
**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 December 2021

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

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Yes No

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Yes No

INFORMATION CONTAINED ON THIS REPORT ON FORM 6-K

On December 6, 2021, Mesoblast Limited filed with the Australian Securities Exchange a new release announcement and investor presentation, which are attached hereto as [Exhibit 99.1](#) and [Exhibit 99.2](#), and are 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/ Niva Sivakumar

Niva Sivakumar
Company Secretary

Dated: December 7, 2021

INDEX TO EXHIBITS

Item	
99.1	Press release of Mesoblast Ltd, dated December 6, 2021.
99.2	Investor presentation of Mesoblast Ltd, dated December 6, 2021.

REXLEMESTROCEL-L SHOWS GREATEST TREATMENT BENEFIT ON MAJOR ADVERSE CARDIOVASCULAR EVENTS IN HIGH-RISK HEART FAILURE PATIENTS WITH DIABETES AND/OR MYOCARDIAL ISCHEMIA
Endpoint in Line with FDA Guidance on Key Outcomes in High-Risk Patients and with Pharma Industry Drugs Approved for Cardiovascular Risk Reduction in Diabetes
Key points:

- Analysis of pre-specified high-risk groups in the DREAM-HF Phase 3 trial of rexllestrocel-L in patients with chronic heart failure and low ejection fraction (HFrEF) showed greatest treatment benefit in major cardiovascular adverse events (MACE) of cardiovascular mortality or irreversible morbidity (non-fatal heart attack or stroke) in patients with diabetes and/or myocardial ischemia (72% of total treated population)
- This target population is at very high risk for mortality and irreversible morbidity due to micro- and macro-vascular disease despite receiving optimal standard of care therapies ¹
- Rxllestrocel-L, added to optimal standard of care therapies, reduced the 3-point MACE composite of cardiovascular death or heart attack or stroke by 37% across all HFrEF patients with diabetes and/or ischemia and by 54% in HFrEF patients with systemic inflammation (elevated baseline hs-CRP)
- United States Food & Drug Administration (FDA) has previously accepted 3-point MACE reductions of 12-14% for approval of multiple pharmaceutical industry drugs to reduce cardiovascular risk in diabetic patients ^{2,3}
- FDA confirmed that reduction in cardiovascular mortality or irreversible morbidity (non-fatal heart attack or stroke) is an acceptable clinically meaningful endpoint for determining the treatment benefit of rexllestrocel-L for patients with HFrEF
- Mesoblast to formally submit to FDA its new analyses of outcomes in high-risk HFrEF patients with diabetes and/or myocardial ischemia to agree on a potential pathway to approval.

Melbourne, Australia; December 6, and New York, USA; December 5, 2021: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today provided new analyses from the landmark DREAM-HF Phase 3 trial showing that the greatest treatment benefit from rexllestrocel-L is in HFrEF patients with diabetes and/or ischemia, who are at high-risk of cardiovascular mortality, heart attacks or strokes.

In recent guidance to Mesoblast, FDA confirmed that reduction in incidence of cardiovascular mortality or irreversible morbidity (non-fatal heart attack or stroke) is a clinically meaningful acceptable endpoint in patients with chronic HFrEF and encouraged Mesoblast to identify the highest-risk group with greatest likelihood of beneficial response to intervention with rexllestrocel-L in the DREAM-HF Phase 3 trial.

In line with this guidance, Mesoblast performed additional analyses of MACE outcomes in pre-specified high-risk patient groups from the landmark DREAM-HF trial, and the results were presented December 3 by Chief Executive Dr Silviu Itescu at the 18th Global Cardiovascular Clinical Trialists Forum (CVCT) in Washington DC.

The data showed that:

- While a single rexllestrocel-L dose on top of maximal standard of care therapies reduced the composite 3-point MACE in all 537 patients by 33% (p=0.02) over a mean follow-up of 30 months, a hierarchical analysis across pre-specified high-risk subgroups showed greatest benefit in patients with diabetes and/or myocardial ischemia (hazard ratio 0.63, p=0.019)
- Among control patients with HFrEF (n=276) all of whom were treated with maximal available standard of care therapies, risk of 3-point MACE was 1.9-fold higher in controls with diabetes and/or myocardial ischemia (n=192) than controls with neither diabetes nor myocardial ischemia (n=84), p=0.02. This confirmed the ongoing high-risk of 3-point MACE in control patients with diabetes and/or myocardial ischemia due to micro- and macro-vascular disease despite receiving optimal standard of care therapies
- Compared to control patients, rexllestrocel-L reduced the incidence of 3-point MACE by 37% overall in NYHA class II or III HFrEF patients with diabetes and/or myocardial ischemia (n=385, p=0.02) and by 54% in those with diabetes and/or myocardial ischemia who had evidence of systemic inflammation, as defined by elevated baseline levels of hs-CRP >2mg/L (n=212, p=0.003).

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Diabetes Mellitus is not only a significant risk factor in the onset of heart failure, it also increases the risk of mortality and morbidity in patients who have existing heart failure.¹⁻³ Type 2 diabetes causes structural heart disease and heart failure through myocardial ischemia involving small and large vessels. Importantly, inflammation which is a critical component of the pathophysiology of the disease is also known to accelerate large vessel atherosclerosis.¹

The 3-point composite MACE is an endpoint the FDA has previously accepted for approval of multiple drugs to reduce cardiovascular risk in diabetic patients. FDA guidance states that reliance on a single study to provide the substantial evidence of effectiveness necessary to support a Biologic License Application (BLA) is generally limited to situations in which a trial has demonstrated a clinically meaningful effect on mortality, irreversible morbidity, or prevention of a disease with potentially serious outcome for which confirmation of the result with a second trial would be practically or ethically impossible. Mesoblast will submit for formal FDA review the new data analyses showing the reduction in mortality and irreversible morbidity by rexlemestrocet-L in HFrEF patients with diabetes and/or myocardial ischemia, to agree on a potential pathway to approval.

About Mesoblast

Mesoblast 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 rexlemestrocet-L 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 moderate to severe acute respiratory distress syndrome. Rexlemestrocet-L is in development 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

Footnotes

1. Dunlay SM., et al. *Circulation*. 2019;140:e294–e324
2. Wang CCL et al. *Circulation* 2019; 139: 1741-1743.
3. McGuire DK et al. *JAMA Cardiol*. 2021; 6:148-158.



Forward-Looking Statements

This announcement 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. All statements other than statements of historical fact, including our intention to agree with FDA on a potential pathway to approval, are forward-looking statements, which are often indicated by terms such as “anticipate,” “believe,” “could,” “estimate,” “expect,” “goal,” “intend,” “likely,” “look forward to,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “will,” “would” and similar expressions and variations thereof. 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. The risks, uncertainties and other factors that may impact our forward-looking statements include, but are not limited to: the timing, progress and results of Mesoblast’s preclinical and clinical studies; Mesoblast’s ability to advance product candidates into, enroll and successfully complete, clinical studies; the timing or likelihood of regulatory filings and approvals; whether the FDA agrees to a regulatory pathway; and the pricing and reimbursement of Mesoblast’s product candidates, if approved; 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. 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. Unless required by law, 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.

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DREAM HF Trial: Rexlemestrocel-L (MPCs) in the Treatment of Heart Failure with Reduced Ejection Fraction (HFrEF)

Presentation at the 18th Global CardioVascular Clinical Trialists Forum (CVCT), Washington DC

DECEMBER 2021

ASX: MSB; Nasdaq: MESO

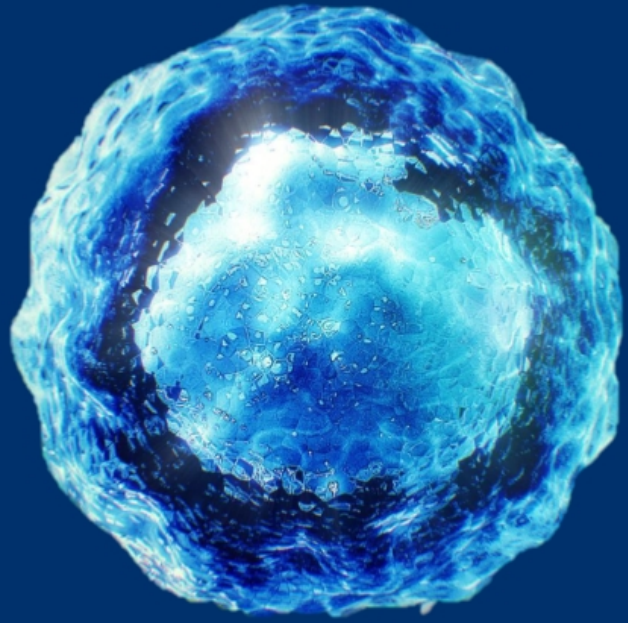


CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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.

Our Mission

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



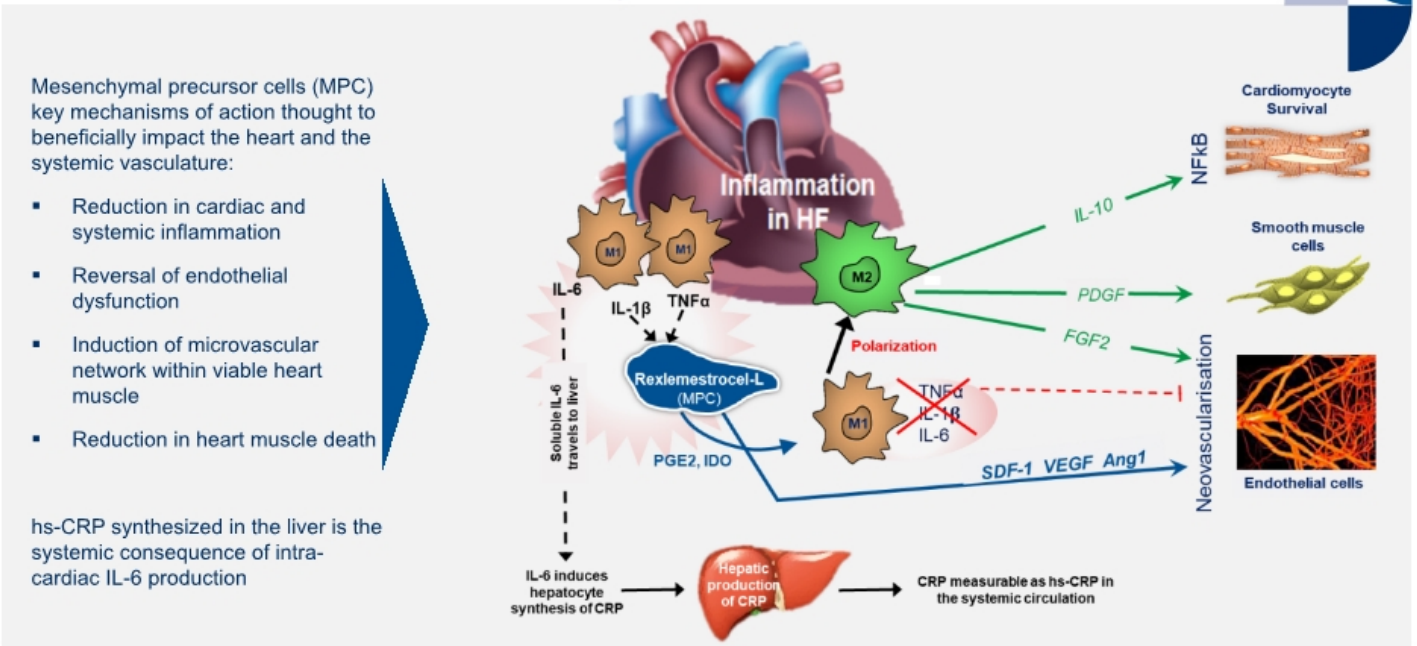
Chronic Heart Failure: Rising Incidence & High Mortality

- Cardiovascular disease (CVD) remains the leading cause of death in the United States¹
- Heart failure affects 6.5 million patients in the US and 26 million patients globally. As populations age, the prevalence is increasing²
- Chronic heart failure is a progressive disease with a high mortality that approaches 50% at 5 years^{2,3}, and at least 75% after an initial hospitalization⁴
- Patients with heart failure are also at high risk of recurrent major adverse cardiac events involving large vessels (heart attacks / strokes)

New therapies for chronic heart failure reduce recurrent hospitalizations due to cardiac decompensation, however they do not materially improve cardiac mortality or major ischemic events (heart attacks/strokes)

1. Muntner BEJ, et al. Heart Disease and Stroke Statistics-2019 Update: A Report From the American Heart Association. *Circulation*. Feb 19, 2019. 2. United States Food & Drug Administration. Treatment for Heart Failure: Endpoints for Drug Development. Draft Guidance. June 2019. 3. Taylor CJ, et al. Trends in survival after a diagnosis of heart failure in the United Kingdom 2000-2017: population-based cohort study. *BMJ*. 2019;364:l223. 4. Shah KS, et al. Heart Failure with Preserve, Borderline, and Reduced Ejection Fraction; 5-Year Outcomes. *JACC*. 2017;Nov12.

Proposed Mechanism of Action of Intra-Cardiac MPC Administration in Treatment of both Heart Failure & Large Vessel Atherosclerosis



Modified from Borow KM, Yaroshinsky A, Greenberg B, Perin E. Phase 3 DREAM-HF Trial of Mesenchymal Precursor Cells in Chronic Heart Failure: A Review of Biological Plausibility and Implementation of Flexible Clinical Trial Design. *Circ Res.* 2019;125:265-281

DREAM-HF Trial: Overview



Key Inclusion Criteria

- 18 to ≤80 years of age
- **NYHA class II / III, LVEF ≤ 40%**
- Receiving **optimal medical therapies for heart failure** at stable and tolerated doses for at least 1 month before study intervention
- No option for percutaneous coronary intervention or coronary artery bypass graft surgery
- Enrichment criteria:
 - **At least 1 heart failure hospitalization or outpatient visit** requiring intravenous diuretic, vasodilator, and/or positive inotropic therapy >1 month but ≤9 months before initiation of screening procedures and/or
 - Plasma levels of **NT-pro-BNP** >1000 pg/mL (>1200 pg/mL for patients with atrial fibrillation)

Trial Design

- Prospective, randomized, double-blind, sham controlled
- 1:1 randomization: Single administration procedure of 150 million allogeneic MPC delivered by transendocardial image-guided injection vs sham-control procedure
- All medical therapies for heart failure continued for all patients
- 565 randomized patients; 537 received treatment
- Mean patient follow-up 30 months
- Prospective adjudication by treatment-blinded independent Clinical Endpoints Committee (CEC) of all Major Adverse Cardiovascular Events (MACE) including potential Cardiovascular death, cardiac deaths or non-cardiac vascular deaths

Clinically Significant Endpoints in Persistent HFrEF

Pre-Specified Endpoints

1. Mortality (cardiovascular death, all-cause cardiac death, cardiac death from pump failure)

2. Irreversible Morbidity (non-fatal myocardial infarction, non-fatal cerebrovascular accident)

3. Non-fatal Decompensated HFrEF Morbidity Events

(non-fatal hospitalization or urgent care treatment for decompensated HFrEF &/or successfully resuscitated cardiac death associated with high-grade ventricular arrhythmias)

3-Point Composite MACE Endpoint

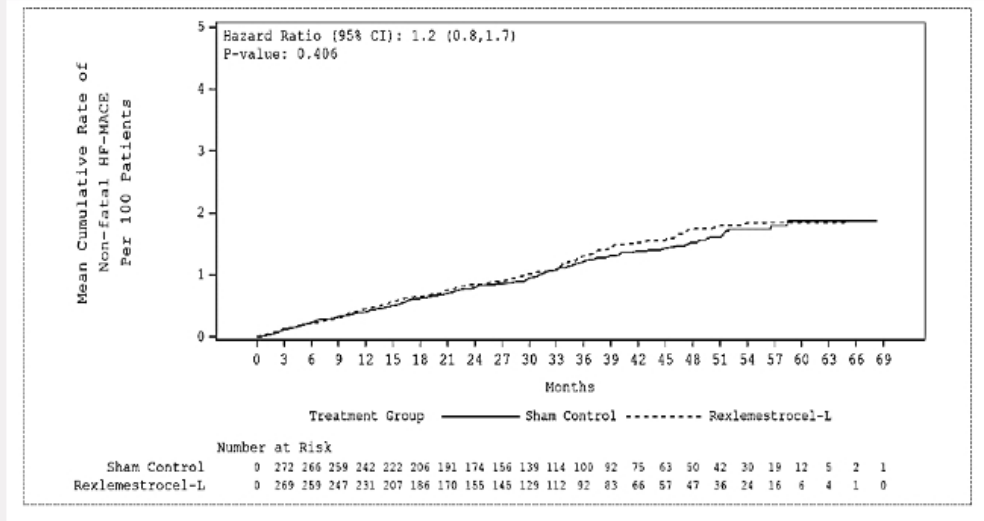
4. Irreversible Morbidity or Mortality: IMM
(cardiovascular/cardiac death, or non-fatal MI, or non-fatal stroke)

NOTE: Adjudication of all deaths in DREAM-HF trial (including CV, all-cause cardiac, or non-cardiac) was prospectively performed by the treatment-blinded independent Clinical Endpoints Committee (CEC) at the Brigham & Women's Hospital using pre-specified causal categories, defined in the study's Adjudication Operations Manual.

Rexlemestrocel-L Did Not Further Reduce Frequency of Hospitalization for Worsening HF Symptoms Over Maximal Standard of Care

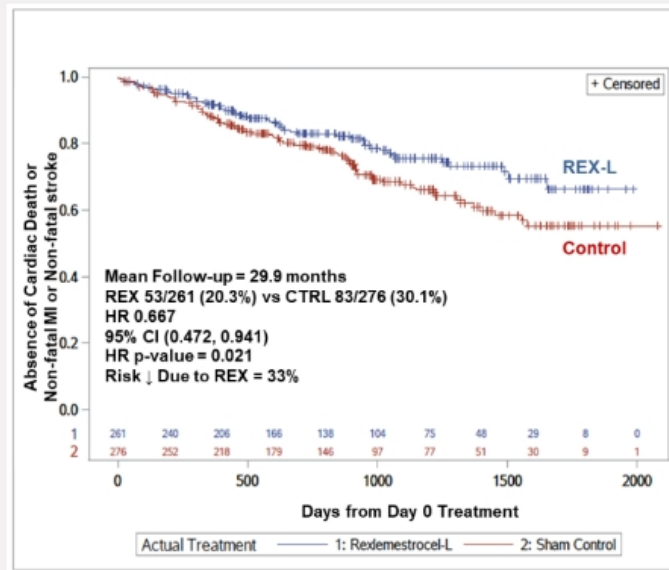


All Patients (n=537)
 HR: 1.2
 p=0.4



Rexlemestrocel-L Reduced Incidence of 3-Point Composite MACE (CV Death, MI or Stroke) Compared to Controls Across All 537 Treated Patients

Time-to-First-Event for Cardiovascular Death or Non-fatal MI or Non-fatal Stroke



Evaluation of Rexamestrocel-L on 3-Point IMM MACE in Pre-Specified Patient Populations With Reproducibly High-Risk for Poor Outcomes:



Greatest Treatment Effect in Patients with Micro- or Macro- Vascular Disease (Myocardial Ischemia and/or Diabetes)

72% of total treated population (n=537) →

Pre-Specified Patient Subset	Number of Patients	Hazard Ratio	95% Confidence Interval
Myocardial Ischemia &/or Diabetes	385	0.63	0.434, 0.928
Myocardial Ischemia ¹	303	0.66	0.436, 0.988
Diabetes ²	231	0.66	0.400, 1.094
HF hospitalization within prior 1-9 months	330	0.66	0.414, 1.048
Prior Myocardial Infarction	280	0.70	0.452, 1.069
NT-proBNP >1000	365	0.74	0.505, 1.083
LVESV >100 mL	431	0.75	0.517, 1.073
LVEF <30%	299	0.77	0.508, 1.116

P = 0.019

P = 0.044

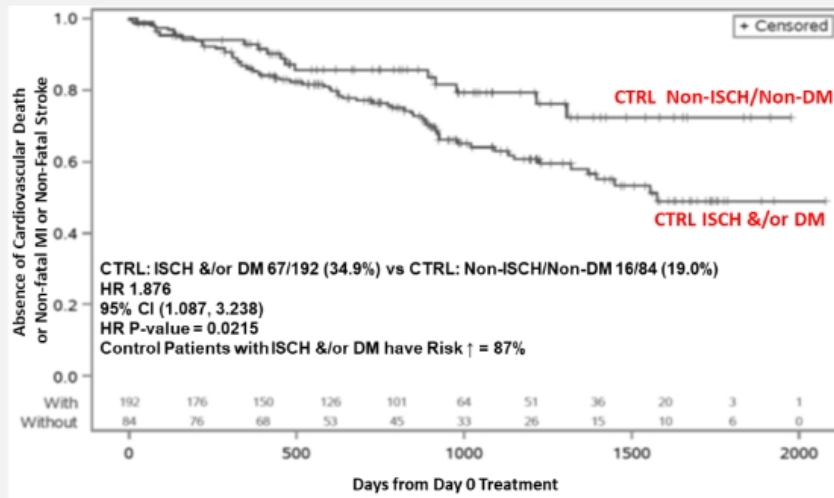
P = 0.108

¹ Chronic HF of ischemic etiology includes epicardial CAD, defined as documented stenosis of at least 50% in one or more major epicardial coronary arteries, documented prior coronary artery revascularization, and/or documented prior MI

² Diabetes includes patients with end-organ involvement due to microvascular disease

Myocardial Ischemia &/or Diabetes in Control Patients in DREAM-HF Trial Identifies Subgroup with Worse Outcomes, as Measured by 3-Point IMM MACE, than other HF rEF Controls

3-Point TTFE Composite IMM MACE (n=276 Control Patients)
 Myocardial Ischemia &/or Diabetes (n=192) vs. Non-Ischemia/Non-Diabetes (n=84)

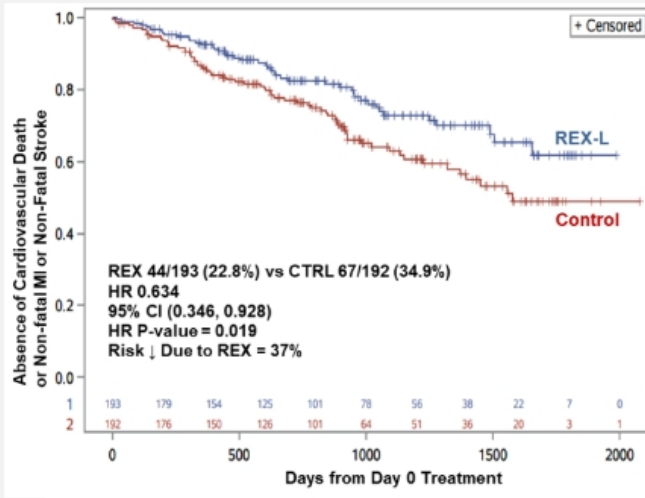


Kaplan-Meier log rank statistics

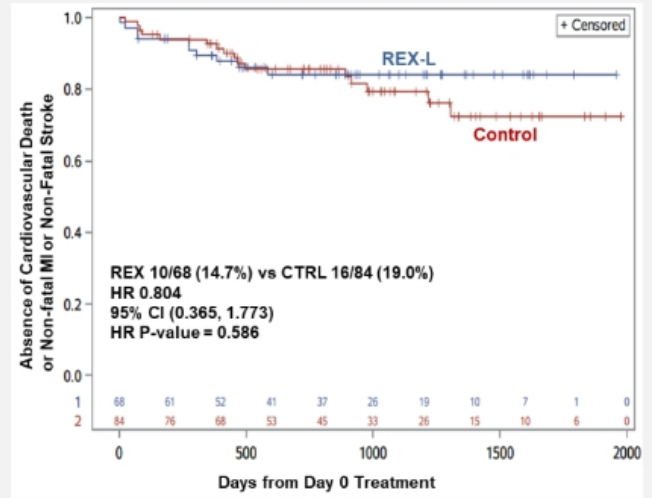
Rexlemestrocel-L Reduced Risk of 3-Point TTFE Composite IMM MACE in High-Risk Patients with Myocardial Ischemia &/or Diabetes by 36%



Ischemic &/or Diabetic Patients
(n=385)



Non-Ischemic/Non-Diabetic Patients
(n=152)



Kaplan-Meier log rank statistics

Pre-Specified Hypotheses

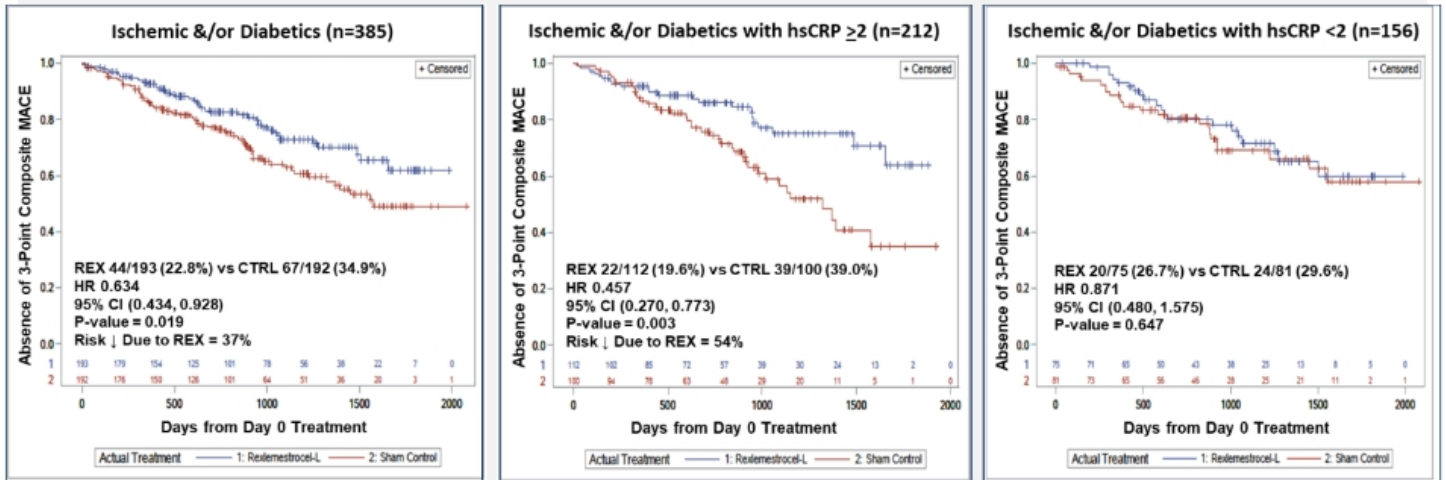
- **hs-CRP** is a validated biomarker for risk of vascular disease, accelerated atherosclerosis, myocardial infarction, and heart failure severity
 - Cut-points of <2mg/L, ≥ 2 mg/L, ≥ 3mg/l, and ≥ 4mg/L were pre-specified for sensitivity analyses in the DREAM-HF SAP
 - Values for hsCRP ≥2 mg/L have previously been used as a threshold for systemic inflammation in cardiovascular disease patient populations, including heart failure¹
- **High levels of hs-CRP may:**
 - Be circulating biomarkers to identify those patients with evidence of inflammatory etiology to their HFrEF
 - Identify those HFrEF patients most likely to respond to the anti-inflammatory effects of rexlemestrocel-L treatment
 - Identify those HFrEF patients with micro- or macro-vascular disease who may be most likely to benefit from rexlemestrocel-L therapy

¹Pellicori P, Zhang J, Cuthert J, et.al. High sensitivity C-reactive protein in chronic heart failure: patient characteristics, phenotypes, and mode of death. Cardiovasc Res 2020;116:91-100

Composite 3-Point MACE and Inflammation



In Patients with Myocardial Ischemia and/or Diabetes with hsCRP ≥ 2 mg/L Rilexlestrocel-L
Reduced Risk of TTFE for 3-Point MACE by 54%



Kaplan-Meier log rank statistics

Investigational Agents Evaluated for Cardiovascular Risk Reduction Using 3-Point IMM MACE*: Comparison With Rexlemestrocel-L in Patients With Myocardial Ischemia &/or Diabetes

Medication	Drug Class	Clinical Trial	Hazard Ratio	Risk Reduction	95% CI	P-value	# Randomized Patients
Liraglutide	GLP-1 Receptor Agonist (RA)	LEADER	0.87	13%	0.78, 0.97	0.01	9,340
		Heart Failure Sub-group	0.94	6%	0.72, 1.21	-----	1,305
Dulaglutide	GLP-1 Receptor Agonist (RA)	REWIND	0.88	12%	0.79, 0.99	0.03	9,901
Empagliflozin	SGLT-2 Inhibitor	EMPA-REG	0.86	14%	0.74, 0.99	0.04	7,020
Canagliflozin	SGLT-2 Inhibitor	CANVAS + CANVAS-R	0.86	14%	0.75, 0.97	0.02	10,142
		Heart Failure Sub-group	0.80	20%	0.61, 1.05	-----	1,461
Dapagliflozin	SGLT-2 Inhibitor	DECLARE Timi 58	0.93	7%	0.84, 1.03	-----	17,160
		Heart Failure Sub-group	1.01	0%	0.81, 1.27	-----	1,724
Ertugliflozin	SGLT-2 Inhibitor	VERTIS CV	0.99	1%	0.88, 1.12	-----	8,246
Rexlemestrocel-L	Mesenchymal Precursor Cells	DREAM HF Ischemics &/or Diabetics	0.63	37%	0.43, 0.93	0.019	385
		Ischemics &/or Diabetics With Baseline hsCRP \geq 2mg/L	0.46	54%	0.27, 0.77	0.003	212

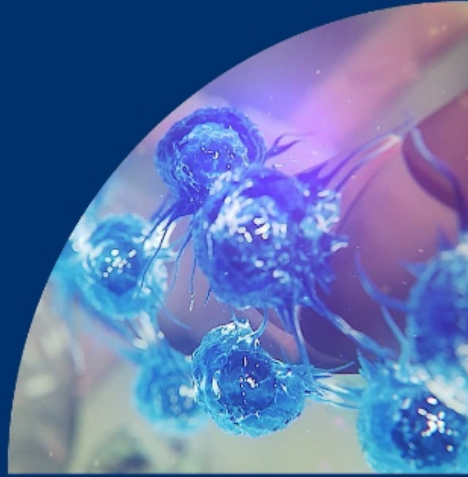
* TTFE Composite for Cardiovascular Death or Non-fatal MI or Non-fatal Stroke

Wang CCL et al. Circulation 2019; 139: 1741-1743. McGuire DK et al. JAMA Cardiol. 2021; 6:148-158.

Conclusion & Key Next Steps



1. Transendocardial delivery of 150 million allogeneic MPCs (rexlemestrocel-L) was safe and did not elicit any clinically meaningful immune-related responses
2. Over a mean follow-up of 30 months, a single rexlemestrocel-L dose on top of maximal standard of care significantly reduced:
 - Composite of cardiovascular death or non-fatal MI or non-fatal stroke in all 537 patients
 - Composite of cardiovascular death or non-fatal MI or non-fatal stroke in all 537 patients
 - A hierarchical analysis of pre-specified risk stratification showed greatest benefit in patients with myocardial ischemia and/or diabetes (72% of total treated population)
 - In controls (treated with maximal current therapies for heart failure), the presence of myocardial ischemia and/or diabetes resulted in 1.9-fold greater risk of 3-Point MACE versus other control patients with heart failure
 - Rexlemestrocel-L reduced 3-Point MACE in myocardial ischemics and/or diabetics by 37%
 - Greatest benefit in patients with elevated CRP at baseline with reduction in 3-Point MACE of 54% (n = 212)
3. Mesoblast to formally submit to FDA its new analyses of outcomes in high-risk HFrEF patients with diabetes and/or myocardial ischemia to agree on a potential pathway to approval



mesoblast



ASX
Nasdaq

