

## asx announcement

## CHAIRMAN'S ADDRESS TO SHAREHOLDERS 2020 MESOBLAST ANNUAL GENERAL MEETING

This has been an unprecedented year due to the coronavirus pandemic, its impact on human health, and the associated collateral economic damage worldwide. The Mesoblast team has responded with great agility and resilience to this urgent medical challenge, creatively applying our technology platform to develop a potential treatment for ventilated patients with moderate to severe acute respiratory distress syndrome (ARDS) due to COVID-19. Through a deep understanding of the mechanism of action and by utilizing clinical and regulatory experience, our team was able to apply these learnings to tackle the primary cause of death due to COVID-19.

The rapid pivot of remestemcel-L from steroid-refractory acute graft versus host disease to ARDS has led to an exclusive worldwide license and collaboration agreement with Novartis, a leading global medicines company. This exciting collaboration will leverage the demonstrated ability of Novartis to rapidly move from clinical to commercial scale with cell-based therapies. It will also play a role in the successful development and potential commercialization of remestemcel-L, as will the nearly two decades of experience Novartis has in delivering first-in-class products that address areas of unmet respiratory need.

Even as COVID-19 vaccines become available, patients who have co-morbidities or are older are likely to continue to be at high risk of ARDS and subsequently death. This is why having a potential treatment that reduces mortality in these patients is so important. The loss of life due to the COVID-19 pandemic is the driving force behind our shared commitment to make available our transformational cellular therapy to these highest risk patients. We look forward to working with Novartis as they develop remestemcel-L for all-cause ARDS, as well as potentially other respiratory conditions.

In parallel, we will continue to rigorously pursue an approval pathway for remestemcel-L in the treatment of children with steroid-refractory acute graft versus host disease, another life-threatening inflammatory condition with no approved therapies for those under 12 years of age. We are seeking accelerated approval from the United States Food and Drug Administration (FDA) with a post-approval requirement to conduct an additional randomized controlled study in patients 12 years and older.

Beyond remestemcel-L, we have a maturing and diverse portfolio of cellular medicines for other serious acute and chronic inflammatory conditions. Upcoming readouts of Phase 3 trials in advanced chronic heart failure and chronic low back pain due to degenerative disc disease will potentially increase our near and mid-term value proposition.

On behalf of your Board of Directors, I would like to take this opportunity to express our deep gratitude for your ongoing support and confidence in our technology.

## **About Mesoblast**

Mesoblast Limited (ASX:MSB; Nasdaq:MESO) is a world leader in developing allogeneic (off-the-shelf) cellular medicines. The Company has leveraged its proprietary mesenchymal lineage cell therapy technology platform to establish a broad portfolio of commercial products and late-stage product candidates. Mesoblast has a strong and extensive global intellectual property (IP) portfolio with protection extending through to at least 2040 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.

Remestemcel-L is being developed for inflammatory diseases in children and adults including steroid-refractory acute graft versus host disease and moderate to severe acute respiratory distress syndrome. Mesoblast is completing Phase 3 trials for its product candidates for advanced 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

## **Forward-Looking Statements**

This announcement 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, 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 further information, please contact:

Media

Julie Meldrum T: +61 3 9639 6036

E: julie.meldrum@mesoblast.com

Investors

Schond Greenway T: +212 880 2060

E: schond.greenway@mesoblast.com

Kristen Bothwell T: +1 917 613 5434

E: kbothwell@rubenstein.com

Paul Hughes

T: +61 3 9639 6036

E: paul.hughes@mesoblast.com