asx announcement

mesoblast

RANDOMIZED CONTROLLED PHASE 3 TRIAL OF REMESTEMCEL-L FOR REDUCED MORTALITY IN COVID-19 ACUTE RESPIRATORY DISTRESS SYNDROME SURPASSES 50% ENROLLMENT

Melbourne, Australia; October 13 and New York, USA; October 12, 2020: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, announced today that the randomized controlled Phase 3 trial of remestemcel-L on top of maximal care in ventilator-dependent patients with acute respiratory distress syndrome (ARDS) due to COVID-19 infection has surpassed 50% enrollment. The trial's primary endpoint is reduction in 30-day mortality relative to maximal care. ARDS continues to be the primary cause of death in COVID-19 patients.

Mesoblast Chief Medical Officer Dr Fred Grossman said: "There is an urgent need for targeted treatments to reduce the continued high mortality in COVID-19 ARDS patients who are dependent on mechanical ventilators. We expect to complete the enrollment target in this important trial by the end of the year as the enrollment rate continues to increase in line with the surge in new infections across the United States."

The randomized, double-blinded, controlled trial is enrolling up to 300 ventilator-dependent patients with moderate to severe ARDS, and aims to confirm findings from a pilot study at New York's Mt Sinai Hospital in March-April this year. In that study, nine of 12 ventilator-dependent patients (75%) were successfully discharged from hospital a median of 10 days after receiving two intravenous doses of remestemcel-L within five days. The United States Food and Drug Administration (FDA) cleared the Phase 3 trial to commence enrollment following a review of the trial design and clinical endpoints.

Remestemcel-L is being developed for the treatment of severe diseases associated with excessive cytokine storm, including COVID-19 ARDS and acute graft versus host disease. The ability to reduce production of damaging pro-inflammatory cytokines, which are central to tissue damage in both ARDS and acute GVHD, provides a unifying mechanism of action for remestemcel-L in the treatment of these diseases. The results from the randomized controlled Phase 3 trial in COVID-19 ARDS patients, if positive, will build upon the totality of the evidence for the effectiveness of remestemcel-L in adults and children with severe and life-threatening inflammatory conditions.

The trial's independent Data Safety Monitoring Board (DSMB) recently completed an interim analysis of safety and efficacy including primary endpoint of all-cause mortality within 30 days of randomization of the trial's first 90 enrolled patients and recommended that the trial continue as planned. The DSMB will perform a second interim analysis in early November when 45% of the enrollment target has completed 30 days of follow-up.

About Remestemcel-L
Mesoblast's lead product candidate, remestemcel-L, is an investigational therapy comprising culture-expanded mesenchymal stem cells derived from the bone marrow of an unrelated donor. It is thought 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.

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 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. All statements other than statements of historical fact are forward-looking statements, which are often indicated by terms such as "anticipate," "believe," "could," "estimate," "expect," "goal," "intend," "likely," "look forward to," "may," "plan," "potential," "predict," "project," "should," "will," "would" and similar expressions and variations thereof. 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. The risks, uncertainties and other factors that may impact our forward-looking statements include, but are not limited to: 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. Unless required by law, 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

Kristen Bothwell
T: +1 917 613 5434
E:kbothwell@rubenstein.com

Investors
Schond Greenway
T: +212 880 2060
E: schond.greenway@mesoblast.com

Paul Hughes
T: +61 3 9639 6036
E: paul.hughes@mesoblast.com