



Financial Results **for the First Quarter Ended** **September 30, 2016**

November 2016

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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Agenda

FINANCIAL RESULTS

OPERATIONAL UPDATE

TIMELINES

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FINANCIAL RESULTS

- At September 30, 2016, the Company had cash reserves of \$60.4 million
- As previously announced, a fully discretionary equity facility has been established for up to \$A120 million/\$US90 million over 36 months
- In order to absorb the incremental costs of the MPC-150-IM program in advanced heart failure in FY17, the Company has executed its planned operational streamlining and re-prioritization of projects
- Cash outflows for Q1 FY17 were \$21.2 million, a reduction of 28% from \$29.4 million in the comparable FY16 quarter
- This was achieved principally through reduced spend on commercial manufacturing, deprioritized Tier 2 clinical projects and reduced labor costs

As previously indicated in July, the Company is planning to absorb the incremental costs of the MPC-150-IM program in FY17 through a range of cost reduction initiatives. To date, the following initiatives have been executed:

Within R&D:

- A 28% reduction in FTEs was achieved primarily through a labor restructure. This, combined with the cost containment of consultants and travel have reduced product support costs within R&D by \$1.9 million (29%) in comparison with Q1 FY16
- Enrollment has been completed for our heart attack study using MPC-25-IC, reducing future expenditure on this Tier 2 program
- Previously-specified Tier 2 programs have been deprioritized

Within Manufacturing Commercialization:

- A labor restructure, combined with cost containment of consultants and travel have reduced manufacturing support costs for the function by \$0.3 million (36%) in comparison with Q1 FY16
- Overall MPC/MSK platform technology costs were reduced by \$2.6 million (49%) as the Company had sufficient clinical grade product on hand to reduce the number of production runs in this period

Reductions to office accommodation and laboratory space have also been executed

FY17 Cash Flows and Cash Position

US\$m

	30 Sep 2016	30 Sep 2015	\$ Change	%
Cash on hand	60.4	77.8	(17.4)	
Cash flows for the quarter:				
Operating cash outflows	(20.8)	(28.1)	7.3	(26%)
Investing cash outflows	(0.3)	(1.5)	1.2	(81%)
Financing cash (outflows)/inflows	(0.1)	0.2	(0.3)	(133%)
Net decrease in cash outflows	(21.2)	(29.4)	8.2	(28%)
Foreign exchange	0.6	(3.5)	4.1	(117%)
Net decrease in cash after FX	(20.6)	(32.9)	12.3	(37%)

- Cash outflows have been reduced by 28% (\$8.2 million) primarily due to operational streamlining, re-prioritization of projects and reduced manufacturing costs in order to absorb the ongoing and incremental costs associated with the MPC-150-IM chronic heart failure program

FY17 Profit and Loss

US\$m

	30 Sep 2016	30 Sep 2015	\$ Change	%
Revenue	0.4	7.5	(7.1)	(95%)
Research and Development	(14.0)	(11.1)	(2.9)	26%
Manufacturing Commercialization	(3.3)	(6.2)	2.9	(47%)
Management & Administration	(5.5)	(5.5)	0.1	(1%)
Contingent Consideration	—	3.7	(3.7)	(100%)
Other Operating Income & Expenses	0.5	0.8	(0.3)	(44%)
Finance Costs	(1.0)	(2.4)	1.4	(57%)
Loss Before Tax	(22.9)	(13.2)	(9.7)	74%

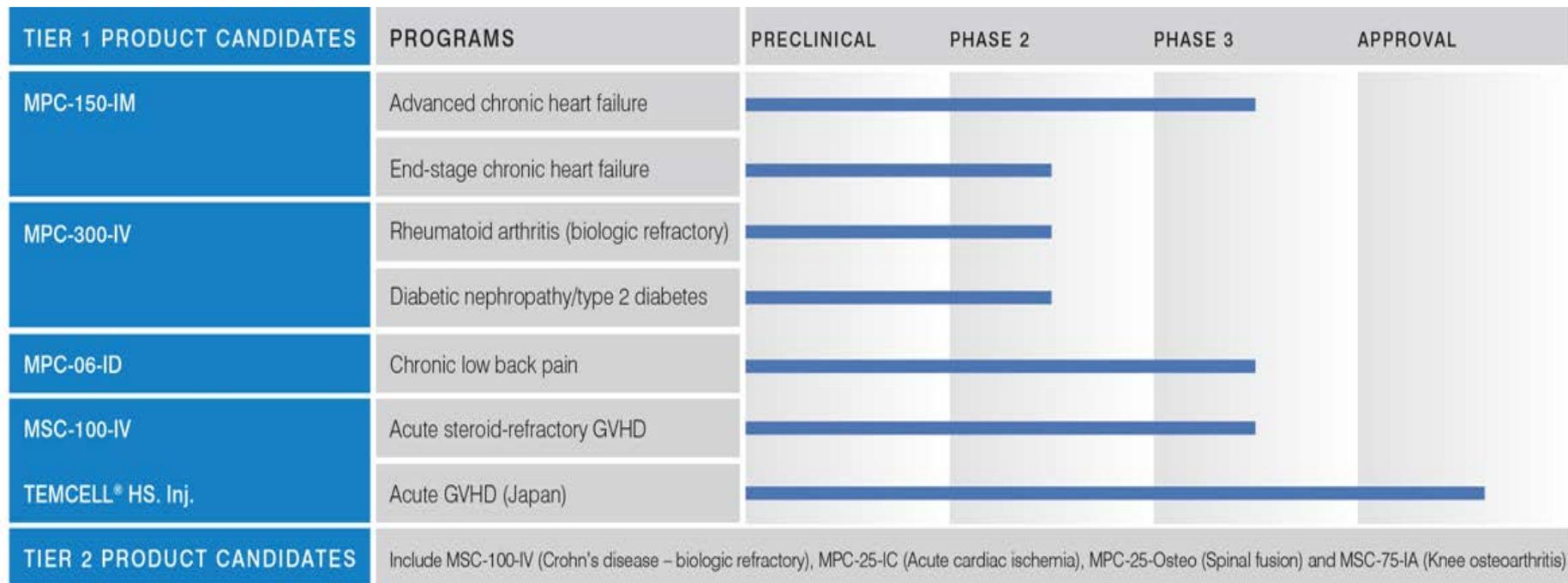
- The overall increase in loss before income tax is primarily attributable to items that did not impact the Company's current cash reserves, such as remeasurement of contingent consideration and reduction in revenue
- Revenue was reduced as the Company has fully recognized its remaining non-cash deferred revenue balance for its MPC-150-IM product in June 2016, and due to having received a one-time milestone payment for TEMCELL[®] HS Inj. in the first quarter of FY2016
- R&D expenses: increased by \$2.9 million (26%) - the incremental costs of the MPC-150-IM program were partially offset by cost reductions achieved from the operational streamlining and the re-prioritization of assets
- Manufacturing Commercialization: decreased by \$2.9 million (47%) – sufficient clinical grade product on hand enabled the number of production runs to be reduced in this period vs the comparative quarter

Agenda

OPERATIONAL UPDATE

Diversified Pipeline of Product Candidates for High Unmet Needs

First Product on market - Three Tier 1 Product Candidates in Phase 3



This chart is figurative and does not purport to show individual trial progress within a clinical program. For product registration purposes, Phase 3 programs may require more than one trial.

MPC-150-IM: Chronic Heart Failure (CHF) – Market Opportunity

MPC-150-IM is in development for patients with New York Heart Association Class II-IV CHF

Market opportunity

- 5.7m patients (prevalence rate of 2% of the population) diagnosed with CHF in the US¹
- 915,000 new cases diagnosed in the US each year¹
 - Growing by 2% per annum
- ~1.9m CHF NYHA Class II-IV patients with low ejection fraction (LVEF<40%) in the US alone²

Gap in treatment options

- Class II / III CHF patients with low ejection fraction continue to be at high risk of repeated hospitalizations and mortality, despite standard of care pharmacological treatments³
- Class III / IV CHF patients only have heart transplant and mechanical support as treatment options

Targeted physician population

- Specialists: Targeted physician audience & commercial footprint
 - Heart failure specialists
 - Interventional cardiologists
 - Cardiac Surgeons

We believe MPC-150-IM is positioned to fill the significant treatment gap in patients with advanced CHF

1. AHA Heart disease and stroke statistics—2016 update: a report from the American Heart Association. *Circulation*. 2016;133:e38-e360 (P e308).
2. 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.
3. *European Heart Journal* (2012) 33, 1750–1757 Figure 3

MPC-150-IM: Operational Update

- Phase 3 trial for 600 patients with advanced heart failure is recruiting well across North American sites; over 300 patients enrolled
- After reviewing patient data in April and October 2016, the trial's DSMB has maintained its recommendation that the study should continue as planned
- The trial's primary endpoint is a comparison of recurrent heart failure-related major adverse cardiovascular events (HF-MACE) in advanced CHF patients receiving either MPC-150-IM by catheter injection into the left ventricular heart muscle, or control
- Based on observed HF-MACE event rates in the trial to date, the Company has decided to bring forward to Q1 CY2017 a previously planned Interim Analysis to assess the trial's primary endpoint

MPC-06-ID: CLBP Due to Degenerative Disc Disease – Market Opportunity

MPC-06-ID is in development for the treatment of chronic low back pain (CLBP) lasting >6 months as a result of moderate degenerative intervertebral disc disease

Market opportunity

- Over approximately 7m patients in the US are estimated to suffer from CLBP due to degenerative disc disease (DDD) in 2016^{1,2,5}
- Current MPC-06-ID development program targets over approximately 3.2m patients

Gap in treatment options

- For patients who fail conservative treatment (rest, analgesia, opioids, and epidural steroids), treatment options are limited to highly invasive therapies such as spinal fusion or artificial disc replacement³
- Surgeons report ~40% of patients ultimately fail back surgery³

Targeted physician population

- Specialists: Targeted physician audience & commercial footprint⁴
 - Pain management specialists and anesthesiologists
 - Orthopedic / spine surgeons

We believe MPC-06-ID is positioned to fill the significant treatment gap in patients with moderate to severe CLBP after conservative treatment options have failed

1. Decision Resources: Chronic Pain December 2015

2. LEK & NCI opinion leader interviews, and secondary analysis

3. Simon et al – Discogenic Low Back Pain Phys Med Rehabil Clin N Am 25 (2014) 305–317

4. Shapiro CM Phys Med Rehabil Clin N Am 2014

5. Navigant: Commercial Assessment for a Proprietary Cell-Based Therapy for DDD in the U.S. and the EU3 – August 2014.

MPC-06-ID: Operational Update

- The current 360 patient Phase 3 trial is actively recruiting across US sites
- The 24-month results from the Company's 100-patient Phase 2 trial of MPC-06-ID for treatment of chronic low back pain were presented at the 24th Annual Scientific Meeting of the Spine Intervention Society and received the 2016 Best Basic Science Abstract award
- FDA has provided written guidance:
 - Use of a composite primary endpoint is acceptable for approval
 - Agreed thresholds for pain (50% decrease in VAS) and function (15 point improvement in ODI)
 - Two time points (12 and 24 months) for meeting pain and functional improvement criteria
 - No intervention at the treated level through 24 months

MPC-300-IV: Biologic Refractory Rheumatoid Arthritis (RA) – Market Opportunity

Ongoing randomized, controlled Phase 2 Trial in 48 patients with biologic refractory rheumatoid arthritis, comparing two doses of MPC-300-IV against placebo

Market opportunity

- There are approximately 5.3 million prevalent cases in the US, Japan, and EU5, of which there were 2.4 million in the US alone in 2014¹
- Incidence increases with age – 8.7 per 100,000 for ages 18-34 vs. 89 per 100,000 for ages 65-74²
- RA treatment is a approximately \$15 billion global market in 2014 projected to grow to over \$18 billion in 2024. primarily due to sales of the anti-TNF agents¹
- In the US, the anti-TNF refractory population is the fastest growing branded market segment, projected to increase by approximately 8% annually and potentially higher with the expected market entry and greater availability of anti-TNF biosimilars¹

Gap in treatment options

- One third of RA patients do not respond or cannot tolerate current biologic therapies³
 - Sustained remission defined by ACR 70 only occurs in 5-15% of patients on biologics⁵
 - Biologics are associated with increased incidence of opportunistic infections and malignancies⁴
- Indications for currently approved biologics target either a single cytokine or immune cell pathway even though RA involves multiple signals / pathways⁴
- Need for disease-modifying therapies that are well tolerated and induce remission in a greater percentage of patients (ACR 70) as early as possible in the disease management³

1. Decision Resources Rheumatoid Arthritis – Disease Landscape & Forecast - January 2016; Market Forecast Methodology; Access & Reimbursement – August 2016.

2. GlobalData®: Rheumatoid Arthritis Therapeutic – Pipeline Oct 2011

3. Decision Resources Rheumatoid Arthritis – Unmet Need – April 2016.

4. Information listed in the package insert of anti-TNF- α therapies such as Enbrel® (etanercept), Rituxan® (rituximab), Remicade® (infliximab), and Humira® (adalimumab).

5. Alivernini, S et. al. Arthritis Research & Therapy 2009, 11:R163

MPC-300-IV: Operational Update

- The Phase 2 trial of Mesoblast's intravenous product candidate, MPC-300-IV, in biologic refractory rheumatoid arthritis has completed enrollment and results of the 12 week primary endpoint were released in August 2016. An intravenous infusion of allogeneic MPCs was well tolerated in biologic refractory RA patients, without serious adverse events over 12 weeks
- A single intravenous MPC infusion in biologic refractory RA patients resulted in dose-related improvements in clinical symptoms, function, and disease activity, with the 2 million MPCs/kg dose providing the greatest benefit
- The responses to date in this 48-patient, randomized, placebo-controlled Phase 2 trial provide support for the potential of Mesoblast's allogeneic MPCs to be positioned early as a treatment option in RA patients who have previously received a prior anti-TNF or other biologic agent
- Given the large market opportunity, the Company believes that MPC-300-IV is well-positioned to advance through a strategic partnership into Phase 3 development for biologic refractory rheumatoid arthritis
- With respect to other indications of the MPC-300-IV product candidate, positive results from the randomized, placebo-controlled Phase 2 trial of MPC-300-IV in patients with diabetic nephropathy were published in the peer-reviewed journal *EBioMedicine*

MSC-100-IV / TEMCELL® HS Inj. : Acute Graft vs Host Disease

MSC-100-IV / TEMCELL® HS Inj. is targeting pediatric and adult patients with acute Graft Versus Host Disease (aGVHD) following allogeneic Bone Marrow Transplant (BMT)

Market opportunity

- ~30,000 allogeneic BMTs performed globally (~20K US/EU5) each year, ~20% pediatric^{1,2}
- ~3,700 allogeneic BMTs performed in Japan each year³
- ~50% of all US patients develop aGVHD (Grades II-IV)⁴

Unmet Need

- Steroid-resistant acute GvHD have a dismal prognosis, with mortality rates in excess of 85%
- No currently approved therapies for steroid refractory patients (ex Japan)
- Off-label options have mixed efficacy with high toxicity
- Significant need for a new treatment with a favorable risk / benefit profile

Path to market

- Japan product (TEMCELL® HS Inj.) launched; reimbursed up to ~\$195K for full treatment course⁵
- US product candidate (MSC-100-IV) currently in 60 patient open-label Phase 3 registration pediatric trial
- Highly targeted physician audience and commercial footprint for pediatric launch in US
- High risk adult population identified for Phase 3 trial
- Planned Interim Analysis Q4 2016, enrollment complete 1H 2017

We believe MSC-100-IV has potential to be first allogeneic non-hematopoietic stem cell products approved in USA, triggering a “halo” effect for Mesoblast’s other Tier 1 products

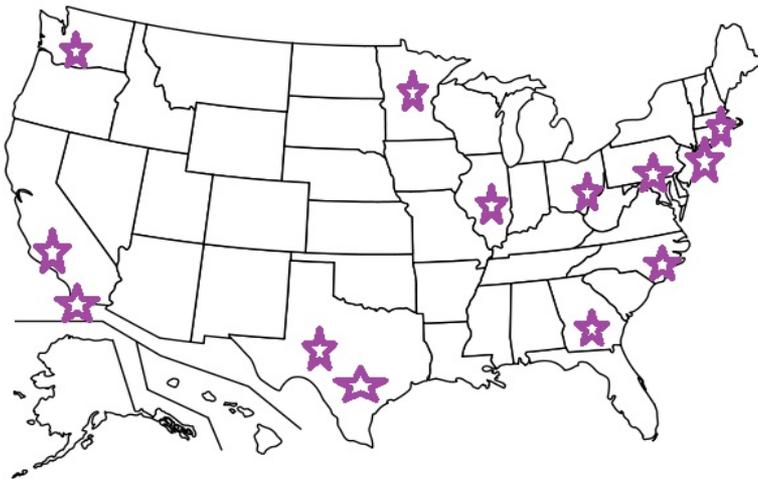
1. Gratwohl A et al Quantitative and qualitative differences in use and trends of hematopoietic stem cell transplantation: a Global Observational Study. Haematologica. 2013 Aug;98(8):1282-90.
2. CIBMTR, Decision resources GVHD Epi Nov 2012.
3. APBMT Annual Report Dec 2012; Assumes a growth rate of approximately 3% per year
4. Jagasia et al Risk factors for acute GVHD and survival after hematopoietic cell transplantation. 2012 January vol 119 (1).
5. Based on a ¥JPY = \$USD 0.009375 spot exchange rate as of the market close on November 11, 2016. Amounts are rounded. Source: Bloomberg.

MSC-100-IV North America aGVHD Market Opportunity

	Target Population	2015	Source
Epidemiology	Allogeneic Hematopoietic Stem Cell Transplants	10,200	<ul style="list-style-type: none"> US: estimated from 2013 CIBMTR (table 6) Canada: estimate based on general population size and US transplant activity per 10m Estimated 53% Rate: Jagasia, M., Arora, M., Flowers, M. (2012) Risk Factors for acute GVHD and Survival after Hematopoietic Cell Transplantation. Blood, 5 January (119):296-307 Estimated 54% Rate: Westin, J., Saliba, RM., Alousi, A. (2011) Steroid Refractory Acute GVHD: Predictors and Outcomes. Advances in Hematology (2011); 1-8
	Acute GVHD Grades II-IV	5,400	
	Steroid Refractory Acute GVHD Grades II-IV	2,900	
Target Population	Pediatric SR aGHVD Grades II-IV	600	<ul style="list-style-type: none"> Pediatric: estimated from Center for International Blood and Marrow Transplant Research -Transplant Activity Report Covering 2009-2013 Adult High Risk: <ul style="list-style-type: none"> MacMillan, ML., Robin, M., Harris, AC. (2015) A refined risk score for acute graft-versus-host disease that predicts response to initial therapy, survival, and transplant-related mortality. Biol Blood Marrow Transplant. Apr;21(4):761-7 Jagasia, M., Arora, M., Flowers, M. (2012) Risk Factors for acute GVHD and Survival after Hematopoietic Cell Transplantation. Blood, 5 January (119):296-307 CIBMTR: Current uses and outcomes of hematopoietic stem cell transplantation 2015 summary slides
	First-Line High Risk Adults with aGVHD	1,900	
	Total North America aGHVD Target Population	~2,500	

MSC-100-IV: Concentrated High Volume Centers Provide Compelling Low Cost Commercial Structure¹

Top Pediatric Transplant Centers



- There are 65 centers in the country that conduct allogeneic transplants in pediatrics
- ~ 50% of all of these transplants happen at 13 influential centers
- Broad overlap between high volume pediatric centers and influential adult centers

Top Adult Transplant Centers



- There are 108 centers in the country that conduct adult allogeneic transplants
- ~50% of all of these transplants happen at 19 influential centers

1. Source: Center for International Blood & Marrow Transplant Research.

MSC-100-IV: Product Development Strategy

■ **Manufacturing**

- Optimised process – modernized and harmonized
- Commercial readiness for launch

■ **Pediatrics**

- Complete targeted Phase 3, 60 patient open label clinical trial in SR-aGVHD for accelerated approval pathway (US)
- Market development and access work in parallel
- Launch pediatric product in 2018 in US

■ **Adults**

- Complete targeted Phase 3 study in high - risk subset of adult patients with aGVHD (with liver and gut disease)
- Market development and access work in parallel
- Launch adult product in 2021 in major markets

■ **Life cycle management and label expansion**

- Prophylaxis
- Acute GVHD, first-line

MSC-100-IV: Phase 3 Trial in Children with Steroid Refractory Acute Graft vs Host Disease (SR-aGVHD)

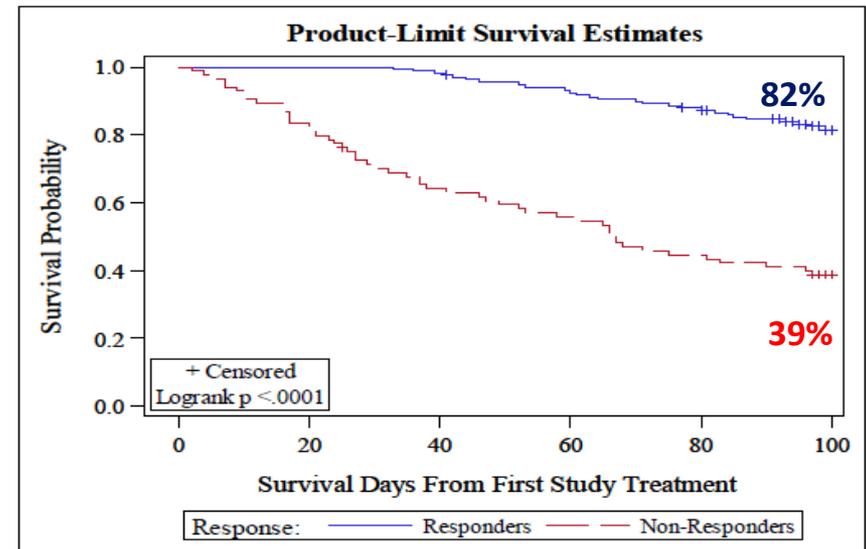
MSC-100-IV as first line therapy in children with SR-aGVHD (Day 28 response)

Response at Day 28	Randomized Placebo Controlled Trial		Open-label Expanded Access Program
	Placebo	MSC-100-IV	MSC-100-IV
Responder	3/14 (21.4%)	9/14 (64.3%)	29/36 (81%)
Non-responder	11/14 (78.6%)	5/14 (35.7%)	7/36 (19%)
	p-value = 0.0014		

Compared with placebo control patients, MSC-100-IV produced markedly superior overall response at day 28, a clinically meaningful endpoint (p=0.0014).

- Evidence that MSC-100-IV is effective when used as first line therapy in children with SR-aGVHD
- FDA agreement on 60 patient open label Phase 3 trial for accelerated US approval pathway
- Enrollment criteria: MSC-100-IV offered as first line therapy in children with SR-aGVHD

MSC-100-IV in children with SR-aGVHD who failed multiple other modalities (Day 100 survival)



Survival at Day 100 of pediatric patients treated with MSC-100-IV stratified by 28-Day responders vs non-responders, n=241

MSC-100-IV: Graft vs Host Disease: Pediatric GVHD001/GVHD002 Phase 3 Study

- Phase 3 study ongoing, ~ 40 sites planned¹
 - Multi-center, Single-Arm, Open-Label to evaluate efficacy and safety to day 100 (study 001) and from day 100 to day 180 (study 002)
 - At least 60 pediatric patients (2 months to 17 years inclusive)
 - aGVHD following allogeneic HSCT failing systemic corticosteroid therapy
 - Grades C and D aGVHD involving skin, liver and/or GI tract
 - Grade B aGVHD involving liver and/or GI tract with or without concomitant skin disease

Endpoints¹:

- Primary endpoint: Overall response at Day 28
- Key secondary endpoint: Survival at Day 100 in responders at Day 28
- Subjects evaluated at Days 28, 56 and 100 in study 001, and out to Day 180 in study 002

1. Clinicaltrials.gov identifier: NCT02652130.

GVHD001 Interim Futility Analysis Method and Results- November 2016

- Predefined Bayesian futility rule that determined the predictive probability of success using the primary endpoint of Day 28 overall response
- Method determined the likelihood of obtaining a statistically significant treatment effect at study completion, conditional on the data observed at this interim time point
- **DSMB notified Mesoblast that analysis was successful**
- Interim analysis outcome is consistent with what has previously been demonstrated for the product used in this indication under both expanded access protocol and earlier placebo-controlled trial
- Enrollment in the study is ongoing across multiple sites in the United States and will continue
 - Completion is expected in mid-2017
 - Commercial launch activities are underway

Other Operational Highlights

- **Award:** In recognition of the Company's continued clinical achievements, it was awarded the Frost & Sullivan Asia Pacific 2016 Cell Therapy Company of the Year award. The Frost & Sullivan awards identify and honor the best-in-class companies that have demonstrated excellence in their industry.
- **Vice Chair:** Mr William (Bill) A. Burns, former CEO of Roche Pharmaceuticals was appointed Vice Chair of Mesoblast after serving as a Mesoblast Non-Executive Director since 2014. In this new role, he will focus his considerable pharmaceutical industry expertise on activities relating to execution of major strategic partnerships and corporate transactions.
- **Intellectual Property:** The Company's intellectual property portfolio was further strengthened by the granting of a key patent by the United States Patent and Trademark Office covering the use of its MPCs in the treatment of rheumatic diseases.

Agenda

TIMELINES

Tier 1 Product Candidate Deliverables (Calendar Year)

Product Candidate	Programs	Milestones	2016				2017			
			Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
MPC-150-IM	Class II and III Heart Failure Class IV Heart Failure Requiring LVAD	Phase 3 Enrollment Complete								■
		Interim Results					■			
		Phase 2b trial results							■	
MPC-300-IV	Rheumatoid Arthritis (Biologic Refractory)	Top line results first cohort	■							
		Full trial results			■					
		6/9 month trial results				■	■			
MPC-06-ID	Chronic Low Back Pain Due to Degenerative Disc Disease	Phase 3 Enrollment Complete								■
		Phase 3 Interim Analysis					■			
MSC-100-IV / Temcell® HS Inj.	Acute Graft Versus Host Disease	TEMCELL® HS Inj. Launched in Japan	■							
		Interim Results			■					
		Phase 3 Enrollment Complete					■	■		

■ Milestone Achieved
 ■ Milestone Target





Thank You and Questions