
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 6-K

Report of Foreign Private Issuer
Pursuant to Rule 13a-16 or 15d-16 under the Securities Exchange Act of 1934

For the month of June 2024

Commission File Number 001-37626

Mesoblast Limited

(Exact name of Registrant as specified in its charter)

Not Applicable

(Translation of Registrant's name into English)

Australia

(Jurisdiction of incorporation or organization)

Silviu Itescu

Chief Executive Officer and Executive Director

Level 38

55 Collins Street

Melbourne 3000

Australia

(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F:

Form 20-F Form 40-F

INFORMATION CONTAINED ON THIS REPORT ON FORM 6-K

On June 3, 2024, Mesoblast Limited filed with the Australian Securities Exchange a new release announcement, which is attached hereto as [Exhibit 99.1](#), and is incorporated herein by reference.

On June 3, 2024, Mesoblast Limited filed with the Australian Securities Exchange a corporate presentation, which is attached hereto as [Exhibit 99.2](#), and is incorporated herein by reference.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly organized.

Mesoblast Limited
/s/ Paul Hughes

Paul Hughes
Company Secretary

Dated: June 4, 2024

INDEX TO EXHIBITS

Item

[99.1](#) Press release of Mesoblast Ltd, dated June 3, 2024.

[99.2](#) Corporate presentation of Mesoblast Ltd, dated June 3, 2024



MESOBLAST CORPORATE PRESENTATION AT INVESTOR CONFERENCE

Melbourne, Australia; June 3 and New York, USA; June 2, 2024: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), Chief Executive Silviu Itescu provided a corporate update at the Bell Potter Emerging Leaders Conference.

Dr. Itescu reiterated that the Company expects to file this quarter the Biologics License Application (BLA) resubmission with the United States Food and Drug Administration (FDA) for its lead product candidate Ryoncil®(remestemcel-L) in the treatment of steroid-refractory acute graft versus host disease, with potential approval in the second half of CY2024.

Dr. Itescu additionally highlighted the heart failure and back pain programs in Phase 3, and the recent feedback from FDA regarding an accelerated approval pathway for the heart failure product Revascor® (rexlemestrocel).

The presentation also highlighted Mesoblast's strong United States intellectual property position, with granted patents through 2032 covering mesenchymal stem cell compositions of matter, irrespective of source, and their broad uses, including for GVHD. On RYONCIL approval, the granted patents may be extended up to 2037. Additional patent filings may extend the commercial barrier to entry through 2043.

About Mesoblast

Mesoblast (the Company) is a world leader in developing allogeneic (off-the-shelf) cellular medicines for the treatment of severe and life-threatening inflammatory conditions. The Company has leveraged its proprietary mesenchymal lineage cell therapy technology platform to establish a broad portfolio of late-stage product candidates which respond to severe inflammation by releasing anti-inflammatory factors that counter and modulate multiple effector arms of the immune system, resulting in significant reduction of the damaging inflammatory process.

Mesoblast has a strong and extensive global intellectual property portfolio with protection extending through to at least 2041 in all major markets. The Company's proprietary manufacturing processes yield industrial-scale, cryopreserved, off-the-shelf, cellular medicines. These cell therapies, with defined pharmaceutical release criteria, are planned to be readily available to patients worldwide.

Mesoblast is developing product candidates for distinct indications based on its remestemcel-L and rexlemestrocel-L allogeneic stromal cell technology platforms. Remestemcel-L is being developed for inflammatory diseases in children and adults including steroid refractory acute graft versus host disease, and biologic-resistant inflammatory bowel disease. Rexlemestrocel-L is being developed for advanced chronic heart failure and chronic low back pain. Two products have been commercialized in Japan and Europe by Mesoblast's licensees, and the Company has established commercial partnerships in Europe and China for certain Phase 3 assets.

Mesoblast has locations in Australia, the United States and Singapore and is listed on the Australian Securities Exchange (MSB) and on the Nasdaq (MESO). For more information, please see www.mesoblast.com, LinkedIn: Mesoblast Limited and Twitter: @Mesoblast

Forward-Looking Statements

This press release includes forward-looking statements that relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. Forward-looking statements should not be read as a guarantee of future performance or results, and actual results may differ from the results anticipated in these forward-looking statements, and the differences may be material and adverse. Forward-looking statements include, but are not limited to, statements about:



the initiation, timing, progress and results of Mesoblast's preclinical and clinical studies, and Mesoblast's research and development programs; Mesoblast's ability to advance product candidates into, enroll and successfully complete, clinical studies, including multi-national clinical trials; Mesoblast's ability to advance its manufacturing capabilities; the timing or likelihood of regulatory filings and approvals (including any future decision that the FDA may make on the BLA for remestemcel-L for pediatric patients with SR-aGVHD), manufacturing activities and product marketing activities, if any; the commercialization of Mesoblast's product candidates, if approved; regulatory or public perceptions and market acceptance surrounding the use of stem-cell based therapies; the potential for Mesoblast's product candidates, if any are approved, to be withdrawn from the market due to patient adverse events or deaths; the potential benefits of strategic collaboration agreements and Mesoblast's ability to enter into and maintain established strategic collaborations; Mesoblast's ability to establish and maintain intellectual property on its product candidates and Mesoblast's ability to successfully defend these in cases of alleged infringement; the scope of protection Mesoblast is able to establish and maintain for intellectual property rights covering its product candidates and technology; estimates of Mesoblast's expenses, future revenues, capital requirements and its needs for additional financing; Mesoblast's financial performance; developments relating to Mesoblast's competitors and industry; and the pricing and reimbursement of Mesoblast's product candidates, if approved. You should read this press release together with our 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, performance or achievements to be materially different from those which may be expressed or implied by such statements, and accordingly, you should not place undue reliance on these forward-looking statements. We do not undertake any obligations to publicly update or revise any forward-looking statements, whether as a result of new information, future developments or otherwise.

Release authorized by the Chief Executive.

For more information, please contact:

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Global Leader in Allogeneic Cellular Medicines for Inflammatory Diseases

Corporate Presentation

May 2024
ASX: MSB; Nasdaq: MESO



CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This presentation includes forward-looking statements that relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this presentation are forward-looking statements. Words such as, but not limited to, "believe," "expect," "anticipate," "estimate," "intend," "plan," "targets," "likely," "will," "would," "could," and similar expressions or phrases identify forward-looking statements. We have based these forward-looking statements largely on our current expectations and future events, recent changes in regulatory laws, and financial trends that we believe may affect our financial condition, results of operation, business strategy and financial needs. These statements may relate to, but are not limited to: expectations regarding the safety or efficacy of, or potential applications for, Mesoblast's adult stem cell technologies; expectations regarding the strength of Mesoblast's intellectual property, the timeline for Mesoblast's regulatory approval process, and the scalability and efficiency of manufacturing processes; expectations about Mesoblast's ability to grow its business and statements regarding its relationships with current and potential future business partners and future benefits of those relationships; statements concerning Mesoblast's share price or potential market capitalization; and statements concerning Mesoblast's capital requirements and ability to raise future capital, among others. Forward-looking statements should not be read as a guarantee of future performance or results, and actual results may differ from the results anticipated in these forward-looking statements, and the differences may be material and adverse. You should read this presentation together with our financial statements 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, performance or achievements to be materially different from those which may be expressed or implied by such statements, include, without limitation: risks inherent in the development and commercialization of potential products; uncertainty of clinical trial results or regulatory approvals or clearances; government regulation; the need for future capital; dependence upon collaborators; and protection of our intellectual property rights, among others. Accordingly, you should not place undue reliance on these forward-looking statements. We do not undertake any obligations to publicly update or revise any forward-looking statements, whether as a result of new information, future developments or otherwise.

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

Our Mission



Global Leader in allogeneic cellular medicines for inflammatory diseases

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



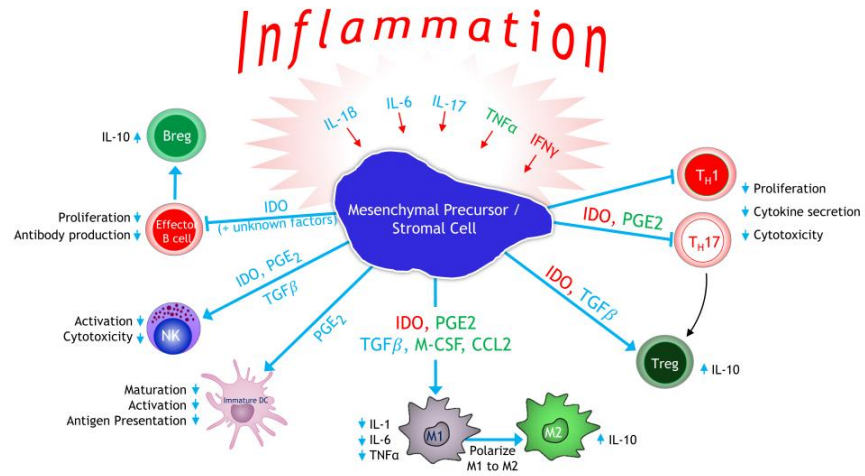
Phase 3 trials
in **THREE**
major
indications

more than
1,100
patents &
applications

TWO products
with clinical
data sufficient
for FDA
regulatory
review

Platform Technology - shared mechanism of action across our products

Our mesenchymal precursor/stromal cells respond to and are activated by multiple inflammatory cytokines through surface receptors, resulting in orchestration of an anti-inflammatory cascade



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



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

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.
- Tasty Pharmaceuticals has exclusive rights for rexlemestrocel-L for the treatment or prevention of chronic heart failure in China.

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

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

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

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

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



Composition of Matter



Manufacturing



Method of Treatment

Positive regulatory interactions with FDA have been the highlight of 2024 year-to-date

- File BLA this quarter for approval of RYONCIL in pediatric acute graft versus host disease
FDA informed the company that following additional consideration the available clinical data from its Phase 3 study MSB-GVHD001 appears sufficient to support submission of the proposed Biologics License Application (BLA) for remestemcel-L (Ryoncil®) for treatment of pediatric patients with steroid-refractory acute graft versus host disease (SR-aGVHD).
- Accelerated approval pathway established for REVASCOR in heart failure
FDA supports an accelerated approval pathway for rexlemestrocel-L (Revascor®) in patients with end-stage ischemic heart failure with reduced ejection fraction (HFrEF) and a left ventricular assist device (LVAD). FDA provided this feedback in formal minutes to the company following the Type B meeting held with FDA in February under the existing Regenerative Medicine Advanced Therapy (RMAT) designation.
- Eligible to receive a Priority Review Voucher for children with hypoplastic left heart syndrome
FDA granted REVASCOR both a Rare Pediatric Disease (RPD) Designation and an Orphan-Drug Designation (ODD) following submission of results from the randomized controlled trial in children with hypoplastic left heart syndrome (HLHS), a potentially life-threatening congenital heart condition.

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

	Program	Key Objectives
1	RYONCIL Steroid-Refractory Acute-Graft versus Host Disease	<i>On-track to submit BLA for approval in pediatric patients this quarter with FDA review expected to take 2 to 6 months</i> <i>Study in adult patients for label extension to follow pediatric approval</i>
2	REVASCOR Heart Failure reduced Ejection Fraction (HFrEF)	<i>FDA pre-BLA meeting to discuss data presentation and timing for an accelerated approval filing in end-stage ischemic HFrEF patients</i>
3	Rexlemestrocel-L for Chronic Low Back Pain	<i>CLBP Phase 3 trial start-up activities with investigators, trial sites & contract research organization (CRO) complete</i> <i>Patient screening/enrollment initiated with first-dosing this quarter</i>

Financials

- ▀ Last quarter we completed the entitlement offer and institutional placement raising A\$97 million.
- ▀ Cash balance at March 31, 2024 was A\$117.0 million (US\$76.4 million).¹
- ▀ Net operating cash spend of US\$11.7 million for the quarter ended March 31, 2024.
- ▀ 28% reduction in net operating cash spend from the comparative quarter in FY2023.
- ▀ We will maintain our focus on cutting costs and preserving cash in the remainder of the year whilst we continue to work on corporate and strategic initiatives to access commercial distribution channels, supplement costs of development, and strengthen our balance sheet.

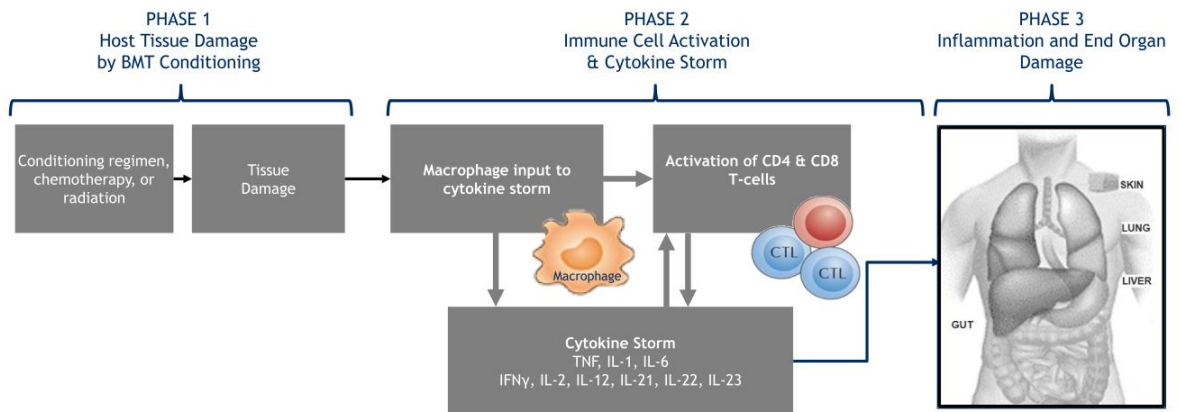
10 ^{1.} Using Reserve Bank of Australia (RBA) published exchange rate from March 31, 2024 of 1A\$:0.6532US\$.



Remestemcel-L

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

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



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

Treatment Options

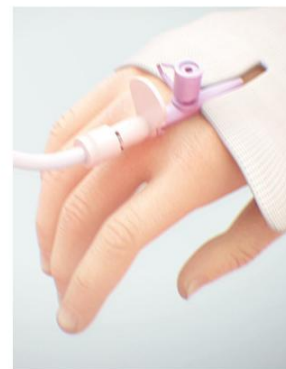
- Corticosteroids are first-line therapy for aGVHD
- There is only one approved treatment for disease refractory to steroids and no approved treatment in the US for children under 12 years old
- In Japan, Mesoblast's licensee received the first product approval for SR-aGVHD in both children and adults

Burden of Illness

- Acute GVHD is a 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 costs²

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 allogeneic BMTs are in children and adolescents in US³



1. Westin, J., Saliba, RM., Lima, M. (2011) Steroid-refractory acute GVHD: predictors and outcomes. *Advances in Hematology*. 2. Niederwieser D, Baldomero H, Szer J. (2016) Hematopoietic stem cell transplantation activity worldwide in 2012 and a SWOT analysis of the Worldwide Network for Blood and Marrow Transplantation Group including the global survey. 3. HRSA Transplant Activity Report, CIBMTR, 2020 4. Axt L, Naumann A, Toennies J (2019) Retrospective single center analysis of outcome, risk factors and therapy in steroid refractory graft-versus-host disease after allogeneic hematopoietic cell transplantation. *Bone Marrow Transplantation*.

Regulatory Status for RYONCIL in pediatric patients with SR-aGVHD

- ▣ FDA informed Mesoblast after its Type C meeting during the quarter that following additional consideration the available clinical data from its Phase 3 study MSB-GVHD001 appears sufficient to support submission of the proposed Biologics License Application (BLA) for remestemcel-L for treatment of pediatric patients with steroid-refractory acute graft versus host disease (SR-aGVHD).
- ▣ Mesoblast intends to file the resubmission this quarter, potentially resulting in an approval for Ryoncil® (remestemcel-L) in the second half of CY2024.
- ▣ Mesoblast will now focus on its original strategy to first gain pediatric approval for RYONCIL, followed by label extension in the larger adult population.

Potential 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 67% after RYONCIL treatment was used under expanded access in 51 adults and children with SR-aGVHD who failed to respond to at least one additional agent, such as ruxolitinib.
- Following approval in pediatric patients, Mesoblast intends to commence a Phase 3 trial of RYONCIL in adults and adolescents, 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.
- Mesoblast is collaborating with the Blood and Marrow Transplant Clinical Trials Network (BMT CTN), a body responsible for approximately 80% of all US transplants, to conduct the trial.

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



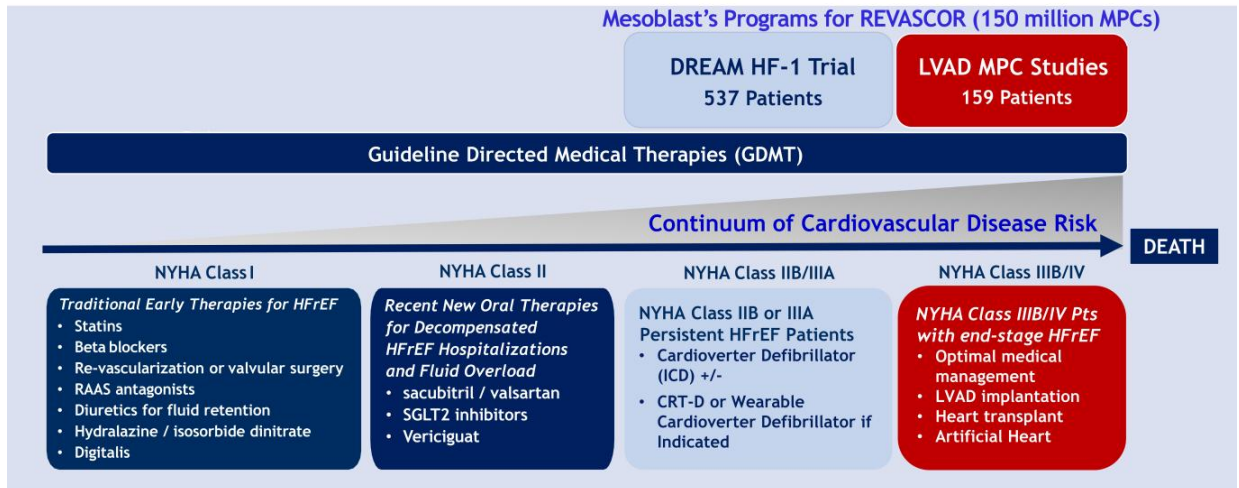
Rexlemestrocel-L

Chronic Heart Failure Reduced Ejection Fraction (HFrEF)

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

- ▶ Heart failure affects 6.5 million patients in the US alone, with prevalence increasing¹
- ▶ Chronic heart failure (CHF) is a progressive disease with a high mortality that approaches 50% at 5 years^{1,2} and at least 75% after an initial hospitalization³
- ▶ Heart failure with low ejection fraction (HFrEF) is associated with greater mortality, occurs in approximately 50% of all patients
- ▶ Over 60% of HFrEF patients have underlying ischemia and these are at highest risk of recurrent major adverse cardiac events involving large vessels (heart attacks / strokes)

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



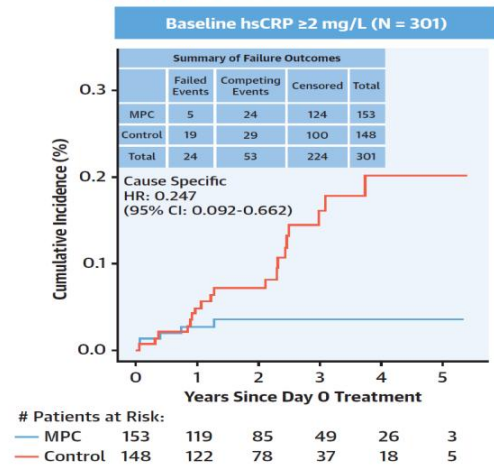
Randomized Trial of Targeted Transcatheter Mesenchymal Precursor Cell Therapy in Patients With Heart Failure



Perin EC, Borow KM, Henry TD, et al. Randomized Trial of Targeted Transcatheter 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 rexllestrocel-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

FIGURE 4 Risk of Myocardial Infarction or Stroke



Results of a single intra-myocardial administration of REVASCOR (150 million MPCs) in patients with ischemic HFrEF which support Accelerated Approval

- ▀ LVAD-MPC Study #2, over 12 months of follow-up:
 - Increased proportion of LVAD recipients with ischemic HFrEF etiology successfully weaned with MPC administration vs controls ($p=0.02$).
 - Reduced mortality by 82% ($p=0.008$) in LVAD recipients with ischemic HFrEF etiology, all of whom also had persistent inflammation ($n=70$).
- ▀ DREAM-HF Trial over a mean follow-up of 30 months:
 - For patients with an ischemic HFrEF etiology and inflammation ($n=158$), MPCs resulted in 88% risk reduction for 2-Point MACE (MI or stroke; hazard ratio 0.12, $p=0.005$) and 52% risk reduction for 3-Point MACE (hazard ratio 0.477, $p=0.018$).
- ▀ Mesoblast intends to request a pre-BLA meeting with FDA to discuss data presentation, timing and FDA expectations for an accelerated approval filing in ischemic HFrEF patients with end-stage heart failure

FDA awarded Rare Pediatric Disease Designation (RPDD) and Orphan Drug Designation (ODD) to REVASCOR for pediatric congenital heart disease - hypoplastic left heart syndrome (HLHS)

- FDA granted Mesoblast's cardiovascular investigational product, REVASCOR, both RPDD and ODD this year. This followed submission of results from the randomized controlled trial in children with hypoplastic left heart syndrome (HLHS), a potentially life-threatening congenital heart condition.
- On FDA approval of a BLA for REVASCOR for the treatment of HLHS, Mesoblast may be eligible to receive a Priority Review Voucher (PRV) that can be redeemed for any subsequent marketing application or may be sold or transferred to a third party.
- Mesoblast plans to meet with FDA to discuss the regulatory path to approval for REVASCOR in children with this life-threatening condition.



Rexlemestrocel-L

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

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

Burden of Illness

- ▶ Back pain causes more disability than any other condition¹
- ▶ Inflicts substantial direct and indirect costs on the healthcare system,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 CLBP²
- ▶ Durable improvement in pain has potential to reduce opioid use and prevent surgical intervention

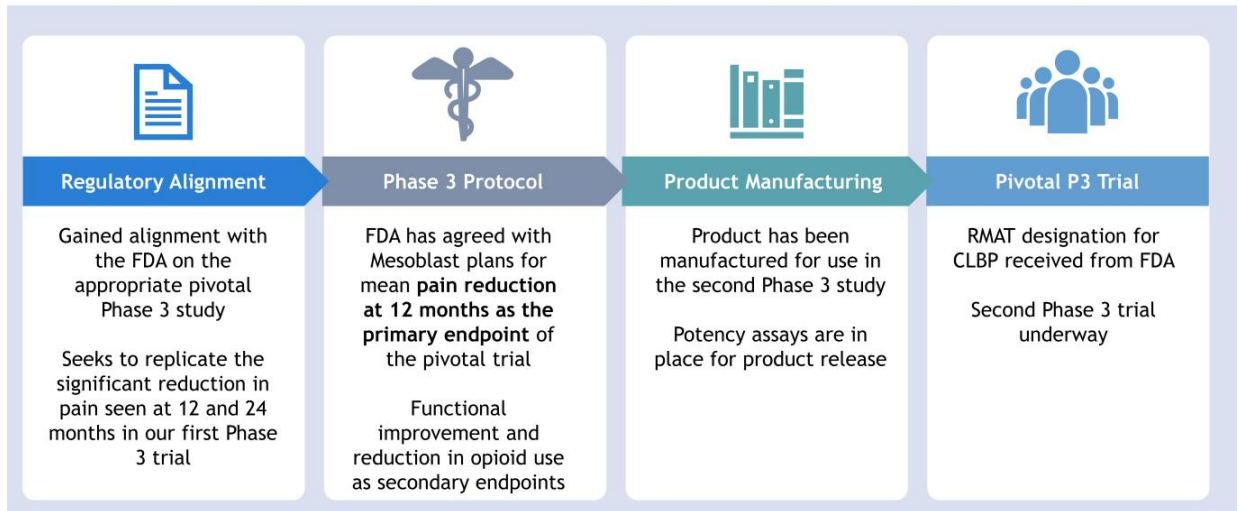
Market Opportunity

- ▶ Over 7m patients are estimated to suffer from CLBP due to degenerative disc disease (DDD) in each of the U.S. and E.U.³⁻⁴



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.

Rexlemestrocel-L / CLBP - program summary





Thank You

