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mesoblast
the regenerative medicine company

MESOBLAST TO EVALUATE ANTI-INFLAMMATORY CELL THERAPY REMESTEMCEL-L FOR TREATMENT OF COVID-19 LUNG DISEASE

Melbourne, Australia; March 10, 2020; and New York, USA; March 9, 2020: Mesoblast Limited (Nasdaq: MESO; ASX:MSB) today announced that it plans to evaluate its allogeneic mesenchymal stem cell (MSC) product candidate remestemcel-L in patients with acute respiratory distress syndrome (ARDS) caused by coronavirus (COVID-19) in the United States, Australia, China and Europe. The Company is in active discussions with various government and regulatory authorities, medical institutions and pharmaceutical companies to implement these activities.

Mortality in COVID-19 infected patients with the inflammatory lung condition acute respiratory distress syndrome (ARDS) is reported to approach 50%, and is associated with older age, co-morbidities such as diabetes, higher disease severity, and elevated markers of inflammation.[1] Current therapeutic interventions do not appear to be improving in-hospital survival.[1]

Remestemcel-L has potential for use in the treatment of ARDS, which is the principal cause of death in COVID-19 infection.[1] This is supported by recently published results from an investigator-initiated clinical study conducted in China which reported that allogeneic MSCs cured or significantly improved functional outcomes in all seven treated patients with severe COVID-19 pneumonia.[2]

Additionally, in post-hoc analyses of a 60-patient randomized controlled study in chronic obstructive pulmonary disease (COPD), remestemcel-L infusions were well tolerated, significantly reduced inflammatory biomarkers, and significantly improved pulmonary function in those patients with elevated inflammatory biomarkers. Since the same inflammatory biomarkers are also elevated in COVID-19, these data suggest that remestemcel-L could be useful in the treatment of patients with ARDS due to COVID-19. The COPD study results have been submitted for presentation at an international conference, with full results to be submitted for publication shortly.

Remestemcel-L is being studied in numerous clinical trials across several inflammatory conditions, including in elderly patients with lung disease and adults and children with steroid-refractory acute graft versus host disease (aGVHD).[3-5] This product candidate is currently being reviewed by the United States Food and Drug Administration (FDA) for potential approval in the treatment of children with steroid-refractory aGVHD.

Remestemcel-L

Remestemcel-L is being developed for rare pediatric and adult inflammatory conditions. It is an investigational therapy comprising culture-expanded MSCs derived from the bone marrow of an unrelated donor and is administered in a series of intravenous infusions. Remestemcel-L is believed to have immunomodulatory properties to counteract the inflammatory processes that are implicated in several diseases 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.

Intellectual Property

Mesoblast's intellectual property (IP) portfolio encompasses over 1,000 patents or patent applications in all major markets and includes the use of MSCs obtained from any source for patients with acute respiratory distress syndrome (ARDS), and for inflammatory lung disease due to coronavirus (COVID-19), influenza and other viruses. Additionally, these patents cover Mesoblast's manufacturing processes that yield industrial-scale cellular medicines. This IP position is expected to provide Mesoblast with substantial commercial advantages as it develops its product candidates for these conditions.

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References
1. Liu Y et al. Clinical features and progression of acute respiratory distress syndrome in coronavirus disease 2019. Medrxiv 2020; https://doi.org/10.1101/2020.02.17.20024166
2. Leng Z, et al. Transplantation of ACE2- Mesenchymal Stem Cells Improves the Outcome of Patients with COVID-19 Pneumonia[J]. Aging and Disease, 10.14336/AD.2020.0228
3. Kurtzberg J et al. Annual Meeting of the American Society for Transplantation Cell Therapy, 2020.
4. Chaudhury S et al. A Phase 3 Single-Arm, Prospective Study of Remestemcel-L, Ex-Vivo Cultured Adult Human Mesenchymal Stromal Cells, for the Treatment of Steroid Refractory Acute GVHD in Pediatric Patients. Biol Blood Marrow Transplant 2018; 24:S119–S290.
5. Kurtzberg J et al. Allogeneic human mesenchymal stem cell therapy (remestemcel-L, Prochymal) as a rescue agent for severe refractory acute graft-versus-host disease in pediatric patients. Biol Blood Marrow Transplant. 2014 Feb;20(2):229-35.

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'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 filed a Biologics License Application to the United States Food and Drug Administration (FDA) to seek approval of its product candidate RYONCIL™ (remestemcel-L) for steroid-refractory acute graft versus host disease (acute GvHD). Remestemcel-L is also being developed for other rare diseases. Mesoblast is completing Phase 3 trials for its product candidates for advanced heart failure and chronic low back pain. If approved, RYONCIL is expected to be launched in the United States in 2020 for pediatric steroid-refractory acute GVHD. 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 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, 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

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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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