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MESOBLAST PRESENTS RESPIRATORY FUNCTION RESULTS OF COVID-19 ARDS TRIAL AT PULMONARY DISEASE CONFERENCE

Melbourne, Australia; July 16 and New York, USA; July 15, 2021: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today presented clinical outcomes from the randomized controlled trial of remestemcel-L in ventilator-dependent COVID-19 patients with moderate/severe acute respiratory distress syndrome (ARDS). Results of respiratory function were highlighted at the biennial Stem Cells, Cell Therapies, and Bioengineering in Lung Biology and Diseases conference hosted by the University of Vermont, Burlington, VT, on July 15. The invited presentation was given by Mesoblast Chief Executive Officer, Dr Silviu Itescu, and materials have been lodged with the ASX.

The trial in mechanically ventilated COVID-19 patients with moderate/severe ARDS enrolled 222 patients across the United States, of whom 217 were randomized 1:1 and received either standard of care alone or standard of care plus 2 intravenous infusions of remestemcel-L at a dose of 2 million cells/kg 3-5 days apart. As previously announced, while the trial did not meet its endpoint of 43% reduction in overall mortality, mortality was reduced through 60 days in the pre-specified subgroup analysis of 123 patients younger than 65, but not in those older than 65 where a more exuberant inflammatory response due to defective immune-mediated viral clearance mechanisms may require more prolonged or higher dosing of anti-inflammatory therapy. The mortality benefit in patients under 65 was even greater when remestemcel-L was used in addition to dexamethasone as standard of care.

Key secondary outcome results that were presented included:

- In patients under 65 years old, remestemcel-L improved respiratory function, as defined in pre-specified analyses by resolution or improvement in ARDS using the Berlin Criteria, at each of days 7, 14, 21, and 30 post-randomization, with Odds Ratio (OR) at Day 30 relative to controls of 2.2, 95% CI (1.0, 4.7)[1]
- In patients older than 65 years old, remestemcel-L improved respiratory function at day 7 relative to controls, but not at later time points, supporting the conclusion that more prolonged or higher dosing may be warranted in those over age 65 with COVID-19 ARDS
- Remestemcel-L improved respiratory function to an even greater extent in patients under 65 who received dexamethasone as part of their standard of care at each of days 7, 14, 21, and 30 post-randomization, with OR at Day 30 relative to controls on Dexamethasone alone of 3.6, 95% CI (1.2, 10.7)[1]
- Remestemcel-L also improved clinical outcomes based on a 7-point ordinal scale in patients under 65 who received dexamethasone as part of their standard of care at each of days 7, 14, 21, and 30 post-randomization, with OR at Day 30 relative to controls on Dexamethasone alone of 2.9, 95% CI (1.1, 7.7)[1]

Mesoblast entered into a license and collaboration agreement with Novartis for the development, manufacture, and commercialization of remestemcel-L, with an initial focus on the treatment of acute respiratory distress syndrome (ARDS), including that associated with COVID-19. The agreement remains subject to certain closing conditions, including time to analyze the results from this COVID-19 ARDS trial.

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 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 has completed Phase 3 trials of rexlemestrocel-L for advanced chronic heart failure and chronic low back pain. 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. 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

Footnotes

1. Treatment groups were compared using a mixed effect logistic regression model with patient as a random effect using all available data. Intermittent missing data assumed to be missing at random

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, including our intention to discuss potential next steps with the FDA, 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; whether the FDA agrees to a path forward; 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.

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