

FDA CLEARS INVESTIGATIONAL NEW DRUG APPLICATION FOR MESOBLAST TO USE REMESTEMCEL-L IN PATIENTS WITH ACUTE RESPIRATORY DISTRESS SYNDROME CAUSED BY COVID-19

Melbourne, Australia; April 6, 2020; and New York, USA; April 5, 2020: Mesoblast Limited (ASX:MSB; Nasdaq: MESO), global leader in cellular medicines for inflammatory diseases, today announced that it has received clearance from the United States Food and Drug Administration (FDA) for an Investigational New Drug (IND) application to treat patients with acute respiratory distress syndrome (ARDS) caused by coronavirus infection (COVID-19) with intravenous infusions of its allogeneic mesenchymal stem cell (MSC) product candidate remestemcel-L.

Mesoblast Chief Medical Officer Dr Fred Grossman said: "The FDA clearance provides a pathway in the United States for use of remestemcel-L in patients with COVID-19 ARDS, where the prognosis is very dismal, under both expanded access compassionate use and in a planned randomized controlled trial."

Remestemcel-L is being developed for various inflammatory conditions, 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. The safety and therapeutic effects of remestemcel-L intravenous infusions have been evaluated in over 1,100 patients in various clinical trials.

Remestemcel-L was successful in a Phase 3 trial for steroid-refractory acute graft versus host disease (aGVHD) in children, a potentially fatal inflammatory condition due to a similar cytokine storm process as is seen in COVID-19 ARDS. Additionally, a post-hoc analysis of a randomized, placebo-controlled study in 60 patients with chronic obstructive pulmonary disease demonstrated that remestemcel-L significantly improved respiratory function in patients with the same elevated inflammatory biomarkers that are also observed in patients with COVID-19 ARDS. Together, these outcomes provide the rationale for evaluating remestemcel-L in patients with COVID-19 ARDS.

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

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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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