
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 January 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 January 11, 2021, 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 January 12, 2021, Mesoblast Limited filed with the Australian Securities Exchange a new release announcement and investor presentation, which are attached hereto as [Exhibit 99.2](#) and [Exhibit 99.3](#), 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: January 19, 2021

INDEX TO EXHIBITS

Item	
99.1	Press release of Mesoblast Ltd, dated January 11, 2021.
99.2	Press release of Mesoblast Ltd, dated January 12, 2021.
99.3	Investor presentation of Mesoblast Ltd, dated January 12, 2021.

SINGLE DOSE OF REXLEMESTROCEL-L PROVIDES SUBSTANTIAL AND DURABLE REDUCTION IN HEART ATTACKS, STROKES AND CARDIAC DEATH IN PATIENTS WITH CHRONIC HEART FAILURE

Melbourne, Australia; January 11, and New York, USA; January 10, 2021: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today announced additional results from the landmark DREAM-HF randomized controlled Phase 3 trial in 537 treated patients with chronic heart failure with reduced left ventricular ejection fraction (HFrEF) who received rexllestrocel-L (REVASCOR®) or control sham. A single dose of rexllestrocel-L resulted in substantial and durable reductions in heart attacks, strokes, and cardiac deaths. Since existing therapies have only minimal or no benefit on these endpoints, these notable outcomes may signal a breakthrough in addressing the principal unmet needs in patients with chronic heart failure. The results of this trial identify New York Heart Association (NYHA) class II HFrEF patients as the optimal target population for greatest rexllestrocel-L treatment effect, and therefore a focus for registration and commercialization of rexllestrocel-L in the largest market in heart failure.

The incidence of heart attacks and strokes were reduced by 60% over a median follow-up period of 30 months following a single dose of rexllestrocel-L in the population of 537 patients with New York Heart Association (NYHA) class II or III chronic heart failure (5% vs 13%, p=0.002). Patients who received rexllestrocel-L had a 68% reduction in the rate of recurrent hospitalizations from non-fatal heart attacks or strokes compared with controls, with a hospitalization rate of 1.90 per 100 patient-years of follow-up in the rexllestrocel-L arm versus 5.95 per 100 patient-years of follow-up in the control arm (p=0.0002).

The incidence of death from cardiovascular causes was reduced by 60% following a single dose of rexllestrocel-L in the 206 patients with NYHA class II disease (8% vs 20%, p=0.037), a significant reduction which was evident in both ischemic and non-ischemic subgroups as well as diabetic and non-diabetic patients. Whereas NYHA class II controls progressed to cardiac death rates of NYHA class III patients after a period of approximately 20 months of disease stability, NYHA class II patients treated with a single dose of rexllestrocel-L did not show such cardiac death progression (p=0.004 compared to Class II control patients).

The combination of the three pre-specified outcomes of cardiac death, heart attack or stroke into a single composite outcome - called the three-point Major Adverse Cardiovascular Event (MACE) is a well-established endpoint used by the United States Food and Drug Administration (FDA) to determine cardiovascular risk. Rxllestrocel-L significantly reduced this three-point MACE by 30% compared to controls across the population of 537 patients (20.6% vs 30%, p=0.027). In the NYHA class II subgroup of 206 patients, rexllestrocel-L reduced the three-point MACE by 55% compared to controls (13% vs 29%, p=0.009).

The ability of rexllestrocel-L to significantly impact cardiac death, heart attacks and strokes on top of maximal HFrEF therapy reflects the unique mechanisms of action of this allogeneic cellular therapy on reduction of inflammation and improved microvasculature. The unchecked intra-cardiac inflammation in HFrEF patients causes progressive loss of heart muscle, replacement with scar tissue, and death. Persistent inflammation in the blood circulation also results in accelerated atherosclerosis with plaque progression and instability resulting in plaque rupture and potential blockage of major arteries. The net result is high rates of heart attacks and strokes in chronic HFrEF patients. Rxllestrocel-L reduces inflammatory cytokine production by immune cells and generates an improved local network of blood vessels in the damaged heart that has the potential protect against heart muscle cell death and replacement by scar tissue. Reduction in inflammation is the likely explanation for the observed reduction in incidence of heart attacks and strokes in patients who received rexllestrocel-L.

Based on the observed reduction in mortality and morbidity in this Phase 3 trial, Mesoblast intends to meet with the FDA to discuss a potential approval pathway.

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About Chronic Heart Failure

Heart failure affects approximately 6.5 million people in the US and 26 million people globally, with increasing prevalence and incidence. Chronic heart failure is a progressive disease associated with cardiac and systemic inflammation and a high mortality rate that approaches 50% at 5 years as patients progress beyond NYHA class II disease. In addition, these patients are at high risk of recurrent heart attacks and strokes, reflecting the high degree of systemic inflammation and progressive atherosclerosis associated with chronic heart failure. The high rate of cardiac death, heart attacks and strokes accompanying disease progression continues to be the most significant unmet need in this patient population since new therapies that have reduced recurrent hospitalizations due to cardiac decompensation have not materially impacted these MACE outcomes.

About the DREAM HF Phase 3 Trial

Clinical outcomes were evaluated in 537 treated advanced HFEF patients (206 with NYHA class II disease and 331 with NYHA class III disease) randomized 1:1 to either a sham-control procedure or a transcatheter injection by catheter of rexllestrocel-L (150 million cells). Inclusion criteria enriched the trial for patients with advanced disease by requiring a prior heart failure hospitalization over the past one-to-nine months and/or a N-terminal pro-B-type natriuretic peptide (NT-proBNP) level of at least 1000 pg/ml (at least 1200 pg/mL in patients with atrial fibrillation). All patients were continued on maximal oral agents for heart failure and were followed for at least twelve months post the index cath lab-procedure. At the end of the trial, vital status (alive or dead) was established in 100% of the randomized patients.

Baseline characteristics for the 537 treated patient population showed that patient groups with baseline NYHA class II or NYHA class III clinical grades had advanced disease, but those with NYHA class III disease had significantly greater severity (mean NT-proBNP 2390 pg/ml for NYHA class III vs 1809 pg/ml for NYHA class II; p=0.001).

Recurrent non-fatal decompensated heart failure hospitalization events, incidence of heart attacks, strokes, and death from cardiac causes, and recurrent hospitalizations from these outcomes were evaluated for the 537 HFrEF patients over a median follow-up period of approximately 30 months.

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 commercial products and 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 2040 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.

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. Mesoblast has completed Phase 3 trials of rexllestrocel-L 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 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 discuss potential pathways to potential approval with the FDA, 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

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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 potential approval 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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MESOBLAST PRESENTS HEART FAILURE PHASE 3 TRIAL RESULTS AT INVESTOR HEALTHCARE CONFERENCE

Melbourne, Australia; January 12, and New York, USA; January 11, 2021: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, announced that its Chief Executive Officer, Dr Silviu Itescu, today presented additional data from the landmark DREAM-HF Phase 3 trial in patients with chronic heart failure. The presentation materials have been lodged with the ASX, and Mesoblast's presentation at the H.C. Wainwright Virtual BioConnect 2021 Conference can be accessed at <https://journey.ct/events/view/f353f7fd-772e-43aa-aab0-e959da38254d>. An archived webcast of the conference presentation will be available for 90 days on the Company's website at www.mesoblast.com.

The randomized controlled Phase 3 trial compared clinical outcomes between rexllestrocel-L and sham control in 537 treated patients with chronic heart failure and reduced left ventricular ejection fraction (HFrEF).

Key Conclusions of the Presentation

Rexlestrocel-L may provide a major breakthrough in reducing heart failure progression and mortality when used early (New York Heart Association, NYHA, class II disease), and may provide durable protection from heart attacks or strokes in high-risk patients. The specific data supporting these conclusions include:

- 60% reduction in incidence of Major Adverse Cardiac Events (MACE) due to heart attacks or strokes across entire 537 patient study population, irrespective of NYHA class II or III, ischemic or non-ischemic etiology (p=0.002);
- 68% reduction in the rate of recurrent hospitalizations from non-fatal heart attacks or strokes, with a hospitalization rate of 1.90 per 100 patient-years of follow-up in the rexllestrocel-L arm versus 5.95 per 100 patient-years of follow-up in the control arm (p=0.0002);
- 60% reduction in cardiac death in NYHA class II patients (p=0.037) and prevention of progression to NYHA class III rate of cardiac death (p=0.004);
- Covariate regression analyses showed that elevated baseline levels of CRP, an important biomarker of systemic inflammation, predicted rexllestrocel-L treatment effect on both MACE in all patients and cardiac death in NYHA class II patients, consistent with the proposed anti-inflammatory mechanism of action of the agent;
- 30% reduction in incidence of three-point MACE (cardiac death, heart attack or stroke) across entire 537 patient study population (p=0.027); and
- 55% reduction in incidence of three-point MACE (cardiac death, heart attack or stroke) in NYHA class II patients (n=206) (p=0.009).

Based on the observed reduction in mortality and morbidity in this Phase 3 trial, Mesoblast intends to meet with the United States Food and Drug Administration (FDA) to discuss a potential approval pathway.

About Chronic Heart Failure

Heart failure affects approximately 6.5 million people in the US and 26 million people globally, with increasing prevalence and incidence. Chronic heart failure is a progressive disease associated with cardiac and systemic inflammation and a high mortality rate that approaches 50% at 5 years as patients progress beyond NYHA class II disease. In addition, these patients are at high risk of recurrent heart attacks and strokes, reflecting the high degree of systemic inflammation and progressive atherosclerosis associated with chronic heart failure. The high rate of cardiac death, heart attacks and strokes accompanying disease progression continues to be the most significant unmet need in this patient population since new therapies that have reduced recurrent hospitalizations due to cardiac decompensation have not materially impacted these MACE outcomes.

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About the DREAM HF Phase 3 Trial

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Rexlemestrocel-L for Cardiovascular Diseases

Heart Failure Phase 3 Trial Top Line Results

January 2021

ASX: MSB; Nasdaq: MESO

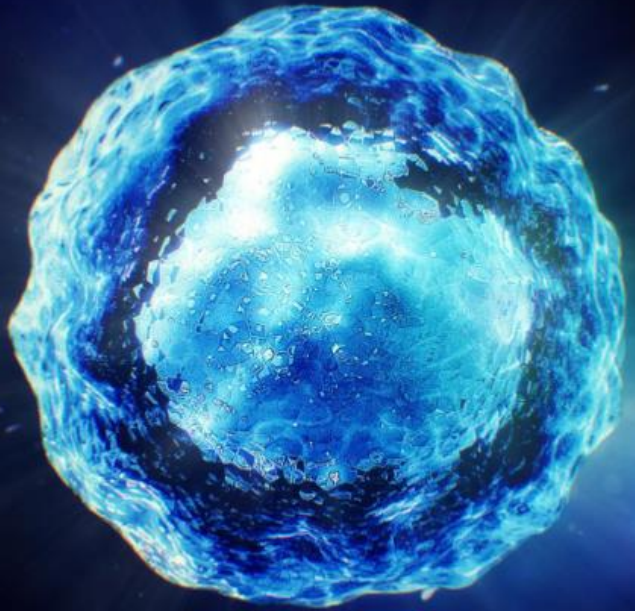


CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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Our Mission

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



Product Pipeline



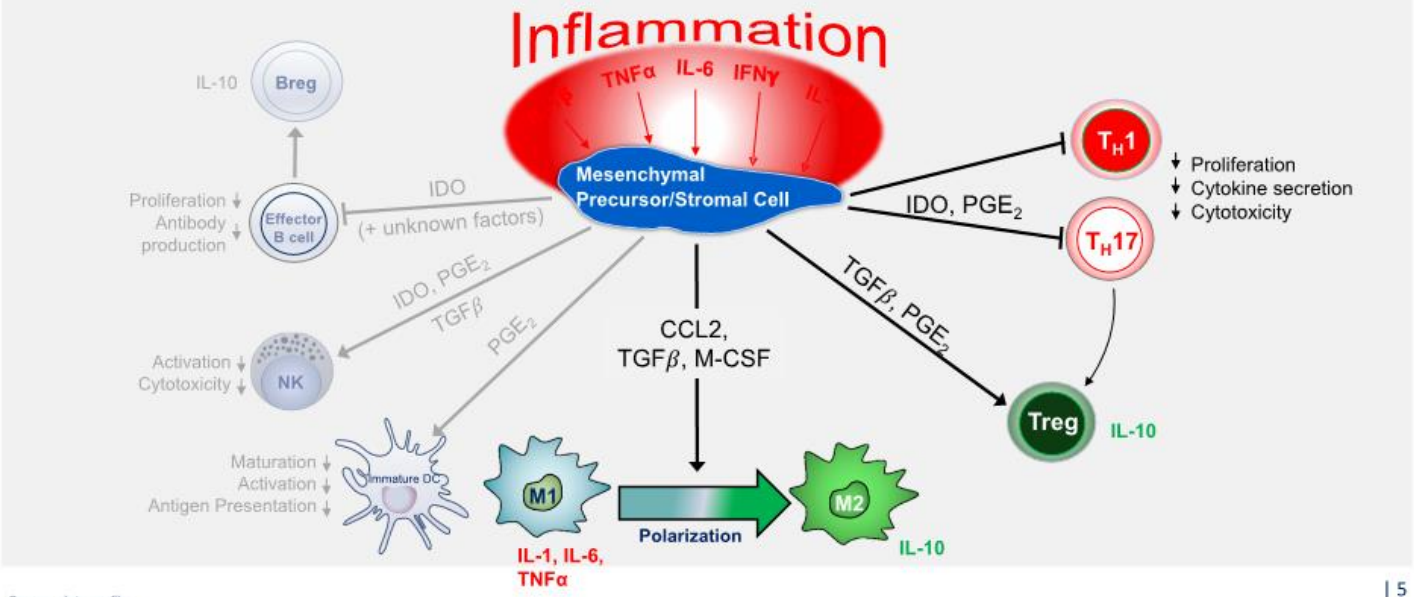
This chart is figurative and does not purport to show individual trial progress within a clinical program.

* Mesoblast has the right to use data generated by JCR Pharmaceuticals Co Ltd in Japan to support its development and commercialization plans for remestemcel-L in the US and other major healthcare markets, including for GVHD, Hypoxic Ischemic Encephalopathy and Epidermolysis Bullosa

[#] The closing of the license agreement is subject to the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act and certain other conditions

Platform Technology – Mechanism of Action

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



Source: data on file

Global IP Estate Provides Substantial Competitive Advantage

- Extensive patent portfolio with protection extending through 2040 in all major markets
- 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
- When outside our core commercial areas, may consider granting rights to third parties who require access to our patent portfolio to commercialize their products
- Mesoblast receives royalty income from its patent licensee 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 adult patients with Crohn's disease, as well as milestone payments



Alofisel® is a registered trademark of TiGenix, S.A.U.

Commercial Scale Manufacturing Capability

- 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
- Projected increase in capacity requirements for maturing pipeline
 - Proprietary xeno-free technologies will increase yields and output
 - Moving to 3D bioreactors will reduce labor and improve manufacturing efficiencies
 - These innovations will significantly reduce cost of goods

Manufacturing Remestemcel-L



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Overview of Collaboration with Novartis for Remestemcel-L



- Worldwide license and collaboration agreement with Novartis for the development, manufacture and commercialization of remestemcel-L*
- Initial focus is on the treatment of acute respiratory distress syndrome (ARDS) and other respiratory conditions
- Novartis intends to initiate a Phase 3 study in non-COVID-19-related ARDS after the anticipated closing of the license agreement and outcome of the current COVID-19 ARDS study
- Mesoblast will retain full rights and economics for remestemcel-L for graft versus host disease (GVHD), and Novartis has an option to, if exercised, become the commercial distributor outside of Japan
- For most non-respiratory indications, the parties may co-fund development and commercialization on a 50:50 profit-share basis

* The closing of the license agreement is subject to the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act and certain other conditions

SR-aGVHD Regulatory & Commercial Update



- On August 13 2020, results from 309 children with steroid refractory acute graft versus host disease (SR-aGVHD) treated with remestemcel-L were presented to the Oncologic Drugs Advisory Committee (ODAC) of the United States Food and Drug Administration (FDA)
- The ODAC panel voted 9:1 that the available data support the efficacy of remestemcel-L in pediatric patients with SR-aGVHD*
- Despite the overwhelming ODAC vote, on September 30, the FDA provided Mesoblast with a Complete Response Letter
- Mesoblast intends to meet with the FDA during Q1 CY2021 through a well-established process for continuing discussions on the potential for accelerated approval with a post-approval commitment to conduct an additional randomized controlled study

* This vote includes a change to the original vote by one of the ODAC panel members after electronic voting closed

MPC-06-ID for Chronic Low Back Pain



- Phase 3 trial of MPC-06-ID for chronic low back pain in 404 patients:
 - Final study visits for all patients have been completed
 - Ongoing quality review of all data is being completed at the study sites
 - Data readout expected shortly

- Continued operational progress in strategic partnership for chronic lower back pain with Grünenthal in Europe to complete clinical protocol design, obtain regulatory input, and receive clearance from European regulatory authorities to begin European Phase 3 trial

- Results from the Phase 3 trials will be considered pivotal to support regulatory approval in the US, as well as in Europe



DREAM HF

- **Phase 3 Trial in Chronic Heart Failure**
- **Rexlemestrocel-L Mechanism of Action**

ASX
gtr Health

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)

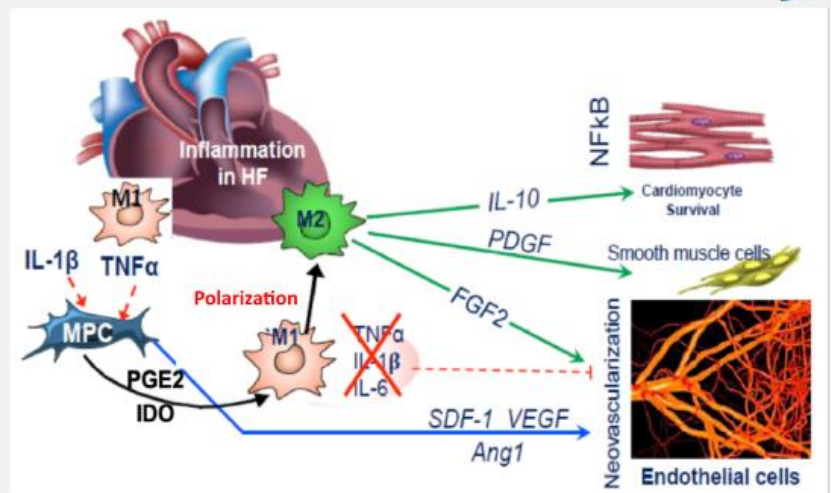
1. Muntner BEJ, et al. Heart Disease and Stroke Statistics-2019 Update: A Report From the American Heart Association. *Circulation*. Feb 19, 2019. 2. United States Food & Drug Administration. Treatment for Heart Failure: Endpoints for Drug Development. Draft Guidance. June 2019. 3. Taylor CJ, et al. 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.

- Each year in the United States approx. 805,000 people suffer from a myocardial infarction (heart attack) and approx. 795,000 people experience a new or recurrent stroke¹
- A major consequence of a heart attack is chronic heart failure, and patients with chronic heart failure are at higher risk of recurrent heart attacks and strokes²
- Atherosclerosis is a chronic inflammatory condition associated with endothelial dysfunction³
- Cardiovascular complications associated with atherosclerosis in chronic heart failure patients may respond to potent anti-inflammatory therapeutic approaches

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

Mesenchymal precursor cells (MPC) key mechanisms of action thought to beneficially impact the heart and the systemic vasculature:

- Reduction in cardiac and systemic inflammation
- Reversal of endothelial dysfunction
- Induction of microvascular network within viable heart muscle
- Reduction in heart muscle death

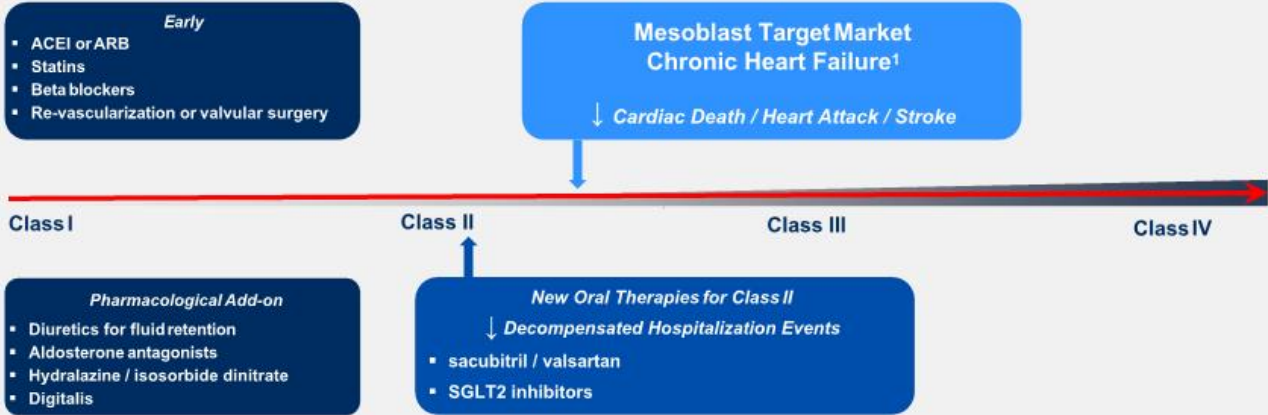


Borow KM, Yaroshinsky A, Greenberg B, Perin E. Phase 3 DREAM-HF Trial of Mesenchymal Precursor Cells in Chronic Heart Failure: A Review of Biological Plausibility and Implementation of Flexible Clinical Trial Design. *Circ Res.* 2019;125:265-281



Treatment Algorithm in Progressive Heart Failure

Progressive Vascular (Endothelial) Dysfunction and Heart Failure



1. GlobalData-PharmaPoint Heart Failure (2016); McMurray et al., 2012; Yancy et al., 2013, 2016 ACC/AHA/HFSA Focused Update on New Pharmacological Therapy for Heart Failure: An Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure.



DREAM HF

- **Phase 3 Trial in Chronic Heart Failure**
- **Rexlemestrocel-L vs Sham Clinical Outcomes**

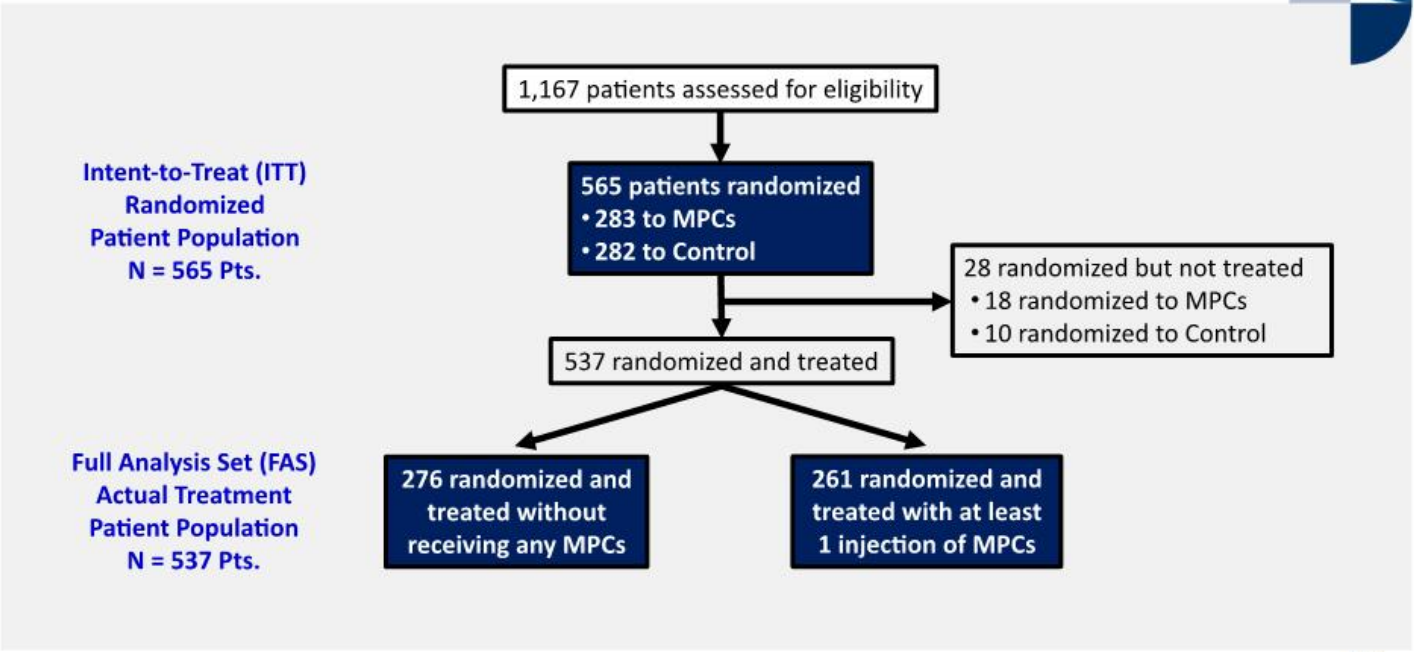
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DREAM HF: Overview of Phase 3 Trial



- Mesoblast's allogeneic cell therapy rexlemestrocel-L has a dual mechanism of action that involves immunomodulation and improvement in blood vessel integrity/function
- DREAM-HF Phase 3 trial was designed to evaluate whether rexlemestrocel-L could improve morbidity and mortality in advanced chronic heart failure patients
- Trial design: 1:1 randomized, controlled, double blinded; conducted over 55 sites across North America using 150 million cell dose vs control in 565 patients
- Primary endpoint: reduction in recurrent heart failure-related hospitalizations
- Additional pre-specified key clinical endpoints:
 - Reduction in ischemic cardiovascular events (heart attack / stroke)
 - Reduction in recurrent hospitalizations due to ischemic events (heart attack / stroke)
 - Reduction in death due to cardiac causes
 - Major Adverse Cardiac Events (MACE: heart attack, stroke or cardiac death)

DREAM HF: Patient Flow



DREAM HF: Baseline FAS Summary Data by NYHA CLASS II or III



Parameter	Units	TOTAL (n=537)		NYHA II		NYHA III	
NYHA Functional Class	Number, %			206	38.4%	331	61.6%
II	Number, %	206	38.4%				
III	Number, %	331	61.6%				
Age (537 unique subjects)	Yrs (mean)	62.7	64.0	62.2	63.0	63.1	65.0
Sex (537 unique subjects)*							
Males	Number, %	428	79.7%	168	81.6%	260	78.5%
Females	Number, %	109	20.3%	38	18.4%	71	21.5%
Race (537 unique subjects)							
White	Number, %	414	77.1%	166	80.6%	248	74.9%
Black	Number, %	99	18.4%	34	16.5%	65	19.6%
Asian	Number, %	7	1.3%	2	1.0%	5	1.5%
Other	Number, %	17	3.2%	4	1.9%	13	3.9%
Ethnic Group (537 unique subjects)							
Hispanic	Number, %	34	6.3%	11	5.3%	23	6.9%
Blood pressure							
Systolic	mmHg (mean)	117.1	114.0	117.2	116	117	113
Diastolic	mmHg (mean)	70.2	70.0	71.2	71	69.5	68
Heart rate	Beats/min (mean)	72.3	71.0	70.9	70	73.1	71
Body weight	kg (mean, median)	92.8	90.9	91.8	89.2	93.4	92.5



DREAM HF: Baseline FAS Summary Data by NYHA CLASS II or III



Parameter	Units	TOTAL (n=537)		NYHA II		NYHA III	
Non-Ischemic vs Ischemic Cardiomyopathy (per baseline CRF)							
Ischemic	Number, %	303	56.4%	111	53.9%	192	58.0%
Non-ischemic	Number, %	234	43.6%	95	46.1%	139	42.0%
Past Myocardial infarction	Number, %	280	52.1%	106	51.5%	174	52.6%
Coronary revascularization							
Previous PCI and/or CABG (unique subjects)	Number, %	307	57.2%	119	57.8%	188	56.8%
Echocardiographic Imaging (530 unique subjects)							
Left ventricular ejection fraction	% (mean, median)	28.6	28.6	28.6	29.0	28.6	28.5
Left ventricular end-systolic volume	mL (mean, median)	149.8	135.9	155.4	137.4	146.2	135.0
<= 100	number, %	101	18.8%	41	19.9%	60	18.1%
> 100	number, %	429	79.9%	163	79.1%	266	80.4%
missing	number, %	7	1.3%	2	1.0%	5	1.5%
Left ventricular end-diastolic volume	mL (mean, median)	206.5	194.0	213.1	193.7	202.3	194.3
6MWT distance (537 unique subjects)	m (mean, median)	331.5	340.5	356.8	367	311.7	329.2
Biomarkers							
NT-proBNP	pg/mL (mean, median)	2166	1400	1809	1322	2390	1458
hsCRP	mg/L (mean, median)	5.3	2.5	3.6	2	6.4	3.3
AICD without CRT	Number, %	245	84.0%	99	81.6%	146	85.5%
CRT-D	Number, %	206		69		137	
Laboratory measurements							
Sodium	mequiv/L (mean)	139.5	140.0	139.5	140.0	139.6	140.0
Potassium	mequiv/L (mean)	4.5	4.5	4.5	4.5	4.5	4.5
Creatinine	mg/dL (mean)	1.2	1.1	1.1	1.1	1.3	1.2
BUN	mg/dL (mean)	24.2	21.0	22.7	20.5	25.2	22.0
HbA1c	% (mean)	6.4	6.1	6.3	6.0	6.4	6.2
Hemoglobin	g/dL (mean)	13.6	13.7	13.8	13.9	13.5	13.5
Hematocrit	% (mean)	41.8	41.8	42.3	42.4	41.5	41.1





DREAM HF

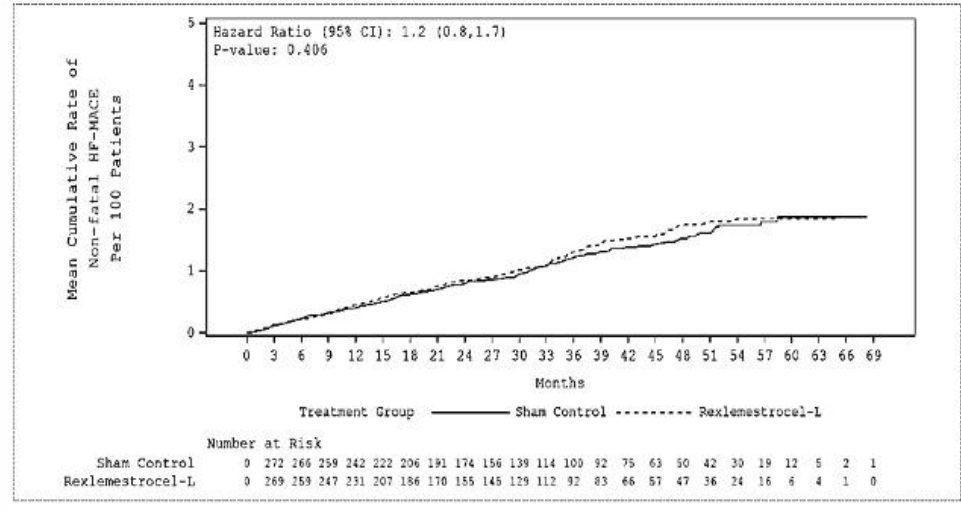
- Recurrent Decompensated Heart Failure Hospitalization Events
- Non-Fatal Ischemic MACE (Heart attacks or Strokes)

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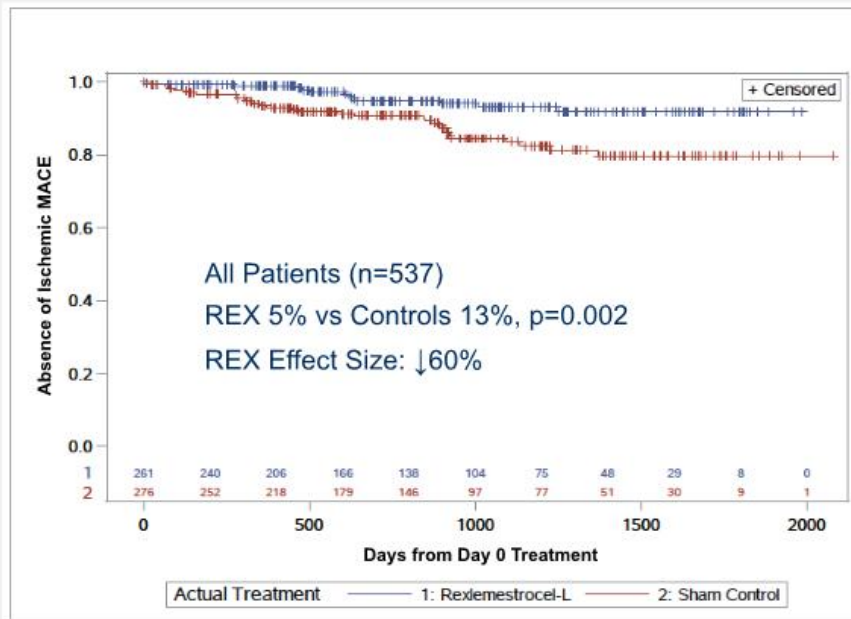
Rexlemestrocel-L Did Not Reduce Non-Fatal Heart Failure MACE (Recurrent Decompensated Heart Failure Events or High-Grade Arrhythmias)



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



Rexlemestrocel-L Significantly Reduced Incidence of Ischemic MACE (MI, Stroke) by 60% Relative to Controls (n=537 Patients)



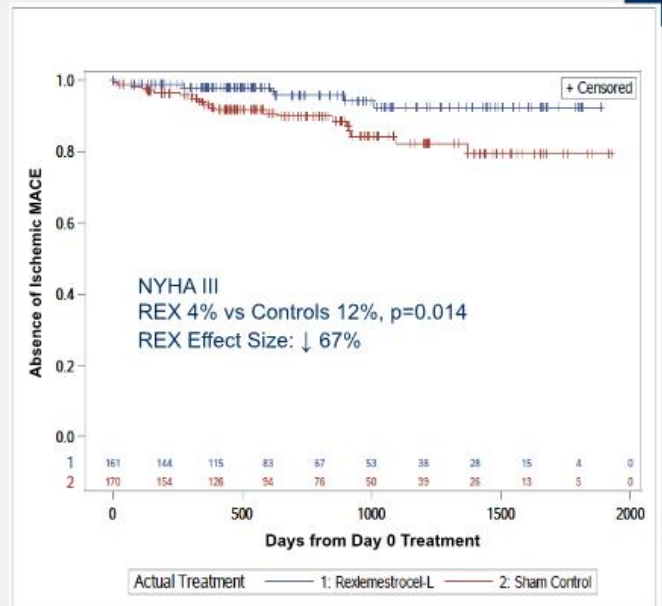
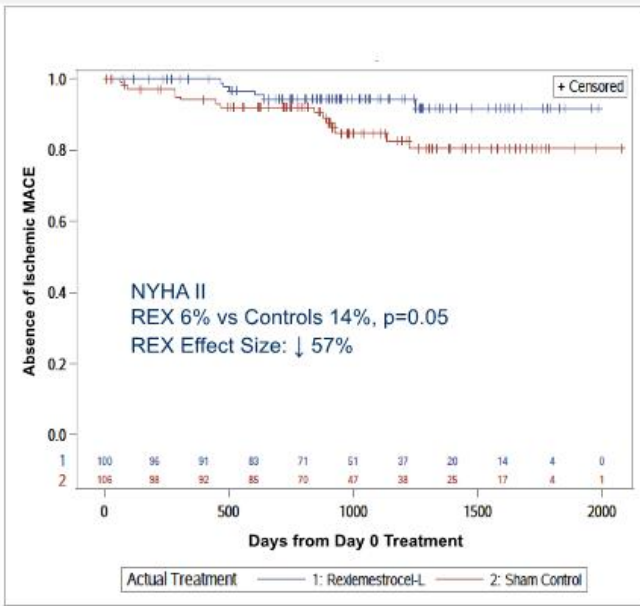
Elevated Baseline CRP Levels Predict REXlemestrocel-L Benefit on Incident Heart Attacks or Strokes ... Consistent with Anti-Inflammatory MOA



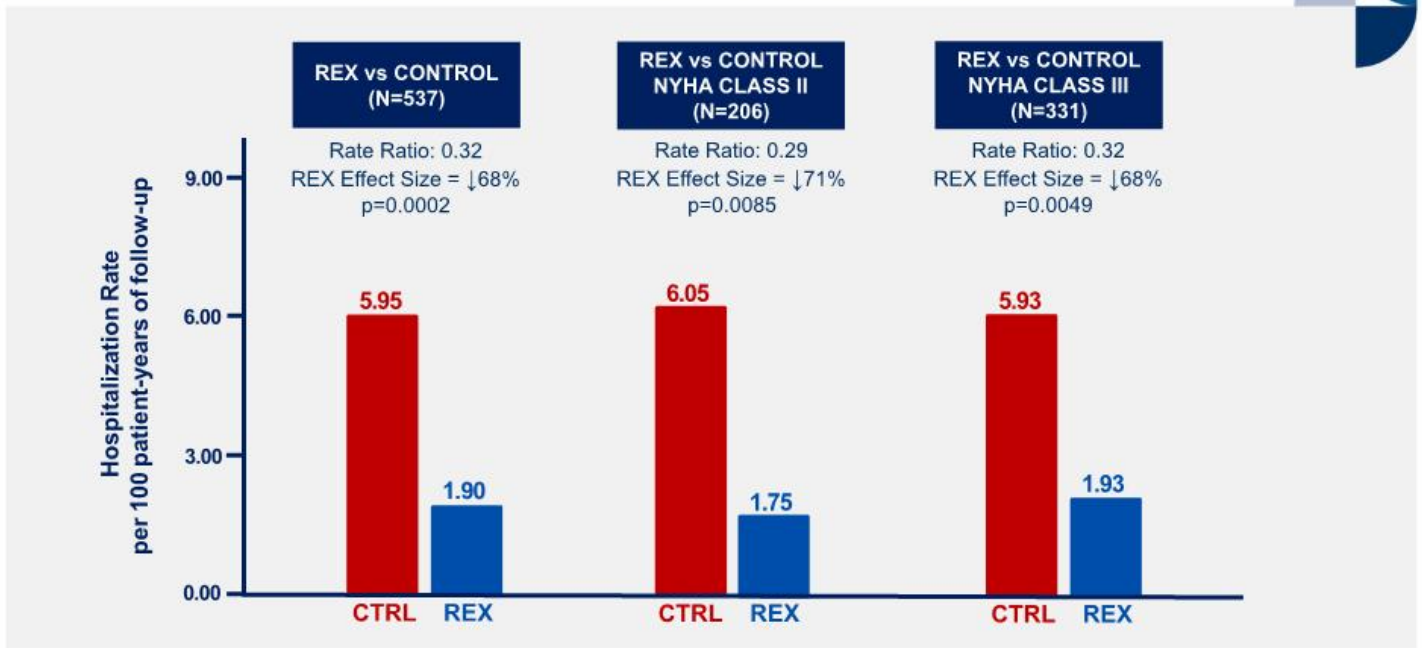
Myocardial Infarction or Cerebrovascular Accident

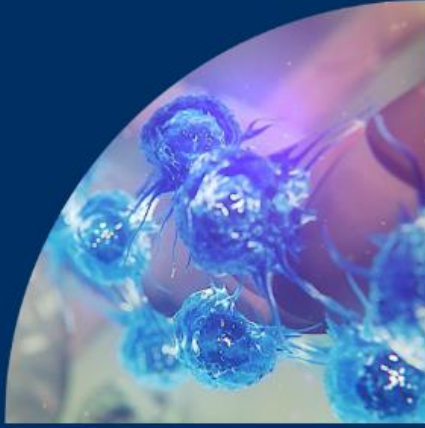
TTFE ANALYSIS	
REX Effect Compared with Controls	↓ 60%
P-value	0.002
COVARIATES	
Ischemic	P = 0.0098
Non-ischemic	P = 0.0995
hsCRP \geq 2	P = 0.0045
hsCRP \geq 3	P = 0.0065
hsCRP \geq 4	P = 0.0430

Rexlemestrocel-L Significantly Reduced Incidence of Ischemic MACE (MI, Stroke) by 57% & 67% Relative to Controls In NYHA Class II & III, respectively



Rexlemestrocel-L Significantly Reduced Hospitalization Rates from Non-Fatal MI or Stroke in All Patients, with Similar Effect Size in NYHA Class II and Class III Patients





DREAM HF

- Death From Cardiac Causes (CV Death)

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High Baseline CRP and NT-proBNP are Significant Predictors of Rexamestrocel-L Treatment Benefit on Cardiac Death

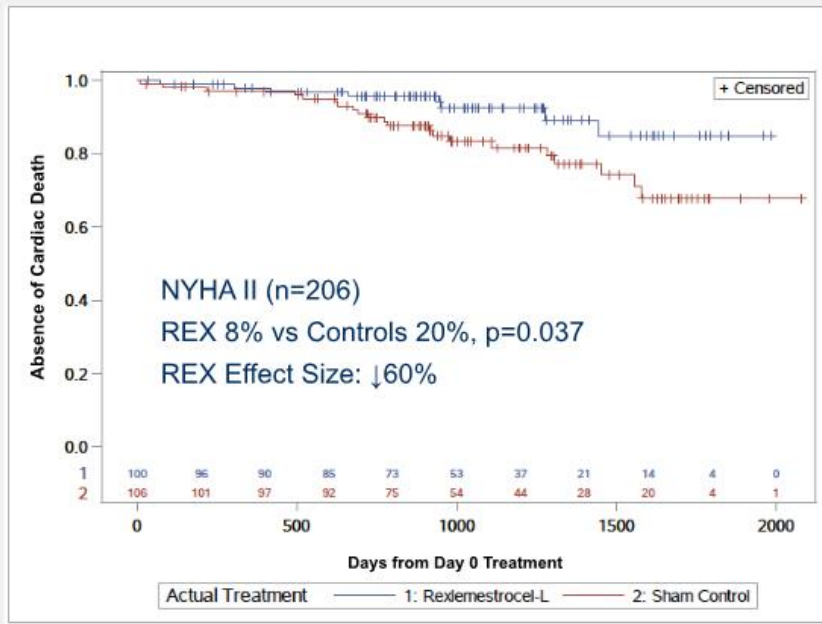


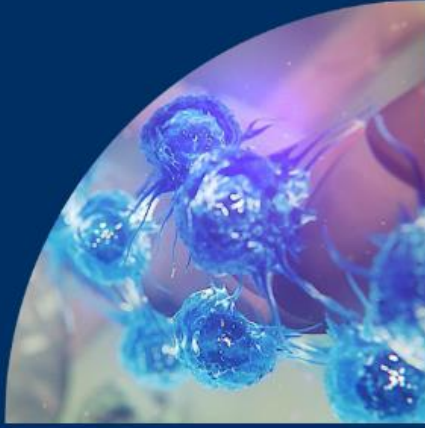
Cardiac Death

	ALL	Class II	Class III
COVARIATES*			
NYHA Class II	P = 0.0430		
NYHA Class III	P = 0.4630		
hsCRP \geq 2	P = 0.1634	P = 0.0062	
hsCRP \geq 3		P = 0.0122	
hsCRP \geq 4		P = 0.0273	
NT-proBNP		P = 0.0139	

* Multi-variate regression analysis using COX proportional hazards

Rexlemestrocel-L Reduced Cardiac Death by 60% in NYHA Class II Patients



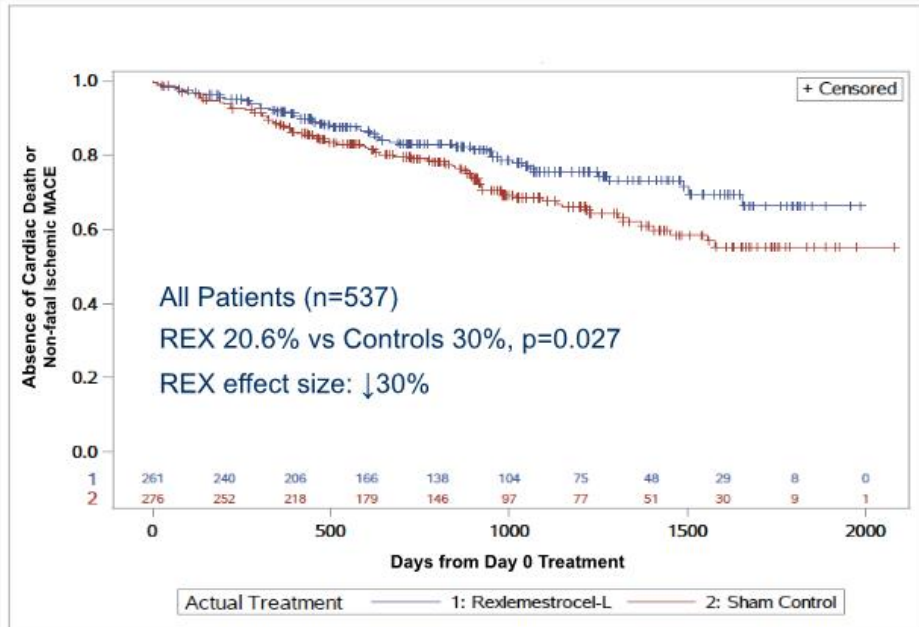


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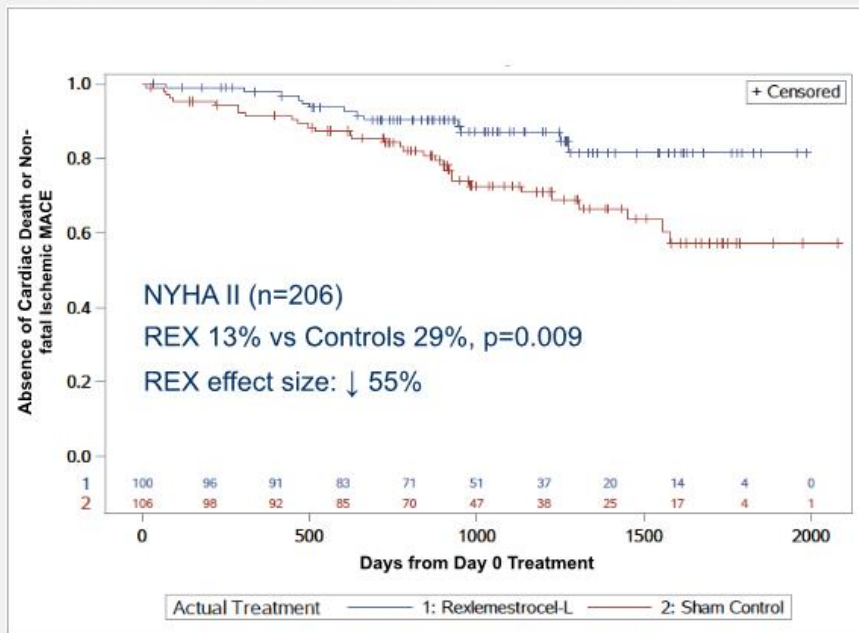
- Three-Point MACE (CV Death, MI or Stroke)

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



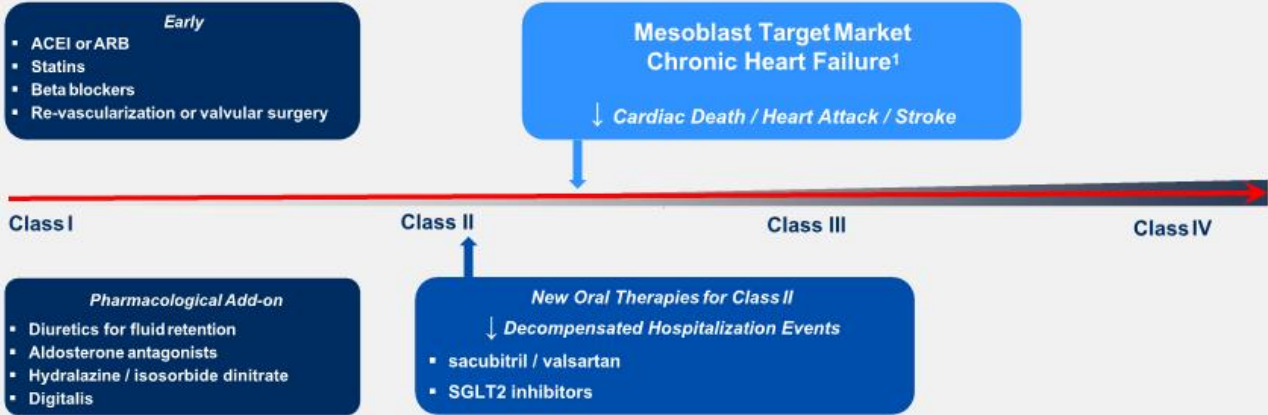
Rexlemestrocel-L Significantly Reduced 3-Point Composite MACE (CV Death, MI or Stroke) in 206 NYHA Class II Patients





Treatment Algorithm in Progressive Heart Failure

Progressive Vascular (Endothelial) Dysfunction and Heart Failure



1. GlobalData-PharmaPoint Heart Failure (2016); McMurray et al., 2012; Yancy et al., 2013, 2016 ACC/AHA/HFSA Focused Update on New Pharmacological Therapy for Heart Failure: An Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure.

Rexlemestrocel-L Phase 3 Trial Conclusions



- Rexlemestrocel-L may provide a major breakthrough in reducing heart failure progression and mortality when used early (class II disease), and may provide durable protection from heart attacks or strokes in high-risk patients
 - 60% reduction in incidence of ischemic MACE (heart attack or stroke) across entire 537 patient study population, irrespective of NYHA class II or III, ischemic or non-ischemic etiology (p=0.002)
 - 30% reduction in incidence of three-point MACE (cardiac death, heart attack or stroke) across entire 537 patient study population (p=0.027)
 - 55% reduction in incidence of three-point MACE (cardiac death, heart attack or stroke) in NYHA class II patients (n=206) (p=0.009)
 - 60% reduction in cardiac death in NYHA class II patients (p=0.037) and prevention of progression to NYHA class III rate of cardiac death
- Based on observed reduction in mortality and morbidity in this Phase 3 trial, Mesoblast intends to meet with the United States Food and Drug Administration (FDA) to discuss potential approval pathways



 mesoblast



