mesoblast

the regenerative medicine company

Operational Highlights and Financial Results for the Nine Months and Quarter Ended March 31, 2019

May 2019

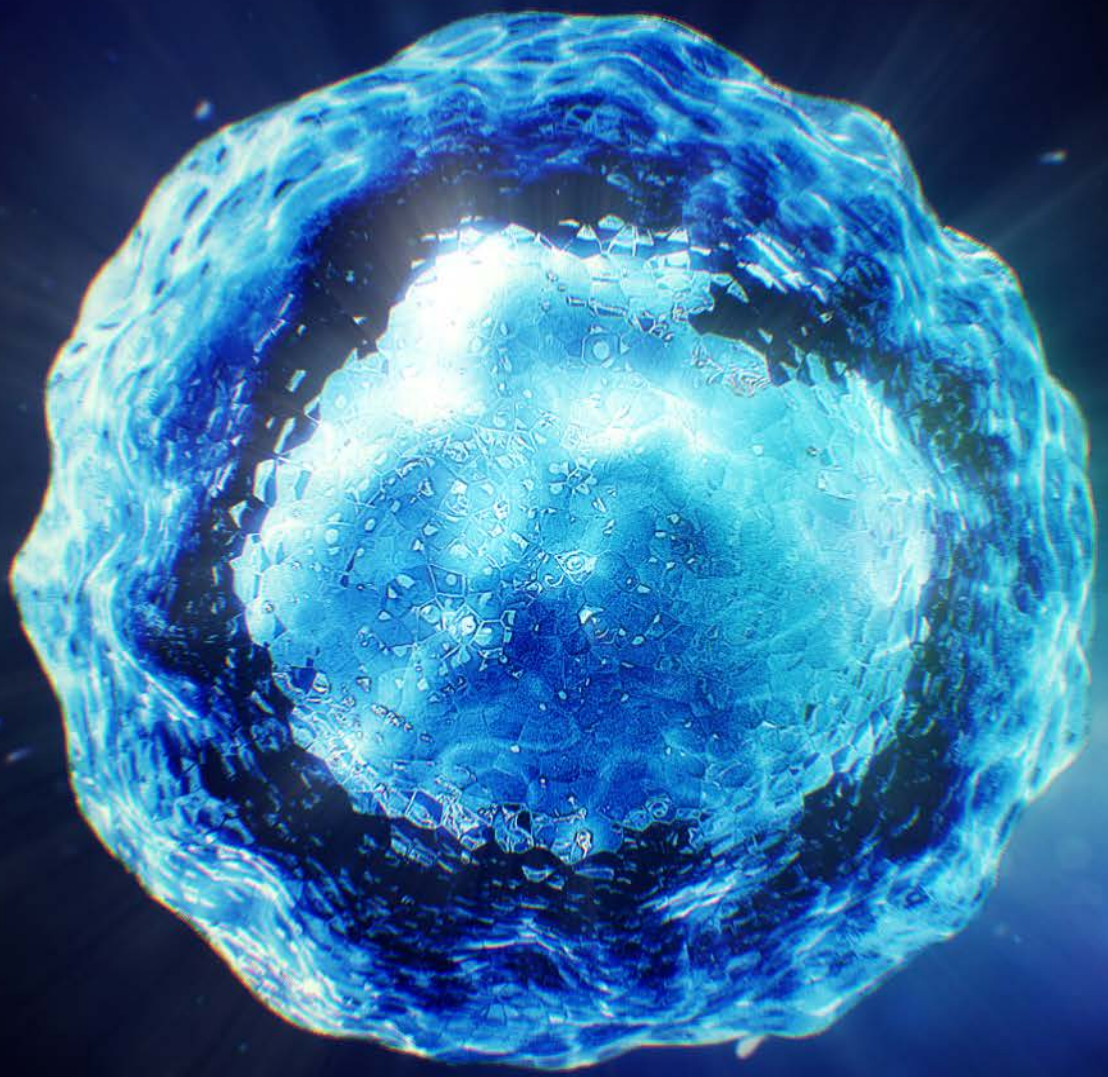
Nasdaq: MESO ASX: MSB

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 bring to market innovative cellular medicines to treat serious and life-threatening illnesses



Premier Global Cellular Medicines Company

Innovative Technology Platform[1]	Late Stage Pipeline	Commercialization
▪ Innovative technology targets the most severe disease states refractory to conventional therapies ▪ Well characterized multimodal mechanisms of action ▪ Underpinned by extensive, global IP estate	▪ Upcoming BLA submission for steroid-refractory acute GVHD ▪ 2 blockbuster product candidates completed Phase 3 trial enrollment - heart failure and back pain ▪ China cardiovascular partnership established	▪ Building focused US sales force for acute GVHD product launch ▪ Industrial-scale manufacturing to meet commercial demand ▪ First approved products commercialized by licensees in Japan[2] and Europe[3] ▪ Increasing revenues and milestone payments

1. Mesenchymal precursor cells (MPCs) and their culture-expanded progeny mesenchymal stem cells (MSCs).
2. Licensee JCR Pharmaceuticals Co., Ltd. received the first full PMDA approval for an allogeneic cellular medicine in Japan and markets this product under its trademark, TEMCELL® Hs Inj.
3. Licensee Takeda Pharmaceuticals Co Ltd received first central marketing authorization approval from the European Commission for an allogeneic stem cell therapy and markets this product under its trademark, Alofisel®.

Recent Corporate Highlights

Remestemcel-L for Steroid-Refractory Acute Graft Versus Host Disease

- FDA has agreed to a rolling Biologics Licence Application (BLA) review of remestemcel-L for the treatment of steroid-refractory acute Graft Versus Host Disease (aGVHD) in children.
- Initiated the BLA rolling submission, with filing of the first module. The rolling process will provide opportunity for ongoing communication, and during this process the Company expects it will be able to adequately address any substantial matters raised by the FDA.

Revascor for Advanced and End-Stage Heart Failure

- Mesoblast and the International Center for Health Outcomes and Innovation Research at the Icahn School of Medicine at Mount Sinai entered into a Memorandum of Understanding to conduct a confirmatory clinical trial using Revascor for reduction of gastrointestinal (GI) bleeding in end-stage heart failure patients implanted with a left ventricular assist device (LVAD).
- Phase 3 trial in advanced heart failure has completed patient enrollment, with 566 patients randomized to receive Revascor or placebo. The study, conducted across 55 centers in North America, will complete when sufficient primary endpoint events have accrued.

Recent Corporate Highlights (continued)

MPC-06-ID for Chronic Lower Back Pain

- Phase 3 trial in chronic low back pain has completed enrollment with 404 patients randomized to receive MPC-06-ID or placebo. All assessable patients have now completed at least 12-months of safety and efficacy follow-up.

Partnerships and License Arrangements

- Mesoblast extended its license with JCR Pharmaceuticals Co., Ltd. (JCR) in Japan for use of TEMCELL®[1] HS Inj. in patients with Epidermolysis Bullosa. JCR has now filed to extend marketing approval for this indication.

Board of Directors – Welcomes New Leadership

- The Board appointed Joseph R. Swedish as Chairman in April 2019. Mr Swedish brings deep healthcare expertise and a track record in healthcare resource allocation and reimbursement metrics, as the Company enters commercial stage.

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

Corporate History

Over a decade of scientific, manufacturing, clinical development and corporate transaction experience targeted at bringing to market, cellular medicines for inflammatory diseases

2004:
Mesoblast is founded in Melbourne, Australia and listed on the ASX

2010:
Entered into strategic alliance to develop and commercialize MPC therapeutics

2011:
Entered into manufacturing partnership with Lonza Group in Singapore for MPC medicines

2013:
Acquired MSC business from Osiris Therapeutics with trailing earn-out and milestone payments on the MSC business

2014:
Granted manufacturing pioneer status by Economic Development Board of Singapore

2015:
Dual listed on the Nasdaq

2016:
TEMCELL® HS Inj (MSC medicine) launched in Japan by Mesoblast licensee JCR

2017:
Entered licensing agreement with Takeda for the treatment of certain fistulae; Alofisel® approved in EU

2018:
Entered into partnership agreement with Tasly for cardiovascular assets in China

2019:
Smith & Nephew acquires Osiris Therapeutics including rights to the trailing earn-out and milestone payments on the MSC business

2019:
Initiates first Biologics License Application (BLA) submission to US FDA: remestemcel-L (MSC) for steroid refractory acute graft versus host disease

Partnerships and License Agreements

- JCR has rights to use our MSC technology to treat SR acute GVHD in Japan
- Its product, TEMCELL® HS Inj.[1], was the first fully approved allogeneic cellular medicine in Japan
- Royalties and milestones received in last twelve months exceed US$5 million
- License expanded in Oct 2018 to cover use in treatment of epidermolysis bullosa – a highly debilitating and sometimes lethal skin disease

- Patent license agreement entered in Dec 2017 with Takeda (formerly TiGenix NV) providing exclusive access to certain IP for local treatment of perianal fistulae
- Mesoblast is eligible to receive up to €20 million in milestone payments plus royalties upon commercial sales of Alofisel® worldwide

- Exclusive cardiovascular rights in China
- Mesoblast received US$40 million on closing, eligible to receive additional milestones and royalties

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

Commercial and Late-Stage Product Pipeline

MARKETED

PLATFORM	PRODUCT	THERAPEUTIC AREA		APPROVAL	COMMERCIAL RIGHTS
MSC (Bone Marrow)	TEMCELL® HS Inj[1]	Acute Graft Versus Host Disease	1st allogeneic regen med approved in Japan	✓	JCR Japan
MSC (Adipose)	Alofisel®[2]	Perianal Fistula	1st allogeneic regen med approved in Europe	✓	Takeda Global

IN DEVELOPMENT

PLATFORM	PRODUCT CANDIDATE	THERAPEUTIC AREA	PRE-CLINICAL / PHASE 2 / PHASE 3	COMMERCIAL RIGHTS
MSC suite	Remestemcel-L	Acute Graft Versus Host Disease		mesoblast
	Remestemcel-L	Crohn's Disease		
	Remestemcel-L	Osteoarthritis/Cartilage Repair		
MPC suite	Revascor	Advanced HF (Class II/III) End-Stage HF (Class III/IV)[3]		TASLY China
	MPC-06-ID	Chronic Low Back Pain		mesoblast
	MPC-300-IV	Rheumatoid Arthritis Diabetic Nephropathy		

1 Mesoblast receives royalty income from its licensee JCR Pharmaceuticals Co Ltd on sales of JCR's TEMCELL® Hs. Inj. product in Japan.
2 Mesoblast will receive royalty income from its licensee Takeda Pharmaceuticals on Takeda's worldwide sales of its product Alofisel® in the local treatment of perianal fistulae.
3 Study funded by the United States National Institutes of Health (NIH) and the Canadian Health Research Institute; conducted by the NIH-funded Cardiothoracic Surgical Trials Network.

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


Dublin
Zurich
San Francisco
New York
Hong Kong
Melbourne
ASX
Nasdaq

Financials

Cash Reserves of US$70.4 million

Significant reduction in operating net cash outflows for the nine months

For the nine months ending (US$m)	March 31, 2019	March 31, 2018
Operating net cash outflows	**(38.7)**	**(54.8)**
Investing net cash outflows	(0.2)	(0.7)
Financing net cash inflows	71.6	69.6
Net increase in cash	32.7	14.1

- Cash reserves of US$70.4 million as at March 31, 2019
- An additional US$35.0 million may be available under existing arrangements with Hercules Capital and NovaQuest, subject to achievement of certain milestones
- 29% (US$16.1 million) reduction in net operating cash outflows for the nine months ended March 31, 2019, primarily due to the timing of receipts of milestone payments

Revenues – Continued Growth in Royalties and Substantial Milestone Revenues from Corporate Transactions

For the nine months ending (US$m)	March 31, 2019	March 31, 2018
Milestone revenue	11.0	12.8
Commercialization revenue	3.3	2.5
Interest revenue	0.5	0.3
Total revenue	**14.8**	**15.6**

- 28% growth in commercialization revenue from royalty income on sales of TEMCELL® HS. Inj.[1]
- Corporate transactions drive milestone revenues
  - US$10.0 million of milestone revenue from licensee Tasly Pharmaceutical Group in FY2019
  - US$11.8 million of milestone revenue from licensee Takeda Pharmaceuticals in FY2018
  - Both periods include US$1.0 million of milestone revenue from JCR Pharmaceuticals

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

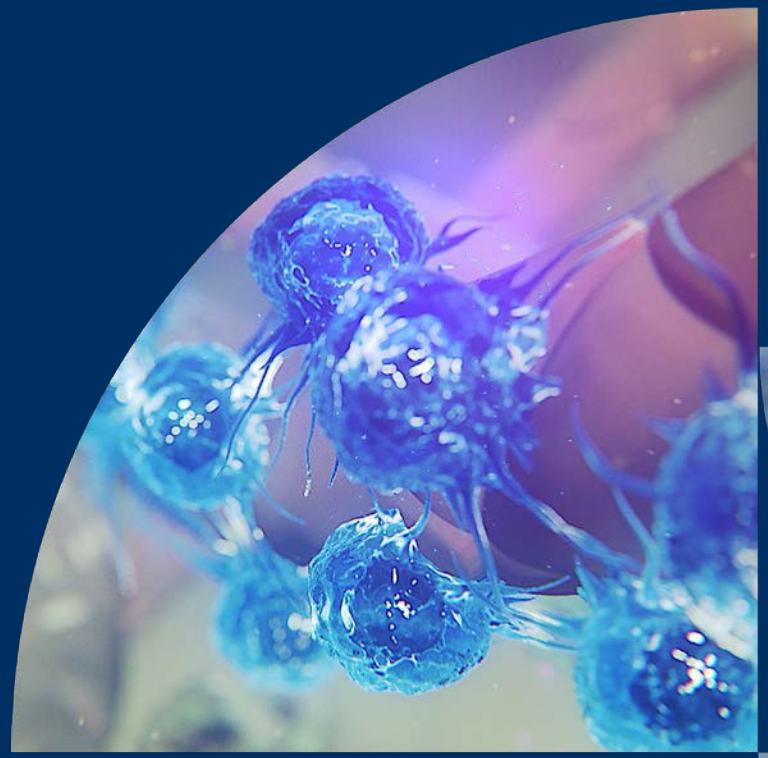
Increased Loss due to Investment in Manufacturing and Financing, and Non-cash Gains in Comparable Period from Revaluation of Tax and Contingent Consideration

Profit and Loss for the nine months ending (US$m)	March 31, 2019	March 31, 2018
Total Revenue	14.8	15.6
Research and development	(48.4)	(48.4)
Manufacturing	(12.9)	(3.4)
Management & administration	(16.0)	(16.7)
Contingent consideration	(3.4)	7.9
Other operating income & expenses	(1.0)	1.2
Finance costs	(7.9)	(0.4)
(Loss)/Profit before tax	(74.9)	(44.1)
Income tax benefit	5.8	29.7
(Loss)/Profit after tax	(69.1)	(14.5)

Increase in loss primarily due to the following items:

- in the current period:
  - o US$9.5 million increase in commercial manufacturing reflects investment to support potential launch for aGVHD product
  - o US$7.5 million of increased finance costs on non-dilutive capital inflows from Hercules and NovaQuest

- and in the comparative period:
  - o a one-off non-cash income tax benefit of US$23.0 million due to a revaluation of tax liabilities given changes in tax rates
  - o non-cash US$7.9 million gain on contingent consideration for reduction of future payments to third parties



Operational Highlights

Acute Graft Versus Host Disease (aGVHD)

Significant market opportunity for remestemcel-L

Burden of Illness

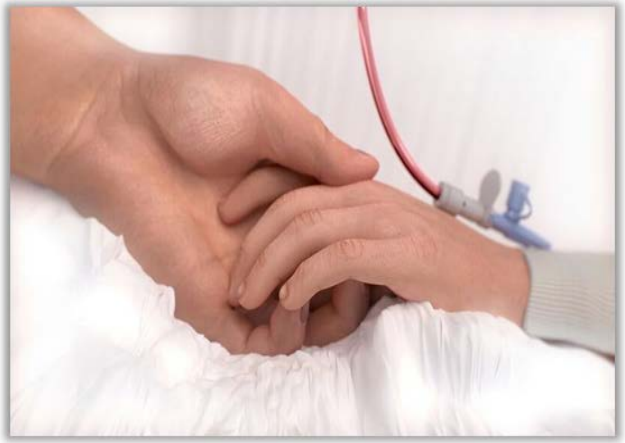
- aGVHD is a life-threatening complication that occurs in ~50% of patients receiving allogeneic bone marrow transplants (BMT)[1]
- Steroid-refractory aGVHD is associated with **mortality rates as high as 90%[1,7] and significant extended hospital stay costs[2]**

Minimal Treatment Options

- There is only one approved treatment for SR-GVHD, and **no approved treatment for children under 12 years old, outside Japan**
- In Japan, Mesoblast's licensee has received the only product approval for SR - aGVHD in both children and adults

Market Opportunity

- >30,000 allogeneic BMTs performed annually worldwide (>20K US/EU) ~20% paediatric[3,4]
- Our licensee, JCR Pharmaceuticals Co., Ltd launched TEMCELL® HS Inj.[5] in Japan for SR-aGVHD in 2016; reimbursed up to ~US$195k[6]
- **SR-aGVHD represents US$ > 700m US/EU market opportunity[4,8]**



1. Westin, J., Saliba, RM., Lima, M. (2011) Steroid-refractory acute GVHD: predictors and outcomes. Advances in Hematology. **2**. Anthem-HealthCore/Mesoblast claims analysis (2016). Data on file **3.** 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. **4.** Source: CIBMTR Current Uses and Outcomes of Hematopoietic Cell Transplantation 2017 Summary. Passweg JR, Baldomero, H (2016) Hematopoietic stem cell transplantation in Europe 2014: more than 40,000 transplants annually. **5.** TEMCELL is the registered trademark of JCR Pharmaceuticals Co. Ltd. **6.**Based on a JPY = USD 0.009375 spot exchange rate on market close on November 11, 2016. Amounts are rounded. Source: Bloomberg. 7. 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 transplantion. Bone Marrow Transplantation. 8.Data on file

Remestemcel-L: SR-aGVHD is Associated with Significant Burden of Illness in Children (US)[1]

1. Data on File: HealthCore® Claims Analysis

Remestemcel-L: Results from Providers/Payers Qualitative US Market Research[1]

(n=20)

Reaction to Tested Target Profile[2]

Median Response

0 — 6 — 7

Most Significant Value Drivers for Remestemcel-L

- Day 28 overall response rate (especially grade C/D)
- Day 100 & Day 180 Survival rates
- No increase in infections
- Large clinical data set (n ~300)
- Ability to administer the drug outpatient

Max Rating Product Attributes

"Remestemcel-L is Expected to Become Standard of Care"

- Multiple Respondents[1]

1. ZS Associates June 2018 Qualitative Market Research: MCO Medical Directors n=5, Transplant Center Directors n= 5, Hospital Pharmacy Directors n=5, AMC-based Hem/Oncs / KOLs n=3
2. Data on file.

Remestemcel-L: Overview of US Product Reimbursement

Pricing of Relevant Agents in the Refractory Hematology / Oncology Setting[1,2]

Treatment	Defitelio (defibrotide sodium)	Yescarta (axicabtagene cilloleucel)	Kymriah (tisagenlecleucel)
Indication(s)	▪ Treatment of adult and pediatric patients with hepatic veno-occlusive disease (VOD), with renal or pulmonary dysfunction following hematopoietic stem-cell transplantation (HSCT)	▪ Treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma(DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma	▪ Patients up to 25 years of age with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse ▪ Adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma and DLBCL arising from follicular lymphoma

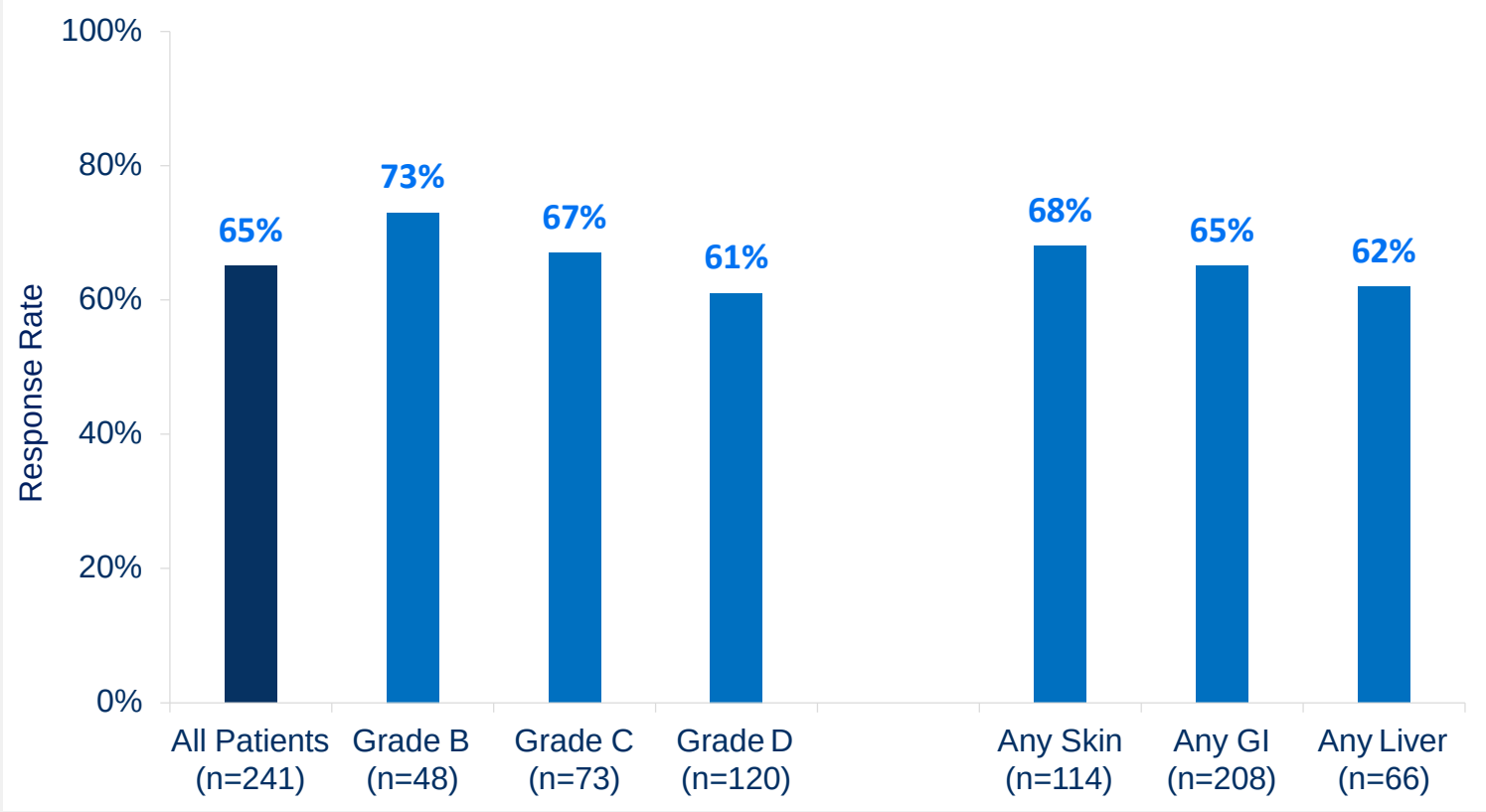
1. Data on File.
2. Redbook May 2019 –Dosing derived from Defitelio package insert with minimum treatment days of 21 and maximum 60 treatment days as defined in label, 75Kg average weight data from CDC.
3. https://www.reuters.com/article/us-gilead-sciences-fda/fda-approves-gilead-cancer-gene-therapy-price-set-at-373000-idUSKBN1CN35H.

Remestemcel-L: Expanded Access Program (Protocol 275)

Overall Day 28 Response in 241 Pediatric aGVHD Patients Receiving Remestemcel-L as First-line or Salvage Therapy After Failing Steroids[1]

Population: steroid-refractory aGVHD pediatric patients

- 241 pediatric patients undergoing HSCT were enrolled and treated at 50 sites in North America and Europe from 2007-2014
- Ages 2 months – 17 years
- Acute GVHD grades B-D (CIBMTR)
- Failed steroid treatment and multiple other agents
- aGVHD not improving after at least 3 days of methylprednisolone (at least 1 mg/kg/day or equivalent)



- Complete Response was 14%, Partial Response was 51%
- Responses were observed for all GVHD grades and did not differ by baseline organ involvement

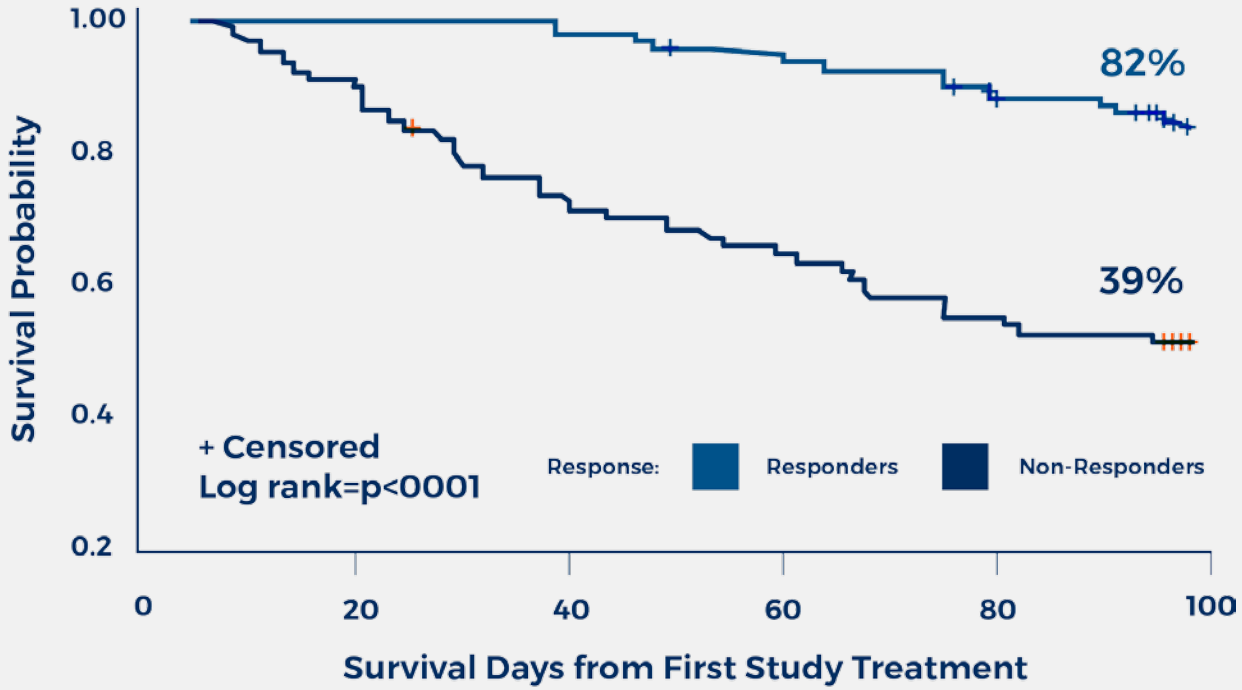
1. Kurtzberg et al: Presentation Tandem Feb 2016

Remestemcel-L: Expanded Access Program

Correlation of Day 28 Overall Response with Day 100 Survival, Using Remestemcel-L as First-line or Salvage Therapy After Failing Steroids and/or Additional Treatments[1]

Remestemcel-L in Children with SR-aGVHD who failed multiple other modalities

- Survival of Pediatric Patients Treated with Remestemcel-L 28-Day Responders vs Non-responders n=241



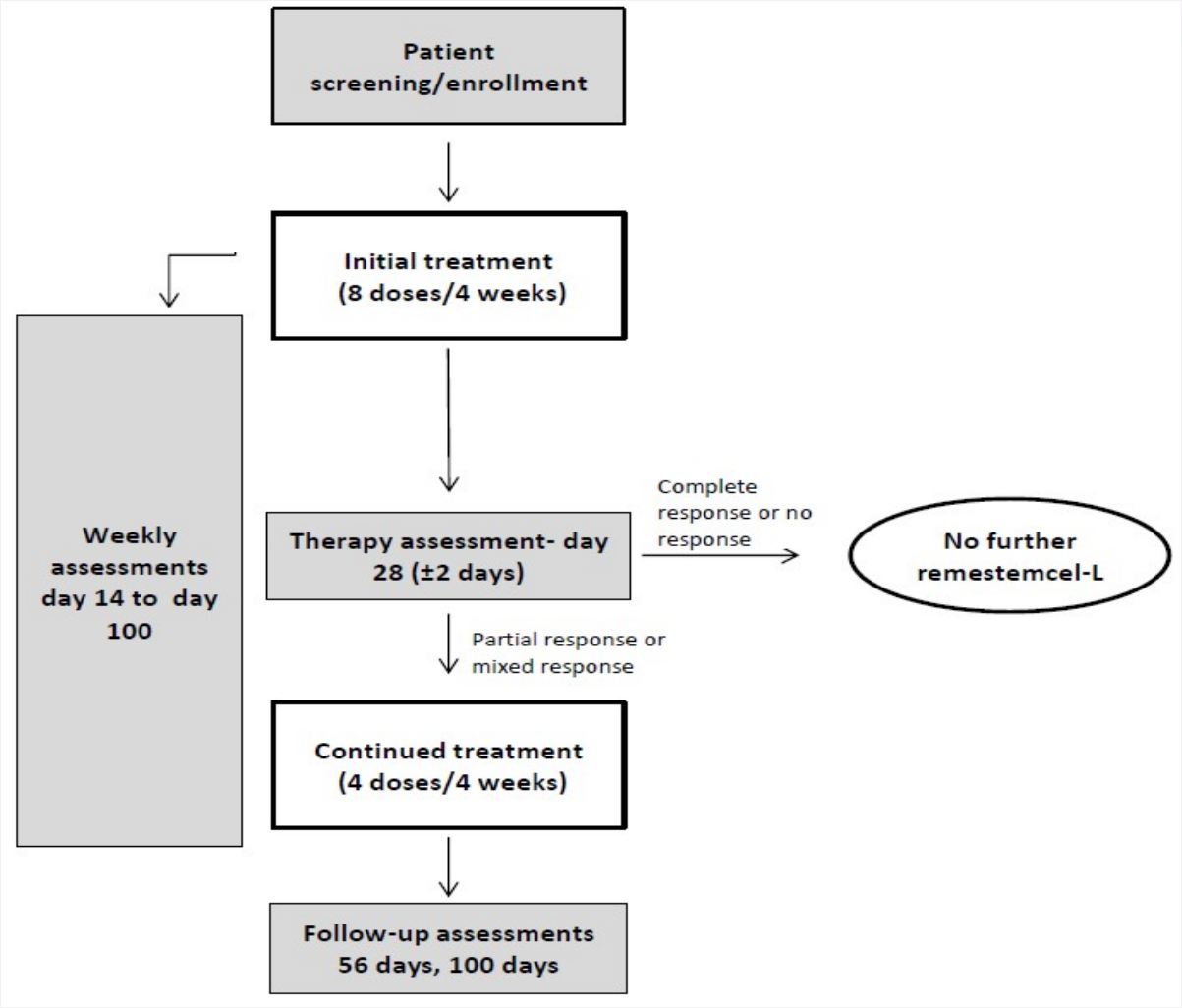
- In 241 Children under EAP, **Overall Response** (CR+PR) at Day 28 was **65%** (95% CI: 58.9%, 70.9%)
- **Day 100 survival** correlated with overall response, and was significantly improved in those who responded at Day 28 **(82% vs. 39%, p<0.0001)**

1. Kurtzberg et al: Presentation Tandem Feb 2016

Remestemcel-L:

Phase 3 Pediatric Trial (GVHD001) - First-line therapy in aGVHD after failing steroids[1]

- Multi-center, single-arm, open-label study to evaluate efficacy and safety to day 100 (GVHD001) and from day 100 to day 180 (GVHD002)
- 55 pediatric patients (2 months to 17 years)
- aGVHD following allogeneic HSCT failing systemic corticosteroid therapy
- Grade B aGVHD involving liver and/or GI tract with or without concomitant skin disease
- Grades C and D aGVHD involving skin, liver and/or GI tract
- Primary endpoint: **Overall response at Day 28**
- Key secondary endpoint: Survival at Day 100



1. Data on file.

Remestemcel-L: Phase 3 Trial

Protocol GVHD001 – Demographics[1]

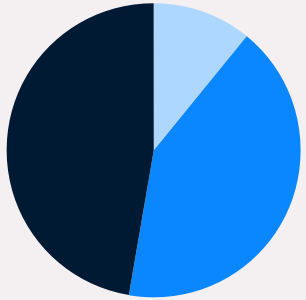
Subjects Enrolled	**55**
Age (years)	
Mean (SD)	**7.8 (5.44)**
Median (minimum, maximum)	**7.6 (0.6, 17.9)**
Gender	
Male	**35 (63.6%)**
Female	**20 (36.4%)**
Underlying Disease	
AML	**18 (32.7%)**
ALL	**12 (21.8%)**
Anemia	**5 (9.1%)**
CML	**4 (7.3%)**
Sickle Cell	**3 (5.5%)**
JML	**2 (3.6%)**
MDS	**2 (3.6%)**
Other	**9 (16.4%)**

1. Data on file.

Remestemcel-L: Phase 3 Trial

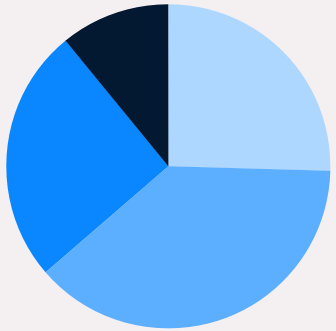
Protocol GVHD001 - Disease characteristics reflect aGVHD severity[1]

GVHD Grade at Baseline



- 89% of subjects had Grade C/D disease at baseline
- 47% of subjects had Grade D disease at baseline

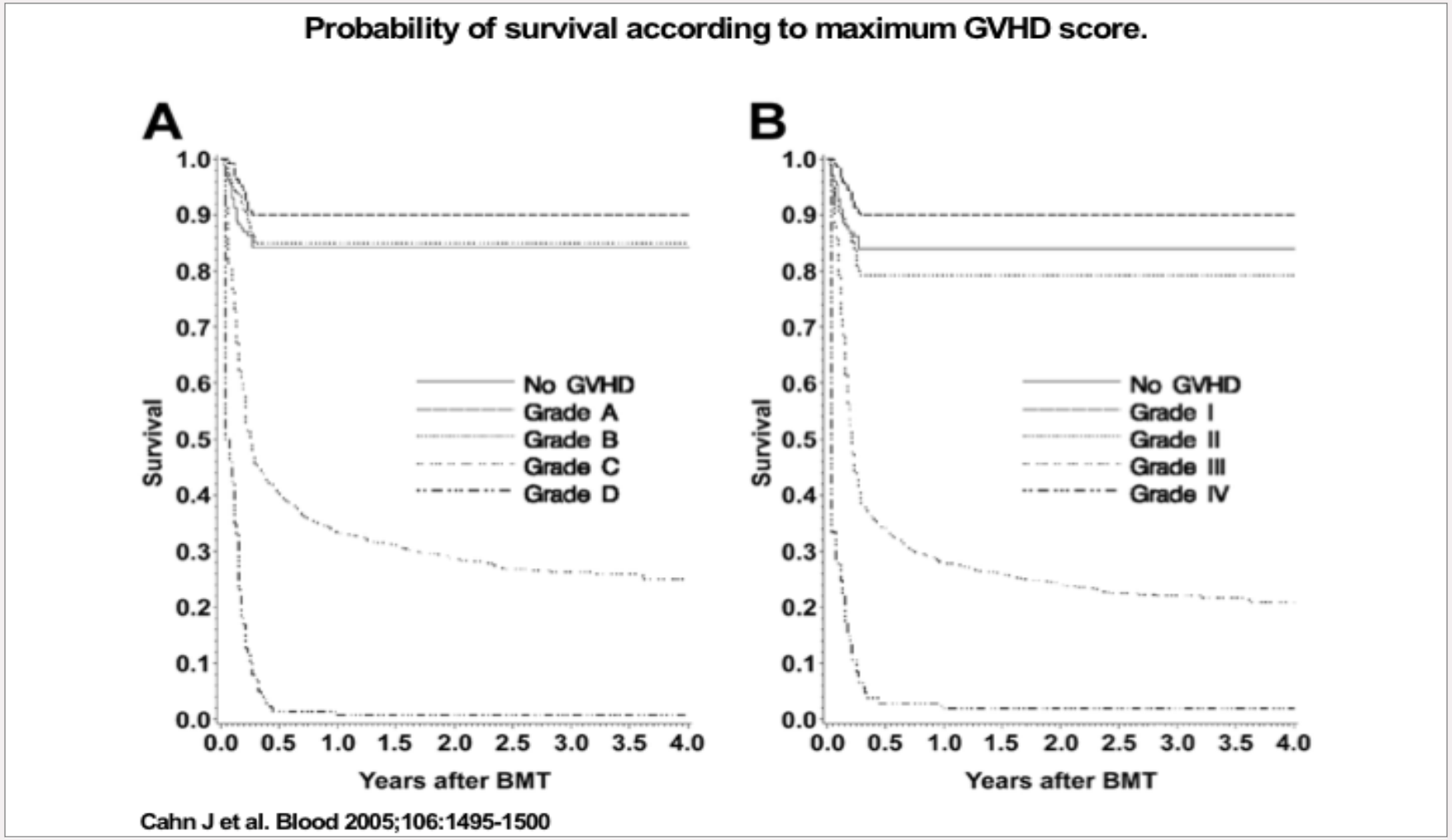
Baseline Organ Involvement



- 26% of subjects had Skin involvement only
  - All had stage 3 (n=10) or stage 4 (n=4) disease
- 38% of subjects had Lower GI involvement only
  - 16/21 had stage 3 (n=6) or stage 4 (n=10) disease
- 36% of subjects had multi-organ involvement, all with Lower GI
  - 6/20 had all three organs involved
  - 10/20 had Lower GI + Skin
  - 4/20 had Lower GI + Liver

1. Data on file.

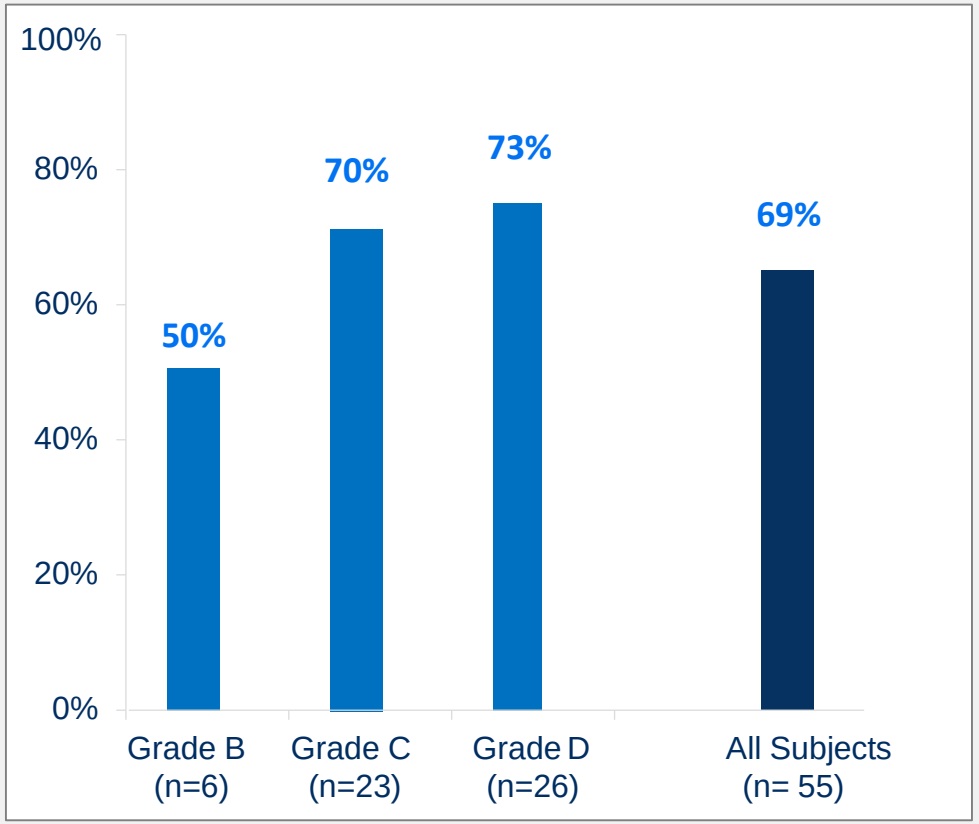
Grade C/D GVHD has Significantly Worse Survival than Grade A/B[1]



Remestemcel-L: Phase 3 Trial

Protocol GVHD001 - Primary efficacy overall response at Day 28 was 69%, p=0.0003[1]

- 69% Overall Response rate at Day 28 (29% CR + 40% PR); (95% CI: 55%, 81%)
- p-value calculated from the binomial distribution, under the assumption of a 0.45 success rate under the null hypothesis



1. Data on file

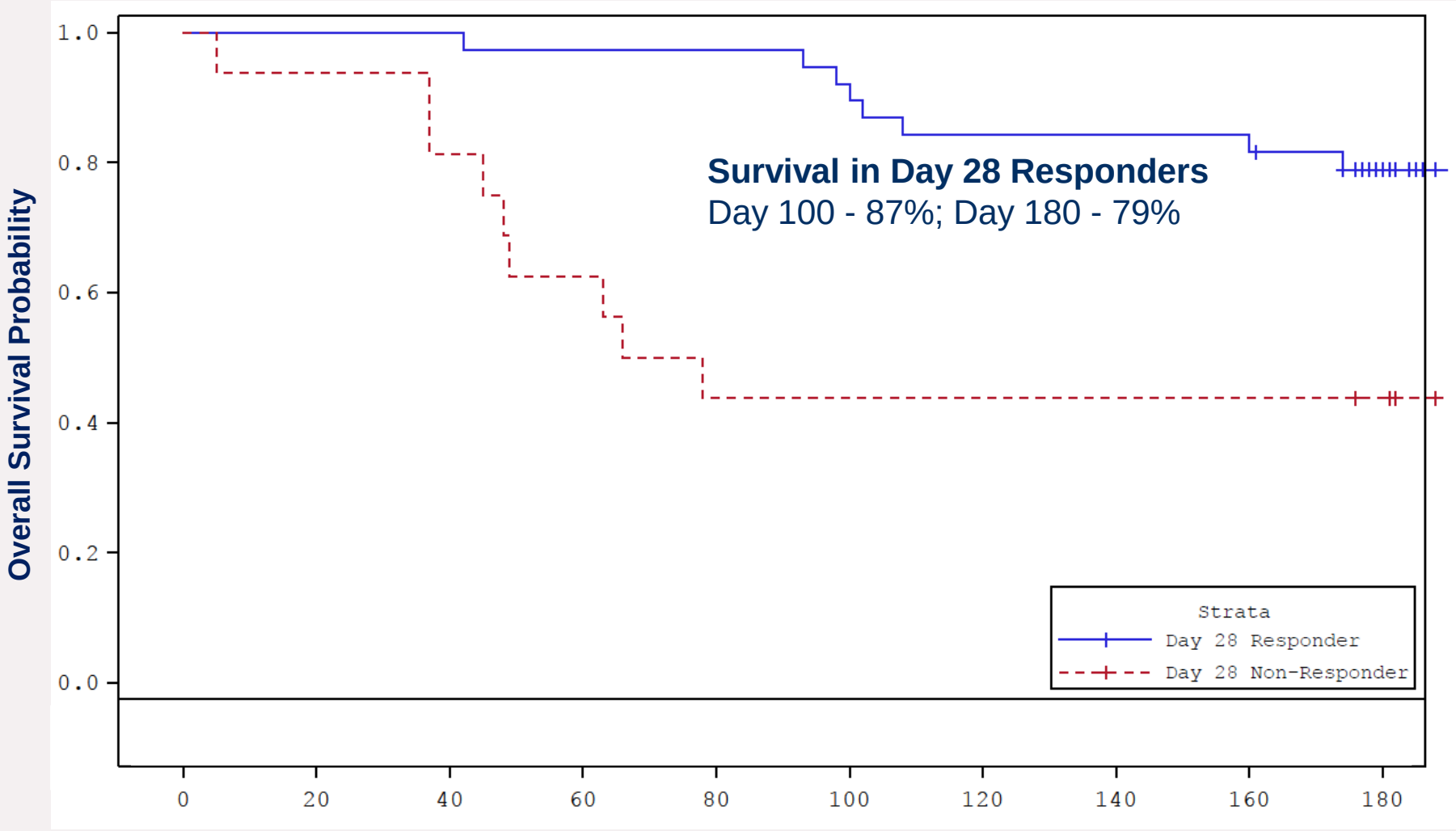
Remestemcel-L: Phase 3 Trial

Overall response at Day 28 predicts survival through six months[1]

- Phase 3 study evaluated remestemcel-L in 55 children to improve overall response rate and survival
  - 89% of children had grade C/D disease, the most severe form and historically associated with up to 90% mortality[2,3]
- Study successfully met the primary endpoint of improved Day 28 Overall Response (OR)
  - 69% vs 45% protocol-defined historical control rate (p=0.0003)
- Day 100 Overall Survival 75%, with 87% survival in Day 28 responders
- Day 180 Overall Survival 69%, with 79% survival in Day 28 responders
- Remestemcel-L infusions well tolerated
- Findings consistent with previous results in 241 SR-aGVHD children under expanded access program who failed to respond to multiple biologic agents[4]

1. Data on file.
2. Westin, J., Saliba, RM., Lima, M. (2011) Steroid-refractory acute GVHD: predictors and outcomes. Advances in Hematology.
3. 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
4. Kurtzberg J. et al. Effect of Human Mesenchymal Stem Cells (remestemcel-L) on Clinical Response and Survival Confirmed in a Large Cohort of Pediatric Patients with Severe High-Risk Steroid-Refractory Acute Graft Versus Host Disease. BBMT. 2016; 22.

Remestemcel-L: Protocol GVHD001/002 survival[1]



1. Data on file.

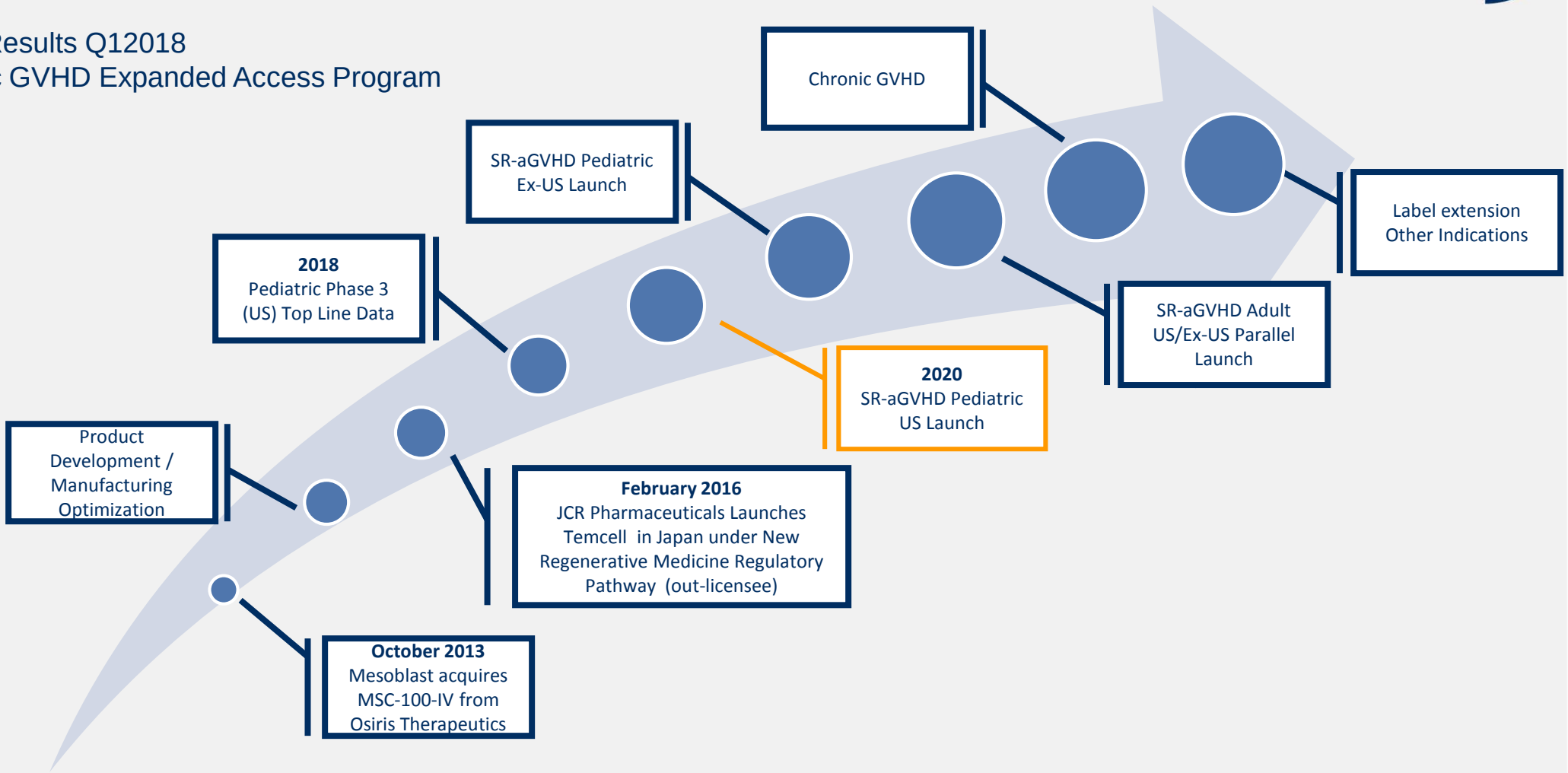
Remestemcel-L: Regulatory and Commercial Strategy Overview

- FDA agreed to rolling review of BLA submission
- Fast Track designation provides eligibility for FDA priority review
- Ramp-up for inventory build is underway
- Commercialization strategy in place for product launch
- Building out efficient, targeted sales force - 15 centers account for ~50% of patients
- TEMCELL®[1] HS Inj. sales experience in Japan informs commercial strategy for the U.S.

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

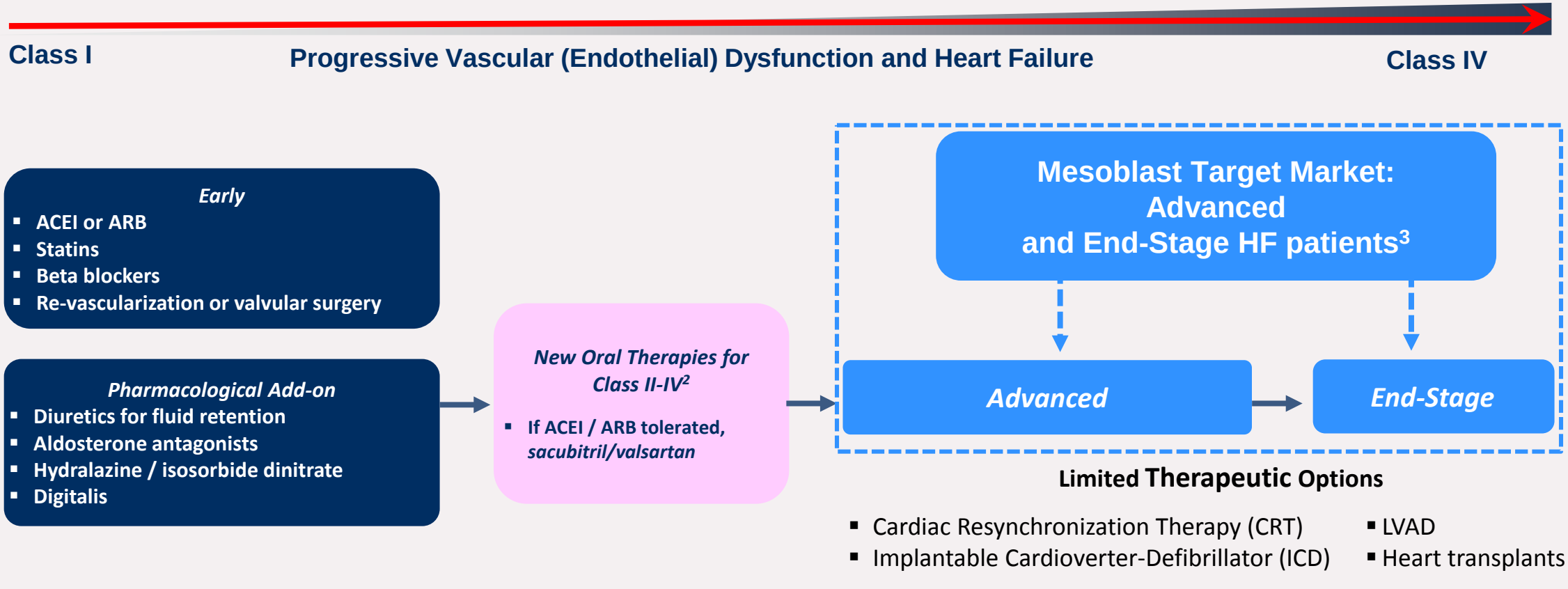
Remestemcel-L: Comprehensive Global GVHD Program

- **Mesoblast has over 10 years of experience in hematology-oncology space**
- **Remestemcel-L:**
  - Positive Phase 3 Results Q12018
  - Large US Pediatric GVHD Expanded Access Program (>240 patients)



Advanced and End-Stage Heart Failure

Common Treatment Pathway in Progressive Heart Failure[1]



1. Source: Simon-Kucher & Partners 2017. Primary research 2017; Payers n=35, KOLs n=15, Cath lab managers n=4.
2. Corlanor® (ivabradine) approved by FDA (April 2015). ENTRESTO® (sacubitril/valsartan) approved by FDA (July 2015).
3. GlobalData-PharmaPoint Heart Failure (2016); McMurray et al., 2012;Yancy et al., 2013, 2016 ACC/AHAHFSA Focused Update on New Pharmacological Therapy for Heart Failure: An Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure.

Advanced Heart Failure

Revascor – Commercial opportunity

Burden of Illness

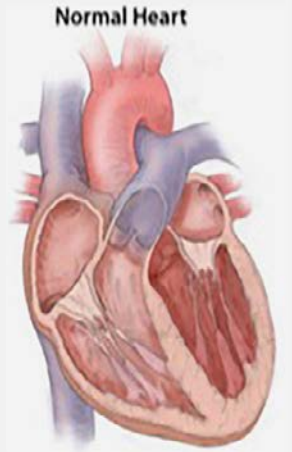
- Approx. 8 million patients with chronic heart failure by 2030 in US alone[1]
- 17-45% globally die within 1 year of hospital admission[1]
- Majority of advanced heart failure patients die within 5 years[1]

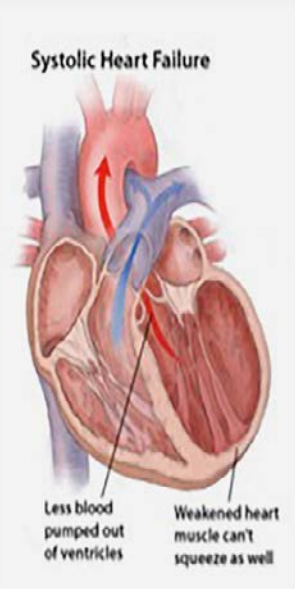
Limited Options / Unmet Need

- Despite recent advances in newly approved drugs, limited treatment options are available for patients with advanced heart failure[2]
- New therapies to reduce hospitalizations and mortality in patients with advanced heart failure who have failed other therapies
- Greatest need is in NYHA class III-IV where event rate is highest

Market Opportunity

- US healthcare costs for NYHA class II-IV patients $USD115bn/year[5]
- Hospitalizations account for ~69% of expenditure[3-5]
- **Multi-billion dollar annual market opportunity in US**[4,5]





1. Heart Failure: Preventing disease and death worldwide – European Society of Cardiology 2014., 2. ACC/AHAHFSA Focused Update on New Pharmacological Therapy for Heart Failure: An Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure., 3. Gurwitz JH, Magid DJ, Smith DH, et al. Contemporary Prevalence and Correlates of Incident Heart Failure with Preserved Ejection Fraction. The American Journal of Medicine. 2013;126(5):393-400. Derived by applying a HF-REF prevalence rate of 32.6% to the U.S. rate of 5.7m U.S. patients., 4.A Reevaluation of the Costs of Heart Failure and its Implications for Allocation of Health Resources in the United States. Voigt J. Clinl.Cardiol. 37, 5, 312-321 (2014)., 5.The Medical and Socioeconomic Burden of Heart Failure: A Comparative Delineation with Cancer. Dimitrios, F. International Journal of Cardiology (2015), doi: 10.1016/j.ijard.2015.10.172.

Revascor: Phase 2 Randomized, Controlled Trial Identified Optimal Therapeutic Dose and Target Patient Population for Phase 3

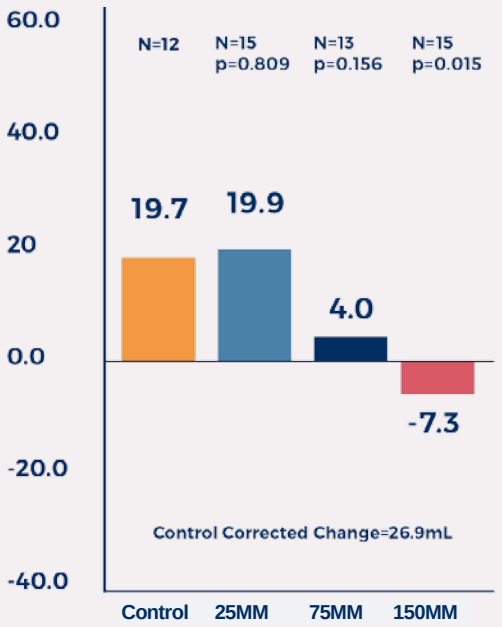
Objectives

- Identify a dose response and an optimal therapeutic dose
- Identify optimal target population for therapeutic effect
- Evaluate placebo vs. 25, 75, 150MM MPCs injected by endomyocardial catheter in 60 patients with class II/III heart failure and EF<40%

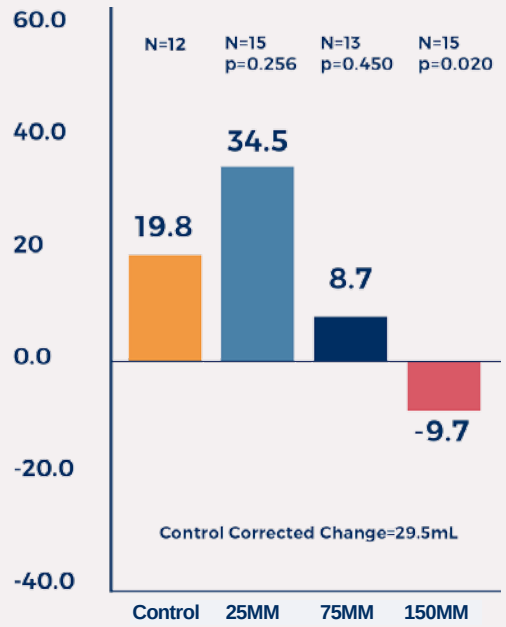
Results

- At 6 months: Dose-dependent effect seen on left ventricular remodeling, with 150MM cell dose (MPC-150-IM) showing greatest effect vs. controls

LVESV Month 6 - Baseline



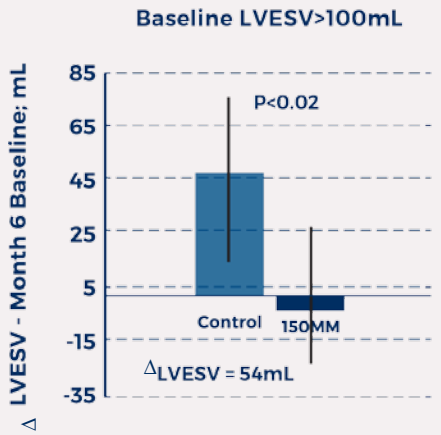
LVEDV Month 6 - Baseline

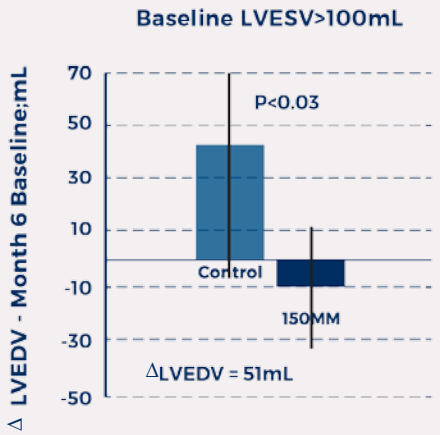


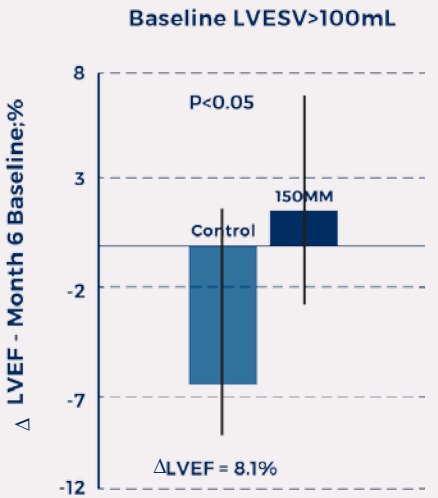
Source: Circ Res. 2015; 117:576-584. Perin E et al. A Phase II Dose-Escalation Study of Allogeneic Mesenchymal Precursor Cells in Patients With Ischemic or Non-Ischemic Heart Failure. LVESV = Left ventricular end systolic volume; LVEDV = Left Ventricular End-Diastolic Volume; EF = Ejection Fraction.

Revascor: Therapeutic Benefit on LV Remodeling in Phase 2 Subjects with LVESV >100ml[1]

- Placebo corrected benefit of 150MM cell dose on cardiac volumes and ejection fraction at 6 months was greatest in patients with more advanced heart failure as defined by baseline LVESV>100ml at baseline





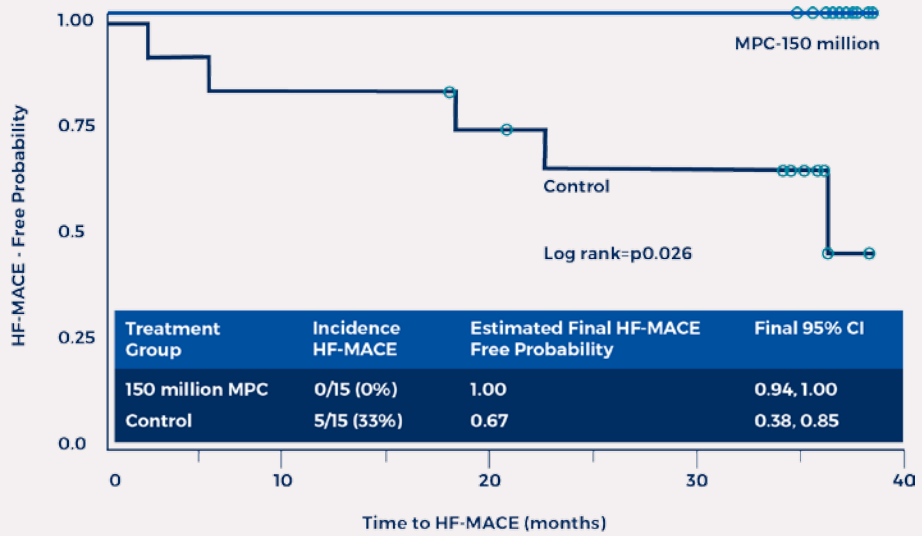


	Change (Entire cohort) Month 6 minus baseline			Change (LVESV>100mL) Month 6 minus baseline			
	PBO (n=15)	150M MPC (n=15)	Δ, PBO corrected	PBO (n=7)	150M MPC (n=11)	Δ, PBO corrected	P-values
LVESV	+20	-7	-27	+46	-8	-54	<0.02
LVEDV	+20	-10	-30	+41	-10	-51	<0.03
LVEF	-2.3	+0.6	+2.9	-6.4	+1.7	+8.1	<0.05

1. Source : Perin et al., Journal of Cardiac Failure 2015; Vol 21(8): S107; 19th Annual Scientific Meeting of the Heart Failure Society of America, Emerson et al. LVESV = Left ventricular end systolic volume; LVEDV = Left Ventricular End-Diastolic Volume; LVEF = Left Ventricular Ejection Fraction.

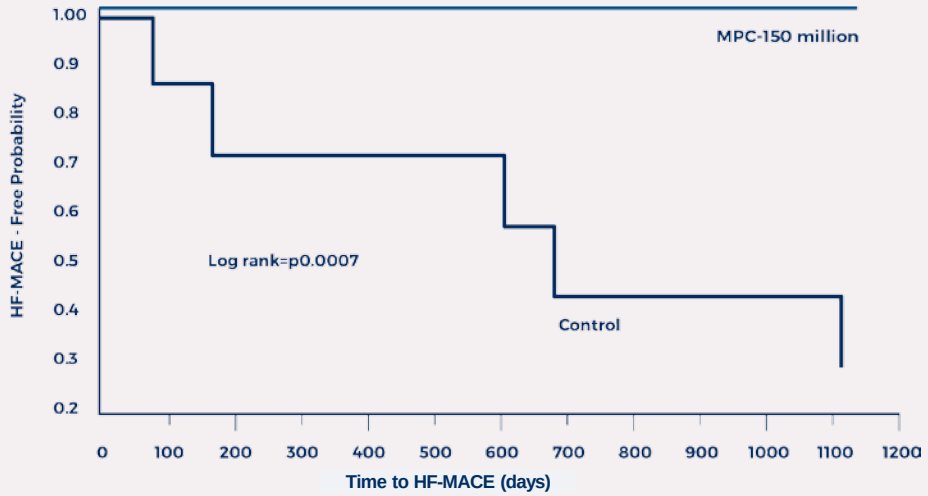
Revascor: A Single Dose Prevented Any HF-MACE for 36 Months in Patients at Highest Risk of Recurrent Events and Death (Those with LVESV>100ml) in Phase 2

% HF-MACE Kaplan-Meier Curve over 36 months following treatment in all patients[1]



Treatment Group	Incidence HF-MACE	Estimated Final HF-MACE Free Probability	Final 95% CI
150 million MPC	0/15 (0%)	1.00	0.94, 1.00
Control	5/15 (33%)	0.67	0.38, 0.85

HF-MACE Kaplan-Meier Curve over 36 months following treatment in patients with LVESV>100ml[2]



- Over 36 months, patients receiving 150M MPC had significantly greater probability of remaining free of a first HF-MACE vs. controls (0% vs. 33%, p = 0.026 by log-rank)
- All HF-MACE events occurred in controls with baseline Left Ventricular End Systolic Volume (LVESV)>100ml, where the treatment effect size was even greater (0% vs. 71%, p = 0.0007 by log rank)
- Controls with baseline LVESV>100ml had 11 total/recurrent HF-MACE events over 36 months vs. 0 in matched patients receiving 150M MPCs (p=0.0007)

1. HF-MACE is defined as a composite of cardiac related death or non-fatal heart failure hospitalisations. 2. Circ Res. 2015; 117:576-584. Perin E et al. A Phase II Dose-Escalation Study of Allogeneic Mesenchymal Precursor Cells in Patients With Ischemic or Non-Ischemic Heart Failure 3. Journal of Cardiac Failure 2015; Vol 21(8): S107; 19th Annual Scientific Meeting of the Heart Failure Society of America, Emerson et al.

Advanced Heart Failure

Revascor - Phase 3 trial fully enrolled

- Trial design is 1:1 randomized, controlled, double blinded; conducted over 55 sites across North America using 150MM cell dose vs control
- Events-driven Phase 3 trial completed enrollment of 566 patients in February 2019
- Primary endpoint: reduction in recurrent heart failure-related major adverse cardiac events such as heart failure-related hospitalizations and cardiac death
- Secondary endpoint: reduction in terminal cardiac events
- Target patient population enriched for those likely to be both highest risk for events and greatest responders to Revascor therapy

End-Stage Heart Failure

Revascor – Commercial opportunity in reducing GI bleeding in patients with LVADs

Burden of Illness

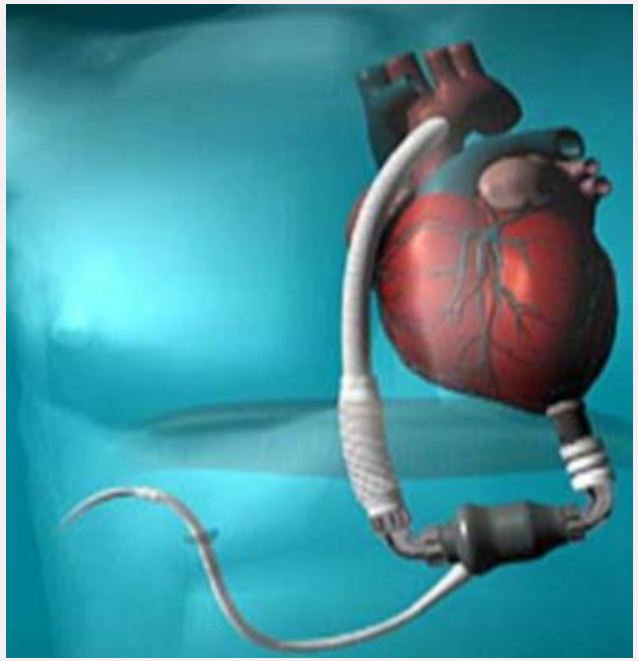
- In the US there are approx. 250,000–300,000 patients annually who suffer from advanced systolic heart failure (NYHA Class III–IV)[1]
- Despite optimal medical therapy, mortality exceeds 50% in class IV patients[1]

Ongoing Unmet Need

- LVADs have improved survival, but morbidity remains high with patients on average experiencing greater than two hospitalization annually[2]
- Gastrointestinal (GI) bleeding is the leading cause of non-surgical hospitalizations in LVAD patients[2]
- **Device attributable major adverse events (DAEs) can cost on average $USD46.5k per hospitalization[2]**

Market Opportunity

- Approx. 4,500 – 5,500 assist devices are implanted annually in the US[3, 4]
- **US LVAD market is growing double-digit CAGR and represents significant market growth opportunity[3,4]**
- US targeted commercial footprint provides low cost market entry



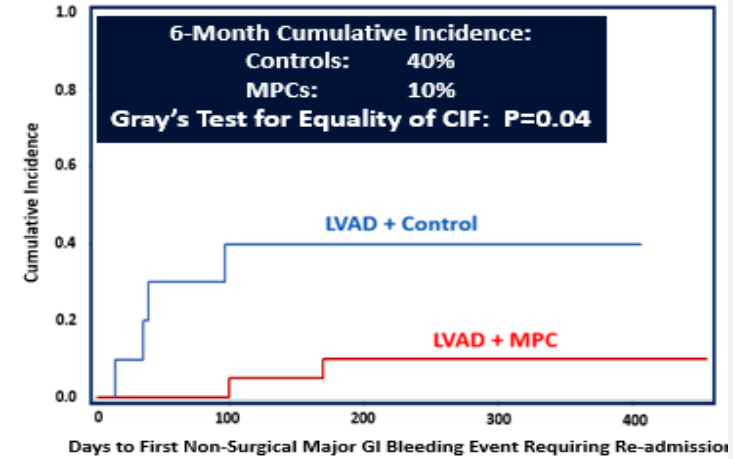
[1]Gustafsson G, Rogers J. (2017) Left ventricular assist device therapy in advanced heart failure: patient selection and outcomes, [2] Mehra, MR Salerno C, Cleveland JC (2018) Health care resources use and cost implications in the MOMENTUM 3 long-term outcome study: a randomized controlled trial of a magnetically levitated cardiac pump in advanced heart failure, [3]Agency for Healthcare Research and Quality – Healthcare Cost and Utilization Project – claims analysis using ICD-9 37.6 implantation of heart and circulatory assist systems, [4] Data on File

End-Stage Heart Failure

Revascor – Trials demonstrated reduced GI bleeding events in LVAD patients

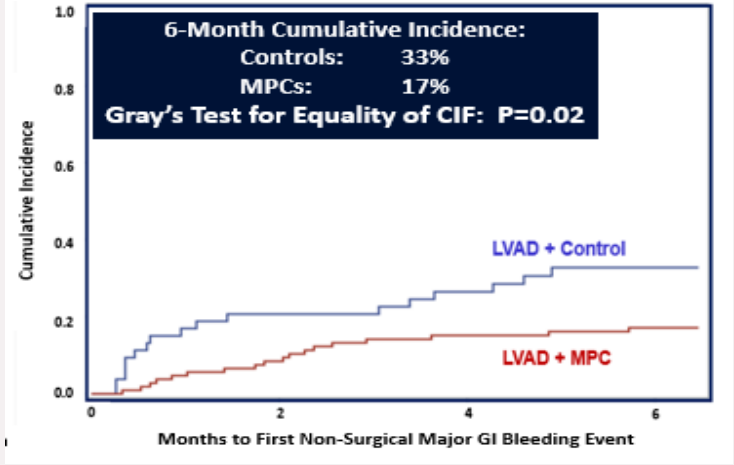
MPCs prolong time-to-first major GI bleeding event and reduced cumulative major GI bleeding events in two randomized controlled trials in LVAD patients[1,2]

Pilot Randomized Controlled Trial (LVAD-MPC Study #1)



MPC (n = 20)	Control (n = 10)	P-value
Event Rate (100-Pt-Months)	Event Rate (100-Pt-Months)	
4.2	**14.2**	**0.06**

Randomized Controlled Trial (LVAD-MPC Study #2)



MPC (n = 106)	Control (n = 53)	P-value
Event Rate (100-Pt-Months)	Event Rate (100-Pt-Months)	
3.8	**15.9**	**<0.001**

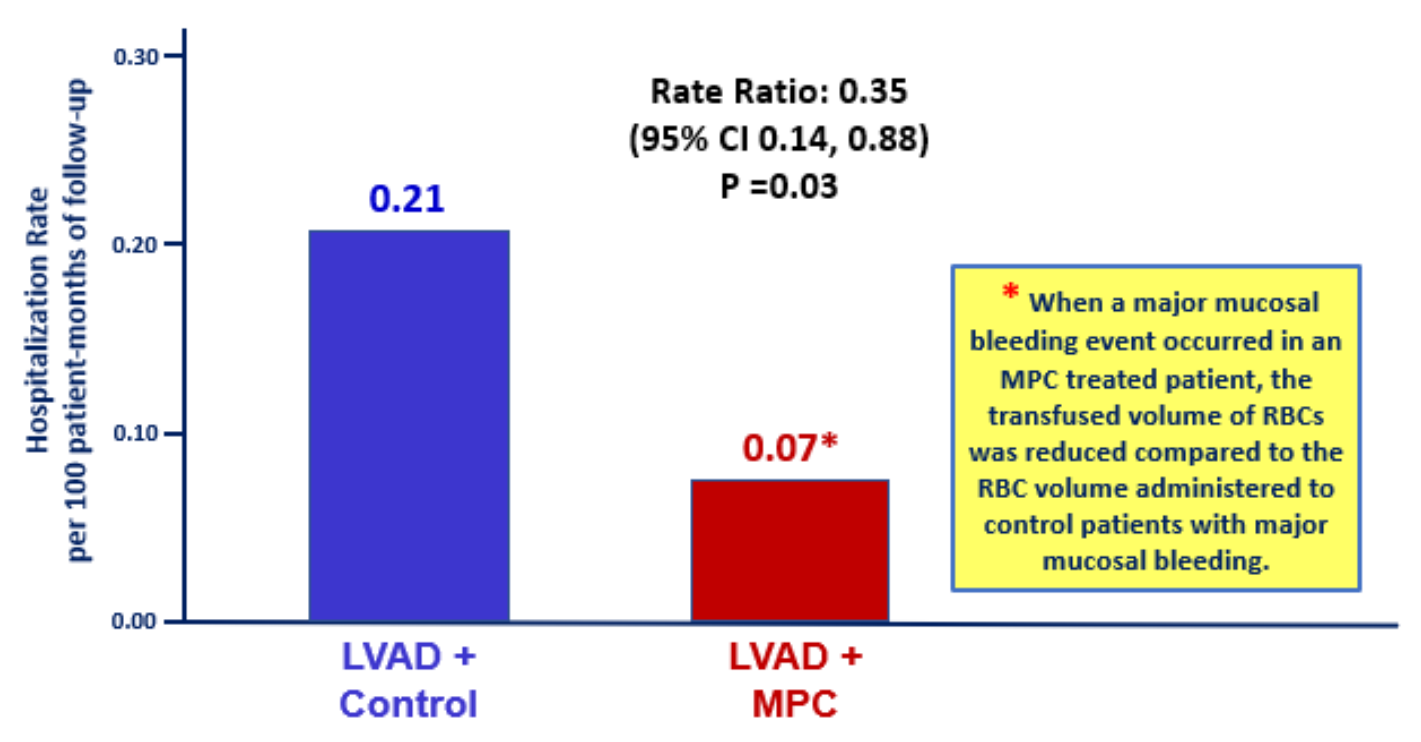
Rate of major GI bleeding events over 6 months in LVAD patients reduced by 70% and 76% with MPCs in two randomized controlled trials

1. Mesoblast internal data post-hoc analysis 2017 (clinicaltrials.gov; identifier: NCT01442129). 2. Presented at American Heart Association Scientific Sessions 2018.

End-Stage Heart Failure

Revascor – Reduced hospitalization rate from GI bleeding in Phase 2 trial

MPCs Reduce Hospitalization Rate from GI Bleeding by 65% in 159-Patient Phase 2 Trial[1]



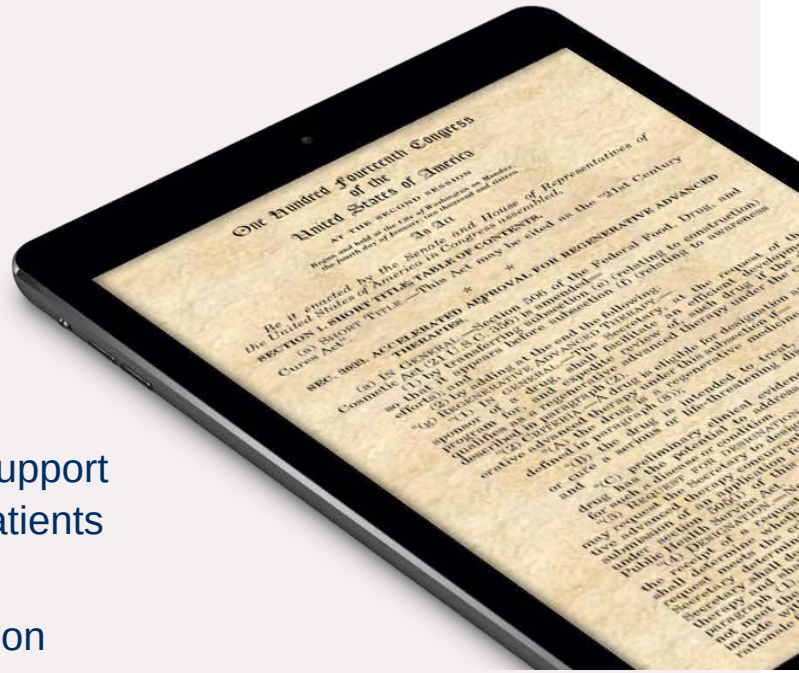
1 Presented at American Heart Association Scientific Sessions 2018.

End-Stage Heart Failure

Revascor – Benefits from an expediated approval path under RMAT

Revascor Has Received RMAT Designation for Use in End-Stage Heart Failure Patients with LVADs

- Key benefits of the Regenerative Medicine Advanced Therapies (RMAT) designation include:
  - Potential eligibility for priority review and accelerated approval
  - Potential to utilize surrogate endpoints for accelerated approval
  - Potential to utilize patient registry data and other sources of “real world evidence” for post approval studies, subject to approval by the FDA
- Mesoblast received guidance from FDA that reduction in major GI bleeding
  - is a clinically meaningful outcome
  - could be used as an endpoint to support product approval
- Next steps:
  - Mesoblast entered into a MOU with InCHOIR[1] to conduct a confirmatory clinical trial to support marketing approval of Revascor for reduction of GI bleeding in end-stage heart failure patients implanted with a LVAD
  - Schedule meeting with FDA to discuss pathway to filing for BLA for marketing authorization



1 InCHOIR = International Center for Health Outcomes and Innovation Research (InCHOIR) at the Icahn School of Medicine at Mount Sinai.

Chronic Low Back Pain (CLBP)

MPC-06-ID – Market opportunity in CLBP due to disc degeneration

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[2]

Minimal Treatment Options

- Treatment options for patients with CLBP who fail conservative therapy include opioids and surgery
- 50% of opioid prescriptions are for chronic low back pain (CLBP)[2]

Unmet Need

- Novel therapeutic approach for durable improvement in pain and function
- Potential alternative for opioid use or surgical intervention

Market Opportunity

- MPC-06-ID development focused on over ~3.2m patients with CLBP due to degenerative disc disease (DDD) in US alone[3,4,5]
- **US market opportunity >$USD $1 billion**[3,4,5.6]

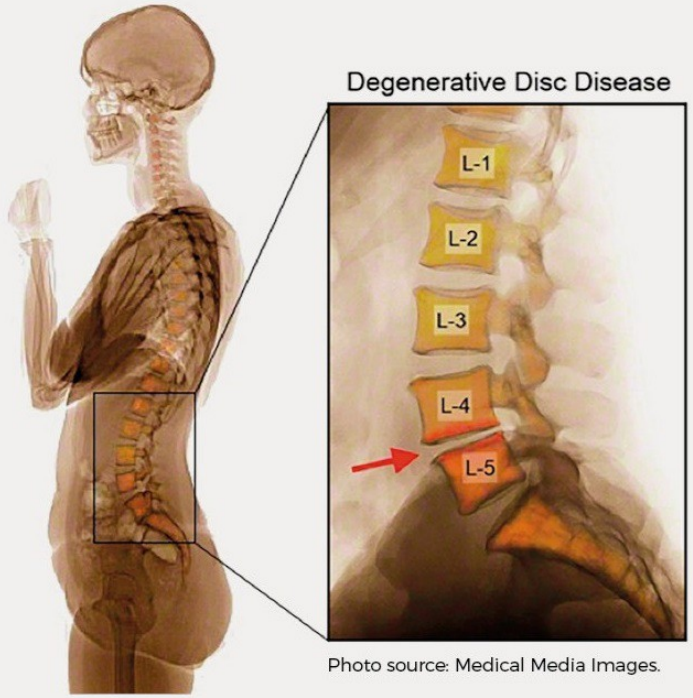


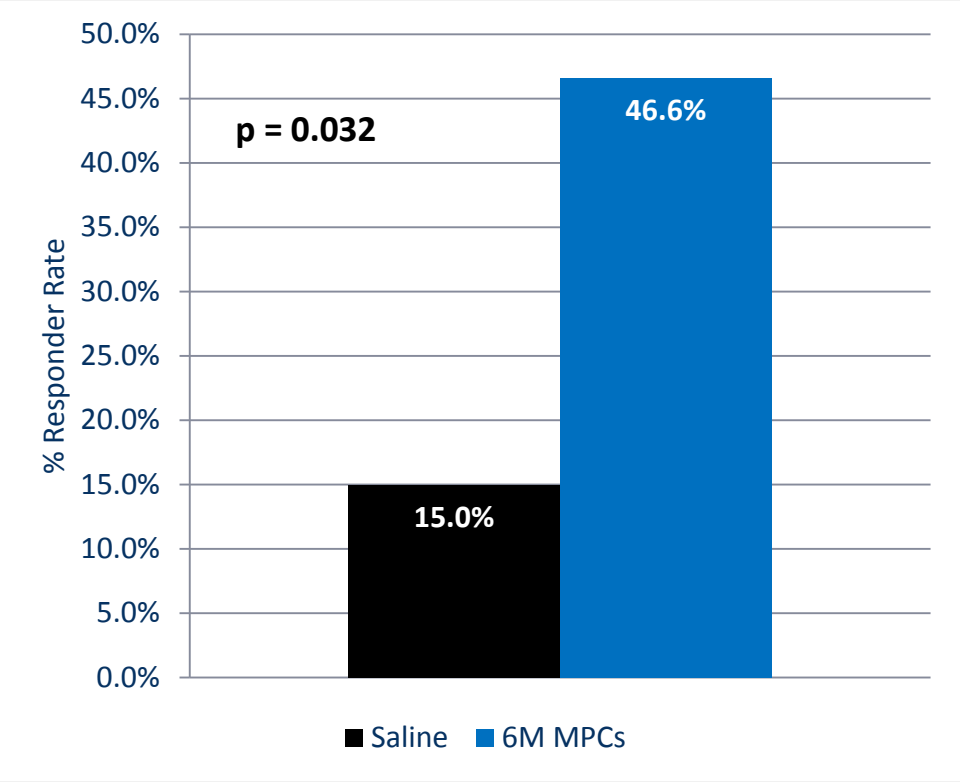
Photo source: Medical Media Images.

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: Pain Management Study, Chronic Pain December 2013., **3.** Decision Resources: Chronic Pain December 2015., **4**. LEK & NCI opinion leader interviews, and secondary analysis., **5.** Navigant: Commercial Assessment for a Proprietary Cell-Based Therapy for DDD in the U.S. and the EU3 – August 2014. **6**. Data on File.

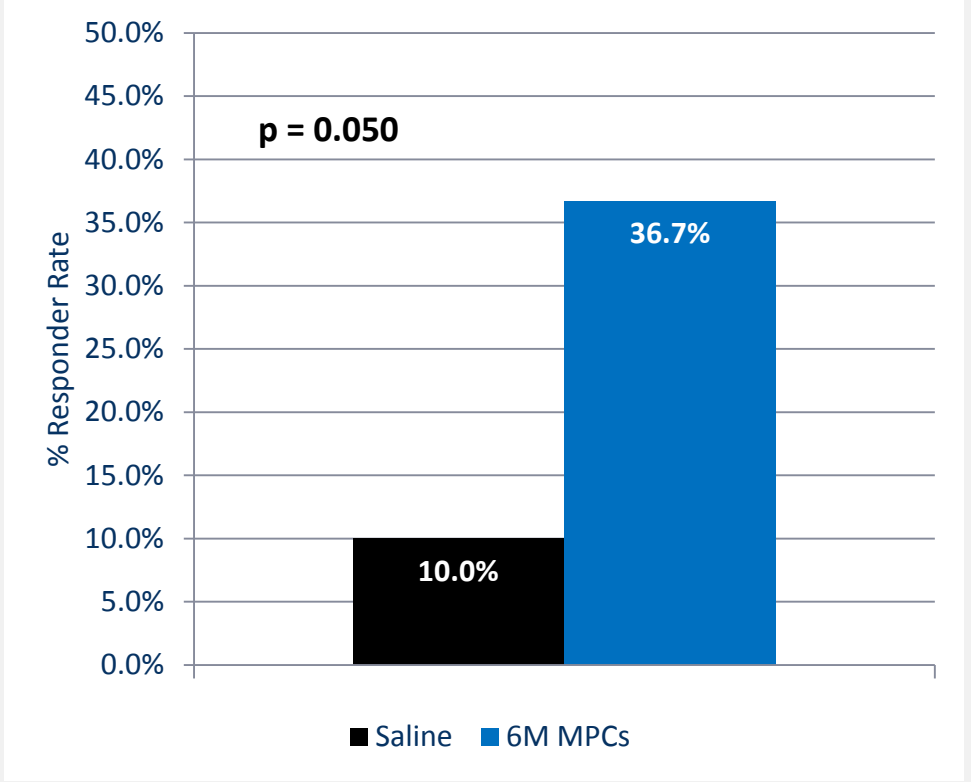
Chronic Low Back Pain

MPC-06-ID – Post-Hoc Phase 2 results provide target endpoints for Phase 3 trial

A: Phase 2: Treatment Success Responders[1,2] at 12 Months



B: Phase 2: Treatment Success Responders[1,2] at both 12 & 24 Months



1. Subjects with missing data are classified as non-responders.
2. Treatment Success Responders have a 50% reduction in LBP as measured by VAS AND a 15 point improvement in function as measured by ODI at a) 12 months, and b) both 12 and 24 months and no intervention through 24 months.

Chronic Low Back Pain

MPC-06-ID – Ongoing Phase 3 clinical trial

- Three-arm study comparing 6-million MPC with or without hyaluronic acid (HA) against saline control
- Primary efficacy endpoint agreed to with FDA:
  - Overall Treatment Success Composite at both 12 and 24 months as measured by:
    - At least 50% reduction from baseline in Visual Analogue Scale (VAS) pain score at both 12 and 24 months post-treatment; and
    - At least a 15 point decrease from baseline in Oswestry Disability Index (ODI) function score at both 12 and 24 months post-treatment; and
    - No interventions affecting the treated disc through 24 months
- Study powered to show efficacy for either 6-million MPC arm (with or without HA)

404 patient 2:1 randomized Phase 3 trial completed enrollment March 2018
All patients have completed 12 month safety and efficacy follow-up

Anticipated CY2019 Milestones

Remestemcel-L for Steroid-Refractory Acute Graft Versus Host Disease

- Completion of BLA filing for remestemcel-L in the treatment of steroid refractory aGVHD in children

Revascor for Advanced and End-Stage Heart Failure

- Phase 3 trial in advanced heart failure continues accrual of primary endpoints through to completion
- Meet with FDA to discuss pathway for approval of Revascor for the reduction of GI bleeding in end-stage heart failure patients implanted with a LVAD
- Our cardiovascular partner in China, Tasly, to receive guidance on regulatory approval pathway for Revascor from the NMPA of China.

MPC-06-ID for Chronic Low Back Pain

- Patient follow up continues through 24-month assessment of safety and efficacy in the Company's Phase 3 trial of MPC-06-ID for chronic lower back pain

Establish global and/or regional partnerships

- In advanced discussions on potential blockbuster products