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MESOBLAST RECEIVES ETHICS APPROVAL TO TREAT COVID-19 PATIENTS IN AUSTRALIA

Melbourne, Australia; September 2, 2020 and New York; USA; September 1, 2020: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today announced that it has received ethics approval to include Australian hospitals in the Phase 3 randomized controlled trial of remestemcel-L in ventilator-dependent COVID-19 patients with acute respiratory distress syndrome (ARDS).

Participating hospitals in Melbourne and Sydney have been granted approval by the Human Research Ethics Committee of Monash Health and will join more than 17 leading US medical centers already in the Phase 3 trial. This study is being conducted by the US National Institutes of Health–funded Cardiothoracic Surgical Trials Network, and cleared by the US Food and Drug Administration (FDA).

Mesoblast Chief Executive Dr Silviu Itescu stated: "As an Australian company developing a potential treatment for COVID-19 ARDS, the primary cause of death in patients infected with COVID-19, we have a responsibility to evaluate remestemcel-L in Australian patients as the country continues to grapple with COVID-19."

Principal Investigator A/Prof. Tony Goldschlager said: "We are pleased that Monash Health is involved in this important COVID-19 trial, especially given the extensive experience we have had with Mesoblast's mesenchymal lineage cells."

The clinical protocol evaluating remestemcel-L in up to 300 patients in the Phase 3 trial was based on results from a pilot study using remestemcel-L under emergency compassionate care at Mt Sinai Hospital in New York, with 75% (nine of 12) of patients with moderate to severe ARDS successfully taken off a ventilator and discharged from hospital within a median of 10 days. The Phase 3 trial is enrolling ventilator-dependent patients in intensive care units with moderate to severe COVID-19 ARDS randomized (1:1) to receive either two intravenous infusions of remestemcel-L three to five days apart or placebo on top of maximal care. The primary endpoint is all-cause mortality within 30 days of randomization, with the key secondary endpoint being the number of days off mechanical ventilator support.

The trial's independent Data Safety Monitoring Board (DSMB) plans to complete an interim analysis this month in the trial's first 90 patients randomized in the US after they have completed 30 days of follow up. After review of the safety and efficacy data, the DSMB will provide a recommendation to Mesoblast on whether the trial should proceed as planned, or stop early.

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. 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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