mesoblast

the regenerative medicine company

Corporate Update on Remestemcel-L

- Strategic Collaboration with Novartis
- COVID-19 ARDS

ASX: MSB; Nasdaq: MESO

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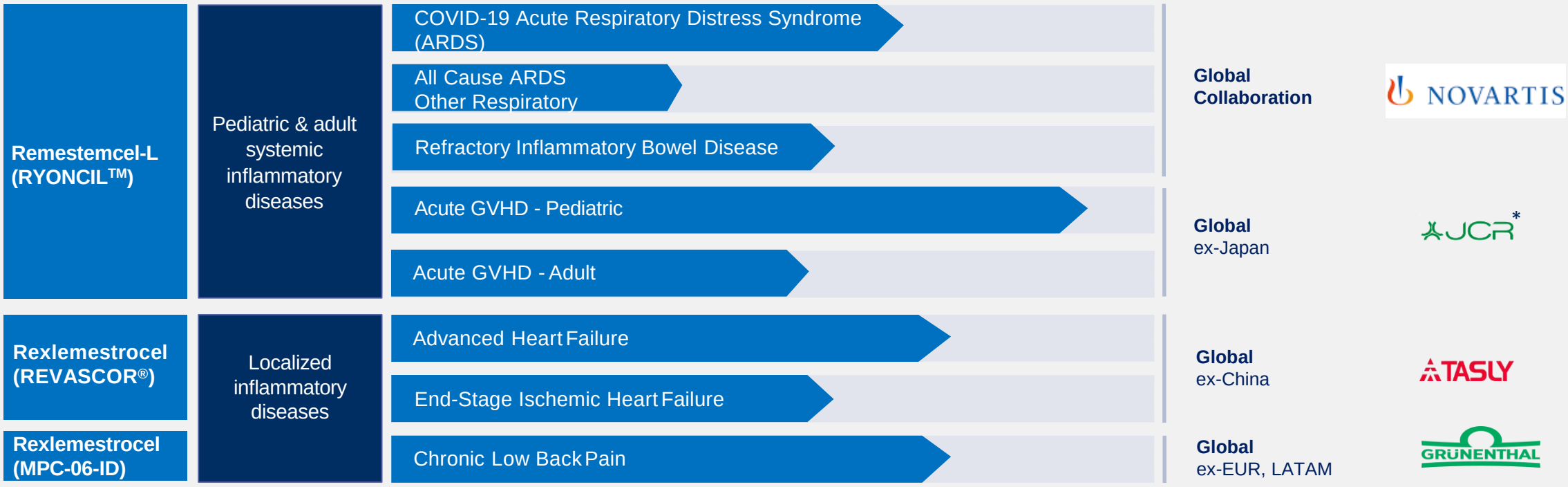
Product Pipeline



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

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 successful completion 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

Key Terms of Collaboration with Novartis

- Novartis will make a US$50 million upfront payment including US$25 million in equity*
- Mesoblast may receive:
  - A total of US$505 million pending achievement of pre-commercialization milestones for ARDS indications;
  - Up to an additional US$50 million reimbursement on the achievement of certain milestones related to the successful implementation of its next-generation manufacturing processes;
  - Additional payments post-commercialization of up to US$750 million based on achieving certain sales milestones; and
  - Tiered double-digit royalties on product sales
- From the initiation of a Phase 3 trial in all-cause ARDS, Novartis will fully fund global clinical development for all-cause ARDS and potentially other respiratory indications
- Mesoblast will be responsible for clinical and commercial manufacturing and Novartis will purchase commercial product under agreed pricing terms
- Novartis will be responsible for any capital expenditure required to meet increased capacity requirements for manufacture of remestemcel-L

* 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 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
- On November 17, a Type A meeting was held with the FDA to discuss the review of the Biologics License Application for remestemcel-L and a potential pathway for accelerated approval with a post-approval requirement to conduct an additional randomized controlled study in patients 12 years and older
- The definitive outcome of the Type A meeting will not be known until Mesoblast receives the formal minutes which are expected within 30 days of the meeting, however it appears that the current FDA review team will not agree to accelerated approval
- If accelerated approval is not agreed to by the current review team, Mesoblast will request a further Type A meeting to initiate the well-established FDA dispute resolution pathway

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

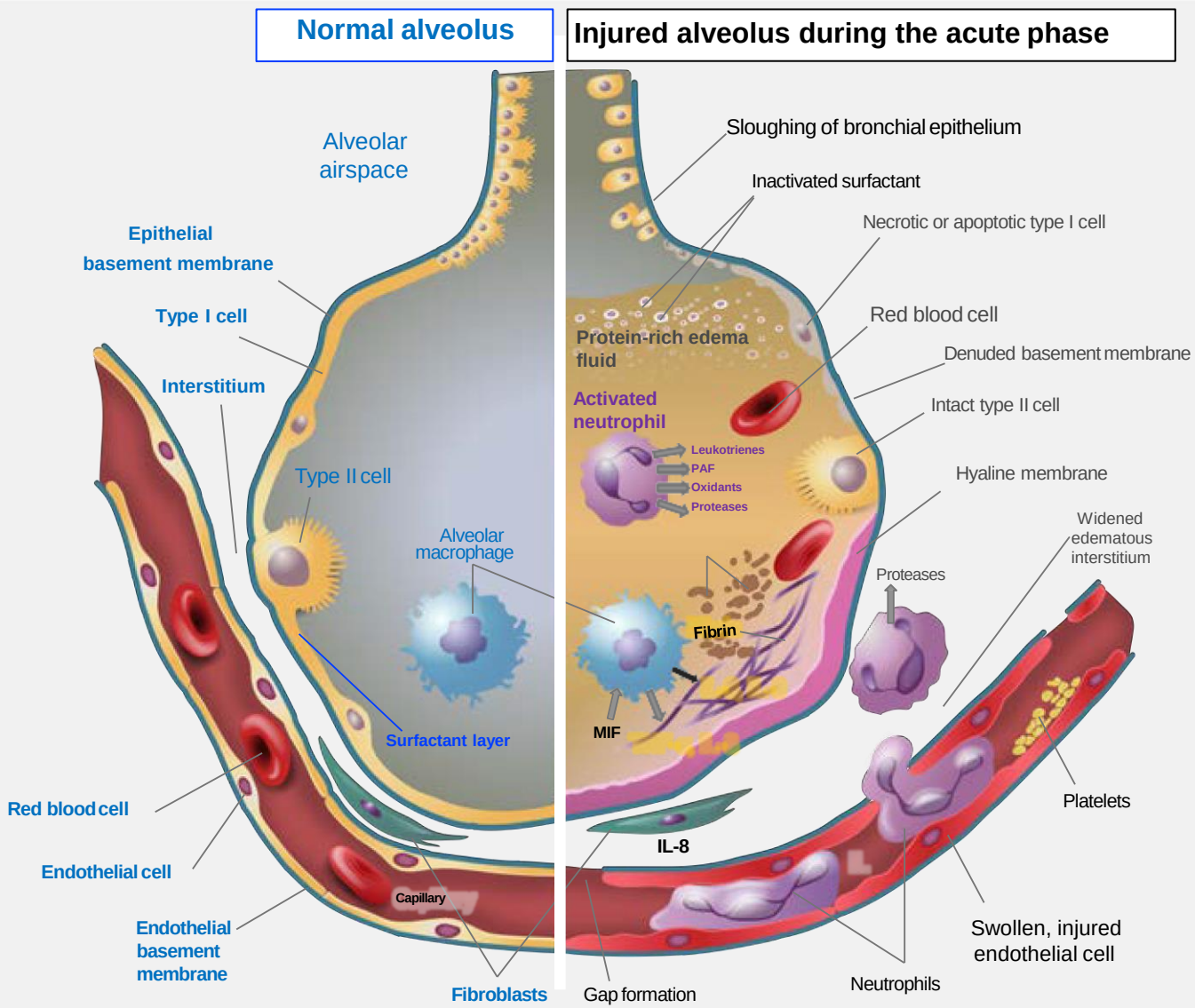
Remestemcel-L: Potential Treatment in Severe Inflammatory Conditions

Remestemcel-L for ARDS – Major Unmet Need

- Multiple triggers including viral (COVID-19, influenza) or bacterial infections
- Typically requires extended ICU hospitalization and intervention by ventilation
- ~40-80% mortality in viral induced ARDS[1-4]
- Up to 61,000 deaths per year in US alone from influenza ARDS[5]
- Intravenous delivery of remestemcel-L results in selective migration to the lungs making inflammatory lung disease an ideal target for this therapy
- COVID-19 ARDS has the highest mortality due to the most severe inflammatory cytokine storm in the lungs
- The extensive safety data of remestemcel-L and its anti-inflammatory effects in aGVHD makes a compelling rationale for evaluating remestemcel-L in COVID-19 ARDS

1. Matthay MA., et al. Acute Respiratory Distress Syndrome. Nature 2019 5:18. doi: 10.1038/s41572-019-0069-0; 2. Bellani G, Laffey JG, Pham T, et al. Epidemiology and patterns of care, and mortality for patients with acute respiratory distress syndrome in intensive care units in 50 countries. JAMA 2016;315:788-800; 3. Petrilli CM et al. Factors associated with hospitalization and critical illness among 4,103 patients with Covid-19 disease in New York City. MedRxiv 2020; 4. Gibson PG., et al. COVID-19 ARDS: clinical features and differences to “usual” pre-COVID ARDS. Med J Aust. 24 April 2020 5. Centers for Disease Control and Prevention. Disease Burden of Influenza. https://www.cdc.gov/flu/about/burden/index.html

ARDS due to COVID-19, Influenza & Bacterial Infection - Pathophysiology



- Activation of alveolar M1 macrophages results in cytokine storm
- Influx of neutrophils results in proteolytic destruction
- Aberrant secretion of fluid by alveolar cells
- Interstitial edema, cell death and influx of inflammatory cells

Source: Matthay MA, Zimmerman GA. Am J Respir Cell Mol Biol. 2005;33:319-27

Promising Pilot Data in Adults & Children with COVID-19

Compassionate Use Emergency IND in Ventilator-Dependent Adults with COVID-19 ARDS

- 12 patients with moderate or severe ARDS received two infusions of remestemcel-L within five days at Mt. Sinai Hospital in New York City
- Nine patients (75%) successfully came off ventilator support at a median of 10 days and were discharged from hospital
- This contrasts with only 9% of all COVID-19 patients able to be extubated and a 12% survival rate in two major NY hospital networks during same time period[1,2]

Children with Multisystem inflammatory Syndrome (MIS-C) due to COVID-19

- In approximately 50% of cases, MIS-C is associated with significant cardiovascular complications that directly involve heart muscle and may result in decreased cardiac function
- Mesoblast has established an EAP which provides physicians with access to remestemcel-L in COVID-19 infected children aged 2 months-17 years with cardiovascular and other complications of MIS-C
- Two children with significant cardiac dysfunction, normalized after two infusions and discharged from the hospital

1 Petrilli CM et al. Factors associated with hospitalization and critical illness among 4,103 patients with Covid-19 disease in New York City. MedRxiv 2020 doi: https://www.medrxiv.org/content/10.1101/2020.04.08.20057794v1.full.pdf
2. Richardson S et al. Presenting characteristics, comorbidities, and outcomes among 5700 patients hospitalized with COVID-19 in the New York City area. JAMA 2020. doi:10.1001/jama.2020.6775

Key Milestones for Remestemcel-L in COVID-19 ARDS

- Phase 3 multi-center, randomized, controlled trial of remestemcel-L versus placebo in ventilator-dependent patients with moderate/severe ARDS due to COVID-19
- Up to 300 patients randomized 1:1 to receive placebo or two infusions of remestemcel-L within 3-5 days
- Primary endpoint all cause mortality up to 30 days; key secondary endpoint days alive off ventilator within 60 days
- Full recruitment expected to complete during Q1 CY2021
- DSMB recommended continuation of the trial after reaching first (30%) and second (45%) interim analyses
- Trial enrollment has now surpassed 180 patients
- Plan to seek Emergency Use Authorization (EUA) subject to positive data read-out

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