

## asx announcement

# REXLEMESTROCEL-L TO BE HIGHLIGHTED AT MAXIM'S PANEL ON LATE-STAGE ADVANCEMENTS IN HEART FAILURE THERAPEUTICS AND MANAGEMENT

Melbourne, Australia; July 12, and New York, USA; July 11, 2022: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today announced that rexlemestrocel-L, its allogeneic "off-the-shelf" product candidate for the treatment of chronic heart failure (CHF) with reduced ejection fraction (HFrEF), will be highlighted in a panel discussion titled "Late-Stage Advancements in Heart Failure Therapeutics and Management", presented by Maxim Group LLC and hosted by M-Vest, on Thursday, July 14th, 2022 at 10:00 a.m. ET. The link to the webcast is available here.

Rexlemestrocel-L is being developed as an immunomodulatory therapy to address the high degree of inflammation in the heart and in the circulation that is present across the spectrum of HFrEF patients, from New York Heart Association (NYHA) class II through end-stage CHF, in order to reduce the high rate of major cardiac events and complications. This investigational therapy has been trialled in two large placebo-controlled randomized studies in patients with CHF, a 565-patient trial in NYHA class II/III patients with chronic heart failure and reduced ejection fraction (HFrEF) and a 159-patient trial in end-stage chronic heart failure (CHF) patients implanted with a left ventricular assist device (LVAD). Rexlemestrocel-L has US Food and Drug Administration (FDA) Regenerative Medicine Advanced Therapy (RMAT) and Orphan Drug designations for patients with end-stage CHF implanted with an LVAD.

Heart failure affects approximately 6.5 million people in the United States and 26 million people globally, with increasing prevalence and incidence. The mortality rate approaches 50% at 5 years as patients progress beyond NYHA class II disease in parallel with increasing inflammation in the heart and in the circulation. Despite recent approvals of new therapies for HFrEF, including SGLT2 inhibitors, that have reduced hospitalizations due to reversible volume-related events, NYHA class II/III HFrEF patients with inflammation remain at high risk for cardiac death, heart attacks and strokes. Over 60,000 patients annually in the US progress to end-stage heart failure (NYHA class IV) and these patients have a one-year mortality exceeding 50%. Use of LVADs in end-stage heart failure patients to improve survival is gaining momentum, with approximately 5,500 LVADs implanted annually in the US. However, systemic inflammation associated with major life-threatening gastrointestinal bleeding high rates of rehospitalization remain a major obstacle to greater LVAD use. The survival is gained annually in the US. The survival is gained annually in the US annually in the US annually in the US. The survival is gained annually in the US annually in the US annually in the US annually in the US. The survival is gained annually in the US an

#### **About Mesoblast**

Mesoblast is a world leader in developing allogeneic (off-the-shelf) cellular medicines for the treatment of severe and life-threatening inflammatory conditions. The Company has leveraged its proprietary mesenchymal lineage cell therapy technology platform to establish a broad portfolio of late-stage product candidates which respond to severe inflammation by releasing anti-inflammatory factors that counter and modulate multiple effector arms of the immune system, resulting in significant reduction of the damaging inflammatory process.

Mesoblast has a strong and extensive global intellectual property portfolio with protection extending through to at least 2041 in all major markets. The Company's proprietary manufacturing processes yield industrial-scale, cryopreserved, off-the-shelf, cellular medicines. These cell therapies, with defined pharmaceutical release criteria, are planned to be readily available to patients worldwide.

Mesoblast is developing product candidates for distinct indications based on its remestemcel-L and rexlemestrocel-L allogeneic stromal cell technology platforms. Remestemcel-L is being developed for inflammatory diseases in children and adults including steroid refractory acute graft versus host disease, biologic-resistant inflammatory bowel disease, and acute respiratory distress syndrome. Rexlemestrocel-L is in development for advanced chronic heart failure and chronic low back pain. Two products have been commercialized in Japan and Europe by Mesoblast's licensees, and the Company has established commercial partnerships in Europe and China for certain Phase 3 assets.

Mesoblast has locations in Australia, the United States and Singapore and is listed on the Australian Securities Exchange (MSB) and on the Nasdaq (MESO). For more information, please see <a href="https://www.mesoblast.com">www.mesoblast.com</a>, LinkedIn: Mesoblast Limited and Twitter: @Mesoblast

#### **Footnotes**

- 1. AHA's 2017 Heart Disease and Stroke Statistics
- 2. Ponikowski P., et al. Heart Failure: Preventing disease and death worldwide. *European Society of Cardiology*. 2014; 1: 4-25
- 3. Gustafsson F, Rogers JG. Left ventricular assist device therapy in advanced heart failure: patient selection and outcomes. European Journal of Heart Failure 2017;19:595-602.
- 4. United Network for Organ Sharing
- 5. Agency for Healthcare Research and Quality Healthcare Cost and Utilization Project Claims Analysis ICD- 37.6.
- 6. Data on file
- 7. Chatterjee A, Feldmann C, Hanke JS (2018) The momentum of HeartMate 3: a novel active magnetically levitated centrifugal left ventricular assist device (LVAD). J Thorac Dis 10 (Suppl 15): S1790-S1793.
- 8. 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.

#### **Forward-Looking Statements**

This press release 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 forwardlooking 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. Forwardlooking 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. Forward-looking statements include, but are not limited to, statements about: the initiation, timing, progress and results of Mesoblast's preclinical and clinical studies, and Mesoblast's research and development programs; Mesoblast's ability to advance product candidates into, enroll and successfully complete, clinical studies, including multi-national clinical trials; Mesoblast's ability to advance its manufacturing capabilities; the timing or likelihood of regulatory filings and approvals (including BLA resubmission), manufacturing activities and product marketing activities, if any; the commercialization of Mesoblast's product candidates, if approved; regulatory or public perceptions and market acceptance surrounding the use of stem-cell based therapies; the potential for Mesoblast's product candidates, if any are approved, to be withdrawn from the market due to patient adverse events or deaths; the potential benefits of strategic collaboration agreements and Mesoblast's ability to enter into and maintain established strategic collaborations; Mesoblast's ability to establish and maintain intellectual property on its product candidates and Mesoblast's ability to successfully defend these in cases of alleged infringement; the scope of protection Mesoblast is able to establish and maintain for intellectual property rights covering its product candidates and technology; estimates of Mesoblast's expenses, future revenues, capital requirements and its needs for additional financing; Mesoblast's financial performance; developments relating to Mesoblast's competitors and industry; and the pricing and reimbursement of Mesoblast's product candidates, if approved. You should read this press release together with our risk factors, in our most recently filed reports with the SEC or on our website. Uncertainties and risks that may cause Mesoblast's actual results, performance or achievements to be materially different from those which may be expressed or implied by such statements, and accordingly, you should not place undue reliance on these forward-looking statements. We do not undertake any obligations to publicly update or revise any forward-looking statements, whether as a result of new information, future developments or otherwise.

Release authorized by the Chief Executive.

### For more information, please contact:

#### Corporate Communications / Investors

Paul Hughes

T: +61 3 9639 6036

E: investors@mesoblast.com

#### Media

Sumit Media Grant Titmus

T: +61 419 388 161

E: grant@sumitmedia.com.au

Rubenstein Tali Mackay

E: tmackay@rubenstein.com