mesoblast

Global Leader in Allogeneic Cellular Medicines for Inflammatory Diseases

Corporate Presentation Bell Potter Healthcare Conference

November 2022

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Our Mission

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



Financial Highlights

- □ At September 30, 2022, cash-on-hand was US\$85.5 million
- □ Up to an additional US\$40 million available from existing facilities subject to certain milestones
- Net cash usage for operating activities in the first quarter FY2023 was US\$14.3 million; this represented a reduction of US\$3.9 million, or 22%, on the comparative quarter in FY2022, and a reduction of \$US8.0 million, or 47%, on the comparative quarter in FY2021
- Total Revenue from royalties and milestones increased 37% to US\$10.2 million for FY2022 compared to US\$7.5 million for FY2021
- Royalties from sales of TEMCELL[®] HS Inj.¹ sold in Japan by our licensee in FY2022, were US\$8.7 million and US\$9.8 million on a constant currency² basis, an increase of 21% and 36% respectively versus FY2021, predominantly due to increased volume of product sold



Continued Growth in Revenues from Sales of TEMCELL in Japan for SR-aGVHD

- JCR Pharmaceuticals has exclusive rights to Mesoblast's MSC technology for acute GVHD in Japan
- FY2022 revenue from TEMCELL® HS Inj¹ royalties increased by 21% from the prior year period to US\$8.7 million
- Product adoption and reimbursement informs Mesoblast US commercial strategy for remestemcel-L in acute GVHD
- US addressable market for acute GVHD in children and adults is approx. eight-fold larger than Japan due to greater patient numbers, incidence and pharmacoeconomics





Remestemcel-L: BLA Response to FDA CRL for Steroid-Refractory Graft Versus Host Disease

- A major milestone in the Company's complete response to the FDA was the submission at the end of the quarter of substantial new information on clinical and potency assay items to the Investigational New Drug (IND) file for remestemcel-L in the treatment of children with SR-aGVHD, as guided by FDA.
- Survival outcomes have not improved over the past two decades for children or adults with the most severe forms of SR-aGVHD. The lack of any approved treatments for children under 12 means that there is an urgent need for a therapy that improves the dismal survival outcomes in children.
- Remestemcel-L treatment has shown improved 6-month survival in children with severe SR-aGVHD in comparison to contemporaneous controls treated with best available therapy.
- Mesoblast has optimized a potency assay that was in place at the time of the 54-patient Phase 3 trial in children with SR-aGVHD and which demonstrates a relationship between the product's activity in vitro and its effects on survival in the Phase 3 trial
- Additionally, Mesoblast has now generated data from the expanded access program (EAP 275) of 241 children which confirm the ability of the in-vitro potency assay to measure product activity relevant to survival outcomes.
- Remestemcel-L has been granted Fast Track Designation and BLA Priority Review from the FDA.



Late-Stage Clinical Pipeline



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

- 1. JCR Pharmaceuticals Co., Ltd. (JCR), has the right to develop mesenchymal stromal cells (MSCs) in certain fields for the Japanese market, including for the treatment of hematological malignancies, such as Graft vs Host Disease, and for hypoxic ischemic encephalopathy (HIE). Mesoblast has the right to use safety and efficacy data generated by JCR to support its development and commercialization plans for remestemcel-L in the US and other major healthcare markets, including for GVHD and HIE
- 2. Grünenthal has exclusive commercial rights to rexlemestrocel-L for chronic low back pain in Europe and Latin America/Caribbean
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7

Clinical Pipeline

Current Status and Anticipated Milestones





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

Significant Unmet Need with High Mortality

Treatment Options

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

Burden of Illness

- Acute GVHD is a lifethreatening complication that occurs in ~50% of patients receiving allogeneic bone marrow transplants (BMTs)¹
- Acute GVHD primarily affects skin, GI tract, and liver
- Steroid-refractory aGVHD is associated with mortality rates as high as 90%^{1,5} and significant extended hospital stay costs²

Market Opportunity

- More than 30,000 allogeneic BMTs performed globally (>20K US/EU) annually, ~20% pediatric^{3,4}
- Approx. 1,500 allogeneic BMTs in children and adolescents in US⁴



Steroid-refractory aGVHD is associated with mortality rates as high as 90%

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. HRSA Transplant Activity Report, CIBMTR, 2019 5. 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.



Remestemcel-L Improved Survival in Children with Steroid-Refractory Graft Versus Host Disease

Remestemcel-L improved survival in three controlled studies:

- 1. First-line therapy after steroids
 - 27 children in a randomized controlled Phase 3 trial of 260 patients with SR-aGVHD
 - 54 children in open-label Phase 3, 89% with Grade C/D disease, compared with 30 propensity controlled children in MAGIC cohort¹⁻³
- 2. Salvage therapy in 241 children after failure of steroids and other biologic agents
 - 51 children in open-label arm with Grade D disease, compared with 327 propensity-controlled children in CIBMTR database

Day 100 Survival	Remestemcel-L	Matched Controls
Protocol 280 (pediatric), Grade B-D	79% (n=14)	⁵ 54% (n=13)
Phase 3 (Study 001), Grade B-D	74% (n=54) ¹	57%² (n=30)³
Expanded Access Protocol 275	66% (n=241)	na
Expanded Access Protocol 275, Grade D	51% (n=51)	31% (n=327) ⁴

1. GVHD001 had 55 randomized patients, however one patient dropped out before receiving any dose of remestemcel-L; 2. Mount Sinai Acute GVHD International Consortium (MAGIC) - a group of ten BMT centers throughout the US and Europe whose purpose is to conduct ground-breaking clinical trials in GVHD, including developing informative biorepositories that assist in developing treatments that can guide GVHD therapy; 3. Two subjects in the MAGIC cohort had follow-up <100 days; these subjects are excluded from the respective survival analyses; 4. Data on file mesons before the mesons of th

Remestemcel-L has the Potential to Improve Bleak Long-Term Survival (>2 Years) in Pediatric SR-aGVHD



1. Adapted and redrawn from Figure 2 of MacMillan, M.L. et al. Pediatric acute GVHD: clinical phenotype and response to upfront steroids. Bone Marrow Transplant 55, 165-171 (2020);

2. Kurtzberg, J. et al. A Phase 3, Single-Arm, Prospective Study of Remestemcel-L, Ex Vivo Culture-Expanded Adult Human Mesenchymal Stromal Cells for the Treatment of Pediatric Patients Who Failed to Respond to Steroid Treatment for Acute Graft-versus-Host Disease. Biol Blood Marrow Transplant 26 (2020) 845-854



Remestemcel-L for Steroid-Refractory Graft Versus Host Disease in Highest-Risk Patients Significantly Greater Day 28 Overall Responses and Day 180 Survival in Highest-Risk Patients (Baseline MAP ≥ 0.29)





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Potential for Label Extension: Remestemcel-L for Acute Respiratory Distress Syndrome (ARDS)

Remestemcel-L Plus Dexamethasone Shows Synergy in Mortality Reduction and Improvement in ARDS Severity* in Exploratory COVID-19 Population < 65 years old



Treated Patients (mITT) < 65 years old on Dexamethasone (n=73)





Rem-L Placebo

* Measured as resolution and/or improvement of ARDS as defined by the Berlin criteria at Days 7, 14, 21, and 30 post-randomizations mesoblas

Remestemcel-L: Regulatory Pathway to Potential EUA for COVID-19 ARDS

- Acute respiratory distress syndrome (ARDS) remains a major cause of mortality for COVID-19 patients who are immunocompromised, unvaccinated, or with comorbidities, as well as those with seasonal influenza and other pathogens
- FDA has advised Mesoblast that an additional clinical study in acute respiratory distress syndrome (ARDS) due to COVID19, if statistically positive, could provide sufficient evidence to support an emergency use authorization (EUA)
- Mesoblast has entered into a non-binding Memorandum of Understanding (MOU) with Vanderbilt University Medical Center, which coordinates and works closely with clinical investigators at over 40 sites across the United States focused on studying ARDS and other critical illnesses
- The MOU proposes a collaboration toward the design and execution of a second COVID-19 trial for remestemcel-L; to jointly develop a trial protocol; and seek FDA approval for the trial



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Rexlemestrocel-L - Opportunity in Chronic Low Back Pain

A New Paradigm for Treatment of Chronic Low Back Pain due to Degenerative Disc Disease

Burden of Illness

- Back pain causes more disability than any other condition¹
- Inflicts substantial direct and indirect costs on the healthcare system,¹ including excessive use of opioids in this patient population

Treatment Options

- Minimal treatment options for patients with chronic low back pain (CLBP) who fail conservative therapy include opioids and surgery
- 50% of opioid prescriptions are for CLBP³
- Durable improvement in pain has potential to reduce opioid use and prevent surgical intervention

Market Opportunity

Over 7m patients are estimated to suffer from CLBP due to degenerative disc disease (DDD) in each of the U.S. and E.U.5 ^{3,4,5}

Healthy Disc DDD DDD

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. Simon, J., McAuliffe, M., Shamim, F. (2015) Discogenic Low Back Pain. Phys Med Rehabil Clin N Am 25 (2014) 305-317., 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. HealthCare Utilization and Cost of Discogenic Lower Back Pain in the US - Anthem/HealthCore.



The Patient Treatment Journey

Rexlemestrocel-L Potential for First-Line CLBP associated with DDD, Refractory to Conservative Treatment





Phase 3 Trial Outcomes - Rexlemestrocel-L for Chronic Low Back Pain

Single Injection of Rexlemestrocel-L + HA Results in >Three Years of Pain Reduction

Greatest pain reduction was observed in the pre-specified population of subjects with CLBP duration shorter than the baseline study median of 68 months (n=202) with significantly greater reduction (nominal p-value < 0.05) at all time points analyzed over 36 months compared with saline controls



Market Access & Pricing Insights: Pricing will be Driven by Overall Value Offering; US Reference Pricing Suggests Higher Price Points for Disease Modifying Agents





Rexlemestrocel-L - Phase 3 Trial in Chronic Low Back Pain

- FDA Office of Tissues and Advanced Therapies (OTAT) agreed with Mesoblast's proposal for mean pain reduction at 12 months to serve as the primary endpoint of the second Phase 3 trial and as an approvable indication for the product
- Mean functional improvement and reduction in opioid use as secondary endpoints
- The planned upcoming US trial will include at least 20% of subjects from the EU to support submissions to both FDA and EMA
- Active discussions ongoing with key investigators and advisors on final protocol design



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Rexlemestrocel-L - 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)

 Muntner BEJ, et al. Heart Disease and Stroke Statistics-2019 Update: A Report From the American Heart Association. Circulation. Feb 19, 2019.
United States Food & Drug Administration. Treatment for Heart Failure: Endpoints for Drug Development. Draft Guidance. June 2019.
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;364:1223.
Shah KS, et al. Heart Failure with Preserve, Borderline, and Reduced Ejection Fraction; 5-Year Outcomes. JACC. 2017;Nov12.



The Patient Treatment Journey

25

Rexlemestrocel-L for Chronic Heart Failure

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/AHAHFSA 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 in Heart Failure with Reduced Ejection Fraction (HFrEF)

Rexlemestrocel-L Improved Left Ventricular Systolic Function, as Measured by Left Ventricular Ejection Fraction (LVEF) at 12 Months: Potential Early Surrogate Endpoint

- In all treated patients (n=537) rexlemestrocel-L resulted in 52% greater increase in LVEF from baseline to 12 months compared with controls
- While both groups had similar LVEF at baseline (28.7% and 28.6%), at 12 months least squared mean change from baseline was 5.0 for the rexlemestrocel-L group and 3.3 for controls (p=0.021)
- In treated patients with CRP >2 (n=301) rexlemestrocel-L resulted in 86% greater increase in LVEF from baseline to 12 months compared with controls
- While both groups had similar LVEF at baseline (29.1% and 28.2%), at 12 months least squared mean change from baseline was 5.6 for the rexlemestrocel-L group and 2.9 for controls (p=0.005)



DREAM-HF Phase 3 Trial in HFrEF

Rexlemestrocel-L Reduced Incidence of 3-Point Composite MACE - CV Death, MI or Stroke - Compared to Controls Across All 537 Treated Patients, with Enhanced Effect in Those with Active Inflammation as Measured by CRP >2



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



MACE=Major Adverse Cardiovascular Event; TTFE=Time To First Event; MI=Myocardial Infarction (Heart Attack)



LVEF, 2-point MACE, and recurrent hospitalizations due to heart attack or stroke were pre-specified endpoints and the 3-point MACE was a post-hoc analysis of pre-specified endpoint components

27

Major Clinical & Regulatory Milestones Next 12 Months

Remestemcel-L

A major milestone in the Company's complete response to the FDA was the submission at the end of the quarter of substantial new information on clinical and potency assay items to the Investigational New Drug (IND) file for remestemcel-L in the treatment of children with SR-aGVHD, as guided by FDA.



Potential FDA approval of BLA H1 CY2023, and planned US product launch

Mesoblast and Vanderbilt University Medical Center, which coordinates a clinical trial network at over 40 sites across the US focused on ARDS, to jointly develop a trial protocol to confirm the previously observed reduction in mortality in COVID-19 ARDS patients under age 65.

Rexlemestrocel-L

- FDA clearance by year end 2022 to commence a pivotal study for potential marketing approval of rexlemestrocel-L in chronic low back pain due to degenerative disc disease
- Plan to meet with FDA under existing RMAT designation to discuss common mechanism of action in HFrEF including those with LVADs, and potential pathway to marketing approval



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Thank You