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SURVIVAL OUTCOMES IN COVID-19 ARDS PATIENTS TREATED WITH REMESTEMCEL-L

Melbourne, Australia; May 31 and New York, USA; May 30, 2022: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today provided an update on survival outcomes from the randomized controlled trial of remestemcel-L in ventilator-dependent COVID-19 patients with moderate/severe acute respiratory distress syndrome (ARDS) and plans for a pivotal trial with collaborative investigators.

Through the initial 90 days, remestemcel-L reduced mortality by 48% compared to controls in a pre-specified analysis of 123 patients below age 65 (26% vs 44%, p=0.038),[1,2] but not in 97 patients over age 65, as previously reported. In an exploratory analysis in patients under age 65 who also received dexamethasone as part of their standard of care, remestemcel-L reduced 90-day mortality by 77% compared to controls (14% vs 48%, p=0.0037).[1,2] These early survival outcomes in the remestemcel-L group relative to controls were maintained at later timepoints in those under age 65, with a 42% reduction in mortality through 12 months and with continued observed synergy with dexamethasone ($p<0.05$).[1,2]

The Phase 2/3 trial in COVID ARDS randomized 1:1 to either standard of care alone or standard of care plus two doses of remestemcel-L 2 million cells/kg 3-5 days apart. This two-dose regimen of remestemcel-L was the same as in the earlier compassionate use program where 11 of 12 patients were younger than 65 and 75% successfully came off ventilatory support. These pilot study results were recently published in the peer-reviewed journal *Cytotherapy.*[3] In contrast, remestemcel-L is used at an eight-dose regimen of 2 million cells/kg over four weeks in patients with steroid-refractory acute graft versus host disease (SR-aGVHD). The established extended dosing regimen in SR-aGVHD, another severe inflammatory condition, provides a rationale for exploring an extended course of remestemcel-L in older patients with COVID ARDS who have higher levels of inflammation.

ARDS remains a major cause of mortality for COVID-19 patients who are immunocompromised, unvaccinated, or with comorbidities, as well as those with seasonal influenza and other pathogens. Mesoblast is working together with investigators from a clinical trial network focused on acute lung injury at over 40 sites across the United States affiliated with Vanderbilt University Medical Center to design and implement a pivotal trial of remestemcel-L to reduce mortality in high-risk patients with ARDS.

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 2041 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 is developing product candidates for distinct indications based on its remestemcel-L and rexlemestrocel-L allogeneic stromal cell technology platforms. Remestemcel-L is being developed for inflammatory diseases in children and adults including steroid refractory acute graft versus host disease, biologic-resistant inflammatory bowel disease, and acute respiratory distress syndrome. Rexlemestrocel-L is in development for advanced chronic 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

Reference / Footnotes

1. All p-values are descriptive and not adjusted for multiplicity
2. Hazard Ratios calculated using Cox regression proportional hazards model without adjustment; p-value from log rank test
3. Whittaker Brown S., et al. Mesenchymal Stromal Cell Therapy for Acute Respiratory Distress Syndrome due to COVID-19. *Cytotherapy*, April 2022, https://doi.org/10.1016/j.jcyt.2022.03.006

Forward-Looking Statements

This press release 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 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 (including BLA resubmission), 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.

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