

FIRST PATIENTS DOSED IN PHASE 2/3 RANDOMIZED CONTROLLED TRIAL OF MESOBLAST'S REMESTEMCEL-L FOR COVID-19 ACUTE RESPIRATORY DISTRESS SYNDROME

Melbourne, Australia; May 6, 2020; and New York, USA; May 5, 2020: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in cellular medicines for inflammatory diseases, today announced that the first patients have been dosed in the 300-patient randomized placebo-controlled Phase 2/3 trial in the United States of Mesoblast's allogeneic cellular medicine remestemcel-L in COVID-19 infected patients with moderate to severe acute respiratory distress syndrome (ARDS) on ventilator support.

Mesoblast holds an Investigational New Drug (IND) application cleared by the FDA for use of remestemcel-L in the treatment of patients with COVID-19 ARDS. The clinical protocol for the Phase 2/3 trial is based on initial promising results from use of remestemcel-L in patients with moderate to severe COVID-19 ARDS under an emergency IND application or expanded access protocol at The Mount Sinai Hospital in New York. The trial will randomize up to 300 ventilator-dependent patients in intensive care units to either remestemcel-L or placebo (1:1) on top of maximal care, in line with specific guidance provided by the United States Food and Drug Administration (FDA) for robust statistical analysis. The primary endpoint is all-cause mortality within 30 days of randomization, with the key secondary endpoint being the number of days alive and off mechanical support.

The trial will include up to 30 sites across North America, with patient screening and enrollment having already commenced at Baylor University Medical Center, a part of Baylor Scott & White Health; Cleveland Clinic, Duke University Hospital, Keck Medical Center of USC, Lutheran Hospital Indiana, The Mount Sinai Hospital, Ochsner Medical Center – Jefferson Highway, and the University of Maryland School of Medicine/University of Maryland Medical Center. Enrollment is expected to complete within three to four months, with interim analyses planned which could result in stopping the trial early for efficacy or futility.

The Clinical and Data Coordinating Center for the trial will be overseen by Dr Annetine Gelijns, Dr Alan Moskowitz and Dr Emilia Bagiella, the co-Directors of the Institute for Transformative Clinical Trials at the Icahn School of Medicine at Mount Sinai.

Dr Moskowitz said: "This rapid mobilization of major medical centers across the United States reflects the urgent need to treat the very large numbers of people in hospital intensive care units suffering with COVID-19 ARDS and requiring ventilation. We expect quick enrollment in this trial to determine whether remestemcel-L can reduce mortality in these patients."

About Remestemcel-L

Remestemcel-L is being developed for various inflammatory conditions, including acute graft versus host disease, and is believed to counteract the inflammatory processes implicated in these 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.

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's Biologics License Application to seek approval of its product candidate RYONCIL™ (remestemcel-L) for steroid-refractory acute graft versus host disease (acute GVHD) has been accepted for priority review by the United States Food and Drug Administration (FDA). 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 a strong and extensive global intellectual property (IP) portfolio with protection extending through to at least 2040 in all major markets. This IP position is expected to provide the Company with substantial commercial advantages as it develops its product candidates for these conditions.

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 include, but are not limited to, statements about the initiation, timing, progress and results of Mesoblast and its collaborators' clinical studies; Mesoblast and its collaborators' 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; the potential benefits of strategic collaboration agreements and Mesoblast's ability to 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. 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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