

DATA SAFETY MONITORING BOARD RECOMMENDS CONTINUATION OF REMESTEMCEL-L PHASE 3 TRIAL IN COVID-19 PATIENTS WITH ACUTE RESPIRATORY DISTRESS SYNDROME

Melbourne, Australia; September 4, 2020 and New York, USA; September 3, 2020: Mesoblast Limited (ASX: MSB; Nasdaq: MESO) today announced that the independent Data Safety Monitoring Board (DSMB) recommended continuation of the Phase 3 trial of remestemcel-L in patients with moderate to severe acute respiratory distress syndrome (ARDS) due to COVID-19 infection, following completion of trial's first interim analysis. The analysis was performed on the first 30% of the total target of randomized patients, with the DSMB reviewing the trial's primary endpoint, all-cause mortality within 30 days of randomization and all safety data.

Mesoblast Chief Medical Officer Dr Fred Grossman said: "We are very pleased with the recommendation by the DSMB. This important trial seeks to confirm whether remestemcel-L improves survival in ventilated COVID-19 patients with moderate to severe ARDS, where death rates remain high despite best existing treatments."

The multi-center study includes three interim analyses for stopping accrual early for efficacy or futility when 30%, 45% and 60% of the total target of randomized patients have reached the primary endpoint. Up to 300 patients are planned to be randomized 1:1 in the double-blinded Phase 3 trial to receive either two intravenous infusions of remestemcel-L within five days, or placebo, on top of maximal care. The primary endpoint is all-cause mortality within 30 days of randomization. The key secondary endpoint is days alive off mechanical ventilatory support within 60 days of randomization. The trial is expected to complete recruitment during Q4 CY2020.

About Remestemcel-L

Mesoblast's lead allogeneic cell therapy product candidate, remestemcel-L, is an investigational therapy comprising culture-expanded mesenchymal stem cells derived from the bone marrow of an unrelated donor. Remestemcel-L is believed to have immunomodulatory properties to counteract the cytokine storms that are implicated in various inflammatory conditions by down-regulating the production of pro-inflammatory cytokines, increasing production of anti-inflammatory cytokines, and enabling recruitment of naturally occurring anti-inflammatory cells to involved tissues.

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.

Mesoblast's Biologics License Application to seek approval of its product candidate RYONCIL™ (remestemcel-L) for pediatric steroid-refractory acute graft versus host disease has been accepted for priority review by the United States Food and Drug Administration (FDA), and if approved, product launch in the United States is expected in 2020. Remestemcel-L is also being developed for other inflammatory diseases in children and adults including moderate to severe acute respiratory distress syndrome (ARDS). 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 www.mesoblast.com, 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 forward-looking 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. Forward-looking 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 timing, progress and results of Mesoblast's preclinical and clinical studies; Mesoblast's ability to advance product candidates into, enroll and successfully complete, clinical studies; the timing or likelihood of regulatory filings and approvals; and the pricing and reimbursement of Mesoblast's product candidates, if approved; 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. 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.

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