable regulatory agencies;<br>▪ substantial delays in clinical studies;<br>▪ difficulties enrolling patients in clinical trials causing product candidate development delay;<br>▪ difficulties associated with running multinational clinical trials, and collaborating with foreign medical institutions and healthcare providers;<br>▪ potential burden of complying with a variety of foreign laws, medical standards and regulatory requirements, including the regulation of pharmaceutical and biotechnology products and treatments, and anti-corruption/anti-bribery laws;<br>▪ the requirements to obtain regulatory approval of the FDA and regulators in other jurisdictions can be costly, time-consuming and unpredictable;<br>▪ ethical and other concerns surrounding the use of embryonic stem cell-based therapy may negatively affect regulatory approval or public perception of non-embryonic stem cell product candidates, which could reduce demand for products or depress share price<br>▪ orphan drug designation may not ensure benefit from market exclusivity in a particular market; and<br>▪ failure to obtain or maintain orphan drug designation or other regulatory exclusivity for some of product candidates may harm competitive position. |

# Key Risks (2 of 5)

| Risk type | Outline |
|---|---|
| **COLLABORATORS** | The Company relies heavily on third parties (e.g. pharmaceutical companies) (**collaborators**) to develop and/or commercialise the Company's current and future product candidates. The failure of collaborators to carry out their contractual duties, meet expected deadlines, or comply with regulatory requirements may lead to the Company not being able to meet expected deadlines, or comply with regulatory requirements. This may result in the Company failing to obtain regulatory approval for, or commercialize, product candidates in a timely and cost-effective manner.<br><br>The Company's ability to successfully collaborate with any existing or future collaborators may be impaired by multiple factors including the following:<br><br>▪ a collaborator may shift its priorities and resources away from programs due to a change in business strategies, or a merger, acquisition, sale or downsizing of its company or business unit;<br>▪ a collaborator may cease development in therapeutic areas which are the subject of strategic alliances;<br>▪ a collaborator may change the success criteria for a particular program or product candidate thereby delaying or ceasing development of such program or candidate;<br>▪ a significant delay in initiation of certain development activities by a collaborator will also delay payments tied to such activities, thereby impacting ability to fund activities;<br>▪ a collaborator could develop a product that competes, either directly or indirectly, with current or future products, if any;<br>▪ a collaborator with commercialization obligations may not commit sufficient financial or human resources to the marketing, distribution or sale of a product;<br>▪ a collaborator with manufacturing responsibilities may encounter regulatory, resource or quality issues and be unable to meet demand requirements;<br>▪ a collaborator may exercise its rights under its agreement to terminate collaboration;<br>▪ a dispute may arise between us and a collaborator concerning the research or development of a product candidate or commercialization of a product resulting in a delay in milestones, royalty payments or termination of a program and possibly resulting in costly litigation or arbitration which may divert management attention and resources;<br>▪ the results of clinical trials may not match collaborators' expectations, even if statistically significant;<br>▪ a collaborator may not adequately protect or enforce the intellectual property rights associated with a product or product candidate; and<br>▪ a collaborator may use proprietary information or intellectual property in such a way as to invite litigation from a third party. |

# Key Risks (3 of 5)

| Risk type | Outline |
|---|---|
| **MANUFACTURING RISK** | The Company has no experience manufacturing its product candidates at a commercial scale. It may not be able to manufacture product candidates in quantities sufficient for development and commercialization if the product candidates are approved, or for any future commercial demand for product candidates. The Company relies on Lonza Singapore to manufacture its mesenchymal lineage cell product candidates. The associated risks include that Lonza may:<br>▪ cease or reduce production or deliveries, raise prices or renegotiate terms;<br>▪ delay or be unable to procure or expand sufficient manufacturing capacity, which may harm reputation or frustrate customers;<br>▪ lack capacity sufficient to support the scale-up of manufacturing for product candidates;<br>▪ experience carrier disruptions or increased costs that it will pass on to the Company;<br>▪ fail to secure adequate supplies of essential ingredients in the manufacturing process; or<br>▪ appropriate or misuse trade secrets and other proprietary information.<br><br>These events may lead to delays in the development of product candidates, including delays in clinical trials, or failure to obtain regulatory approval for product candidates, or it could impact ability to successfully commercialize current product candidates or any future products. |
| **SUPPLY CHAIN RISK** | The following factors present a risk to the Company's supply chain efficiency:<br>• the Company and its collaborators depend on a limited number of suppliers for product candidates' materials, equipment or supplies and components required to manufacture product candidates;<br>• the loss of these suppliers, or their failure to provide quality supplies on a timely basis, could cause delays in current and future capacity;<br>• the Company and its collaborators are subject to significant regulation with respect to manufacturing product candidates. The Lonza manufacturing facilities on which we rely may not continue to meet regulatory requirements or may not be able to meet supply demands;<br>• the Company relies on third parties to perform many necessary services for the commercialization of product candidates, including services related to the distribution, storage and transportation of products;<br>• product recalls or inventory losses caused by unforeseen events may adversely affect operating results and financial condition; and<br>• global events, including geopolitical disruption and climate events, may adversely impact the supply chain, as well as the manufacturing and commercialization of remestemcel-L and other product candidates. Cybersecurity events may also disrupt supply chain, research and development activities. |

# Key Risks (4 of 5)

| Risk type | Outline |
|---|---|
| **COMMERCIALISATION RISK** | Future commercial success depends upon attaining significant market acceptance of product candidates, if approved, among physicians, patients and healthcare payors. The market acceptance of each of product candidates is volatile and depends upon the following factors, each posing a potential risk:<br>▪ the efficacy and safety of the product candidate, as demonstrated in clinical trials;<br>▪ the clinical indications for which the product is approved, and the label approved by regulatory authorities for use with the product, including any warnings or contraindications that may be required on the label;<br>▪ acceptance by physicians, patients, and with paediatric indications by parents/caregivers of the product as a safe and effective treatment;<br>▪ the cost, safety and efficacy of treatment in relation to alternative treatments;<br>▪ the continued projected growth of markets for various indications;<br>▪ relative convenience and ease of administration;<br>▪ the prevalence and severity of adverse side effects;<br>▪ the effectiveness of the Company's and its collaborators' sales and marketing efforts; and<br>▪ sufficient third-party insurance and other payor (e.g., governmental) coverage and reimbursement.<br><br>The Company also faces substantial competition, which may result in other entities discovering, developing or commercialising products before, or more successfully, than the Company. Further, due to the novel nature of cell therapy and the potential for product candidates to offer therapeutic benefit in a single administration, the Company faces uncertainty related to pricing and reimbursement for these product candidates. |
| **INTELLECTUAL PROPERTY RISK** | The success of future product sales will depend in part on the Company's ability to obtain patents, protect its trade secrets, and operate its business without infringing on the proprietary rights of others. Risks associated with the Company's intellectual property include the following:<br>• the patent positions of biopharmaceutical products are complex and uncertain;<br>• current patent applications may not be successful and issued or granted patents may later be found to be invalid or unenforceable, be interpreted in a manner that does not adequately protect current product or any future products, or fail to otherwise provide us with any competitive advantage. Accordingly, the Company is unable to precisely identify the degree of future protection that it will have over proprietary products and technology;<br>• the potential financial and reputational costs associated with intellectual property litigation, and the risk that because of the substantial amount of discovery required in connection with intellectual property litigation, the Company's confidential and proprietary information could be compromised; and<br>• failure to obtain patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of marketing exclusivity of product candidates, may materially harm the long-term commercial viability of products. |

# Key Risks (5 of 5)

| Risk type | Outline |
|---|---|
| **INDUSTRY RISK** | The Company conducts operations in multiple tax jurisdictions. The laws of those jurisdictions generally require that the transfer pricing between affiliated companies in different jurisdictions be the same as those between unrelated companies dealing at arms' length. The following industry factors may pose risk to the Company:<br>▪ taxing authorities may reallocate taxable income within subsidiaries, which could increase consolidated tax liability; and<br>▪ the pharmaceutical industry is highly regulated and pharmaceutical companies are subject to various federal and state fraud and abuse laws; |
| **TRADING MARKET RISK** | The market price and trading volume of the Company's ordinary shares and American Depository Shares (**ADSs**) may be volatile and may be affected by economic conditions beyond the Company's control. Such volatility may lead to securities litigation. The trading volume of ordinary shares and ADSs may fluctuate and cause significant price variations to occur. The Company can therefore not provide assurance that the market price of ordinary shares and ADSs will not fluctuate or significantly decline in the future. Specific factors that could negatively affect the price of ordinary shares and ADSs or result in fluctuations in their price and trading volume include:<br><br>▪ results of clinical trials of product candidates;<br>▪ results of clinical trials of competitors' products;<br>▪ regulatory actions with respect to products or competitors' products;<br>▪ actual or anticipated fluctuations in quarterly operating results or those of competitors;<br>▪ publication of research reports in the industry;<br>▪ the passage of legislation or other regulatory developments affecting us or the industry;<br>▪ failure or the failure of competitors to meet analysts' projections or guidance that we or competitors may give to the market;<br>▪ issuances by us of debt or equity securities;<br>▪ strategic decisions by us or competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;<br>▪ fluctuations in the valuation of companies perceived by investors;<br>▪ changes in trading volume of ADSs on the Nasdaq and of ordinary shares on the ASX;<br>▪ announcement or expectation of additional financing efforts;<br>▪ changes in market conditions for biopharmaceutical companies; and<br>▪ conditions in the U.S. or Australian financial markets or changes in general economic conditions. |
| **OWNERSHIP OF ADSs** | As a foreign private issuer, the Company is permitted and expected to follow certain home country corporate governance practices in lieu of certain Nasdaq requirements applicable to domestic issuers and we are permitted to file less information with the US Securities and Exchange Commission than a company that is not a foreign private issuer. This may afford less protection to holders of ADSs. The following risks are also relevant in relation to the ownership of ADSs:<br>▪ ADS holders may be subject to additional risks related to holding ADSs rather than ordinary shares;<br>▪ If the Company becomes classified as a passive foreign investment company, the Company's U.S. security holders may suffer adverse tax consequences;<br>▪ Changes in foreign currency exchange rates could impact amounts received as a result of any dividend or distribution the Company declares on ordinary shares; and<br>▪ U.S. investors may have difficulty enforcing civil liabilities against the Company. |

# Foreign Selling Restrictions





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# International Offer Restrictions

**Bahamas**

This document has not been, and will not be, registered as a preliminary prospectus or a prospectus under the Securities Industry Act, 2011 of the Commonwealth of The Bahamas.

The information in this document is intended solely for the designated recipient. It is not an offer to the public. No distribution of this information to anyone other than the designated recipient is intended or authorized.

**Hong Kong**

WARNING: This document has not been, and will not be, registered as a prospectus under the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32) of Hong Kong, nor has it been authorised by the Securities and Futures Commission in Hong Kong pursuant to the Securities and Futures Ordinance (Cap. 571) of the Laws of Hong Kong (the "SFO"). Accordingly, this document may not be distributed, and the New Shares may not be offered or sold, in Hong Kong other than to "professional investors" (as defined in the SFO and any rules made under that ordinance).

No advertisement, invitation or document relating to the New Shares has been or will be issued, or has been or will be in the possession of any person for the purpose of issue, in Hong Kong or elsewhere that is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to New Shares that are or are intended to be disposed of only to persons outside Hong Kong or only to professional investors. No person allotted New Shares may sell, or offer to sell, such securities in circumstances that amount to an offer to the public in Hong Kong within six months following the date of issue of such securities.

The contents of this document have not been reviewed by any Hong Kong regulatory authority. You are advised to exercise caution in relation to the offer. If you are in doubt about any contents of this document, you should obtain independent professional advice.

# International Offer Restrictions

### Liechtenstein

This document has not been, and will not be, registered with or approved by the Financial Market Authority of Liechtenstein. Accordingly, this document may not be made available, nor may the New Shares be offered for sale, in Liechtenstein except in circumstances that do not require a prospectus under the Prospectus Regulation Implementation Act of Liechtenstein.

Accordingly, an offer of New Shares in Liechtenstein is limited to persons who are "qualified investors" (as defined in Article 2(e) of the Regulation (EU) 2017/1129 of the European Parliament and the Council of the European Union).

### Luxembourg

This document has not been, and will not be, registered with or approved by any securities regulator in the European Union. Accordingly, this document may not be made available, nor may the New Shares be offered for sale, in Luxembourg or in the European Union except in circumstances that do not require a prospectus under Article 1(4) of Regulation (EU) 2017/1129 of the European Parliament and the Council of the European Union (the "Prospectus Regulation").

In accordance with Article 1(4)(a) of the Prospectus Regulation, an offer of New Shares in Luxembourg is limited to persons who are "qualified investors" (as defined in Article 2(e) of the Prospectus Regulation).

### New Zealand

This document has not been registered, filed with or approved by any New Zealand regulatory authority under the Financial Markets Conduct Act 2013 (the "FMC Act").

The New Shares are not being offered to the public within New Zealand other than to existing shareholders of the Company with registered addresses in New Zealand to whom the Offer of these securities is being made in reliance on the Financial Markets Conduct (Incidental Offers) Exemption Notice 2021.

Other than in the entitlement offer, the New Shares may only be offered or sold in New Zealand (or allotted with a view to being offered for sale in New Zealand) to a person who:

- is an investment business within the meaning of clause 37 of Schedule 1 of the FMC Act;
- meets the investment activity criteria specified in clause 38 of Schedule 1 of the FMC Act;
- is large within the meaning of clause 39 of Schedule 1 of the FMC Act;
- is a government agency within the meaning of clause 40 of Schedule 1 of the FMC Act; or
- is an eligible investor within the meaning of clause 41 of Schedule 1 of the FMC Act.

# International Offer Restrictions

## Norway

This document has not been approved by, or registered with, any Norwegian securities regulator under the Norwegian Securities Trading Act of 29 June 2007 no. 75. Accordingly, this document shall not be deemed to constitute an offer to the public in Norway within the meaning of the Norwegian Securities Trading Act. The New Shares may not be offered or sold, directly or indirectly, in Norway except to "professional clients" (as defined in the Norwegian Securities Trading Act).

## Singapore

This document and any other materials relating to the New Shares have not been, and will not be, lodged or registered as a prospectus in Singapore with the Monetary Authority of Singapore. Accordingly, this document and any other document or materials in connection with the offer or sale, or invitation for subscription or purchase, of New Shares, may not be issued, circulated or distributed, nor may the New Shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore except pursuant to and in accordance with exemptions in Subdivision (4) Division 1, Part 13 of the Securities and Futures Act 2001 of Singapore (the "SFA") or another exemption under the SFA.

This document has been given to you on the basis that you are an "institutional investor" or an "accredited investor" (as such terms are defined in the SFA). If you are not such an investor, please return this document immediately. You may not forward or circulate this document to any other person in Singapore.

Any offer is not made to you with a view to the New Shares being subsequently offered for sale to any other party in Singapore. On-sale restrictions in Singapore may be applicable to investors who acquire New Shares. As such, investors are advised to acquaint themselves with the SFA provisions relating to resale restrictions in Singapore and comply accordingly.

## Switzerland

The New Shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange or on any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the New Shares constitutes a prospectus or a similar notice, as such terms are understood under art. 35 of the Swiss Financial Services Act or the listing rules of any stock exchange or regulated trading facility in Switzerland.

No offering or marketing material relating to the New Shares has been, nor will be, filed with or approved by any Swiss regulatory authority or authorised review body. In particular, this document will not be filed with, and the offer of New Shares will not be supervised by, the Swiss Financial Market Supervisory Authority (FINMA).

Neither this document nor any other offering or marketing material relating to the New Shares may be publicly distributed or otherwise made publicly available in Switzerland. The New Shares will only be offered to investors who qualify as "professional clients" (as defined in the Swiss Financial Services Act). This document is personal to the recipient and not for general circulation in Switzerland.

# International Offer Restrictions

## United Kingdom

Neither this document nor any other document relating to the offer has been delivered for approval to the Financial Conduct Authority in the United Kingdom and no prospectus (within the meaning of section 85 of the Financial Services and Markets Act 2000, as amended ("FSMA")) has been published or is intended to be published in respect of the New Shares.

The New Shares may not be offered or sold in the United Kingdom by means of this document or any other document, except in circumstances that do not require the publication of a prospectus under section 86(1) of the FSMA. This document is issued on a confidential basis in the United Kingdom to "qualified investors" within the meaning of Article 2(e) of the UK Prospectus Regulation. This document may not be distributed or reproduced, in whole or in part, nor may its contents be disclosed by recipients, to any other person in the United Kingdom.

Any invitation or inducement to engage in investment activity (within the meaning of section 21 of the FSMA) received in connection with the issue or sale of the New Shares has only been communicated or caused to be communicated and will only be communicated or caused to be communicated in the United Kingdom in circumstances in which section 21(1) of the FSMA does not apply to the Company.

In the United Kingdom, this document is being distributed only to, and is directed at, persons (i) who have professional experience in matters relating to investments falling within Article 19(5) (investment professionals) of the Financial Services and Markets Act 2000 (Financial Promotions) Order 2005 ("FPO"), (ii) who fall within the categories of persons referred to in Article 49(2)(a) to (d) (high net worth companies, unincorporated associations, etc.) of the FPO or (iii) to whom it may otherwise be lawfully communicated ("relevant persons"). The investment to which this document relates is available only to relevant persons. Any person who is not a relevant person should not act or rely on this document.

## United States

This document does not constitute an offer to sell, or a solicitation of an offer to buy, securities in the United States. The New Shares have not been registered under the US Securities Act of 1933 or the securities laws of any state or other jurisdiction of the United States. Accordingly, the New Shares may not be offered or sold in the United States except in transactions exempt from, or not subject to, the registration requirements of the US Securities Act and applicable US state securities laws.

# Thank You