

REMESTEMCEL-L IMPROVES RESPIRATORY AND FUNCTIONAL OUTCOMES IN PATIENTS WITH INFLAMMATORY LUNG DISEASE***Phase 2 Trial Results Presented At 2020 International Society for Cell & Gene Therapy Annual Meeting***

Melbourne, Australia; June 1, 2020 and New York, USA; May 31, 2020: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today announced that treatment with its lead mesenchymal stem cell (MSC) product candidate remestemcel-L in patients with chronic obstructive pulmonary disease (COPD) and an elevated state of inflammation resulted in improved respiratory and functional outcomes. The results were presented as a virtual oral presentation delivered to the 2020 International Society for Cell & Gene Therapy (ISCT) annual meeting held May 28-29, 2020.

The post-hoc analysis from a randomized, placebo-controlled 60-patient Phase 2 trial in patients with COPD showed that remestemcel-L, given in four monthly intravenous doses of 100 million cells, significantly improved respiratory and functional clinical outcomes in patients with elevated levels of the inflammatory biomarker C-reactive protein (CRP). Significantly elevated CRP levels are predictive of increased hospitalization and death in patients with COPD¹, and are seen in various acute lung diseases, including acute respiratory distress syndrome (ARDS), a life-threatening complication of COVID-19. These results support potential of remestemcel-L to effectively treat inflammatory lung diseases, such as acutely decompensated COPD and ARDS.

Key findings were:

- The greater the degree of inflammation, as measured by elevated CRP levels, the greater the signal of efficacy of remestemcel-L treatment in improving moderate to severe lung disease
- Significant improvements were observed in each of the pre-specified endpoints tested, forced expiratory volume, forced vital capacity, and the distance walked in the six-minute walk test (all $p < 0.01$), with maximal effects on all parameters seen at four months
- In patients with the highest level of CRP ($>4\text{mg/L}$), those who received remestemcel-L were able to walk 55 meters further than placebo-treated patients in the six-minute walk test at four months ($p=0.004$); the six-minute walk test is a major independent predictor of mortality in COPD²
- The dose administered was well tolerated with no infusion-related toxicity and no identified safety concerns.

Mesoblast Chief Medical Officer Dr Fred Grossman said: "The correlation between highest CRP levels and greatest degree of response to remestemcel-L suggests that the inflammatory component of the lung disease may trigger and be amenable to the immunomodulatory effects of treatment with remestemcel-L in patients with acute inflammatory conditions. Since recurrent hospitalization rates and mortality in COPD are associated with both high levels of CRP and progressive decline in the six-minute walk test, these results suggest that remestemcel-L could provide longer-term benefits for COPD patients with high levels of inflammation. They also provide a compelling rationale for the evaluation of remestemcel-L in the current United States Phase 3 randomized controlled trial of 300 patients with moderate to severe COVID-19 ARDS."

References

¹ Dahl, M, et al. C-reactive Protein As a Predictor of Prognosis in Chronic Obstructive Pulmonary Disease. *Am J Respir Crit Care Med* Vol 175. pp 250–255, 2007.

² Polkey MI, et al. Evaluation of COPD Longitudinally to Identify Predictive Surrogate Endpoints (ECLIPSE) Study Investigators. Six-minute-walk test in chronic obstructive pulmonary disease: minimal clinically important difference for death or hospitalization. *Am J Respir Crit Care Med*. 2013;187:382–386.

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 (acute GVHD) 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. 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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