

PHASE 2/3 RANDOMIZED CONTROLLED TRIAL OF REMESTEMCEL-L IN 300 PATIENTS WITH COVID-19 ACUTE RESPIRATORY DISTRESS SYNDROME BEGINS ENROLLMENT

Melbourne, Australia; April 30, 2020; and New York, USA; April 29, 2020: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in cellular medicines for inflammatory diseases, today announced a Phase 2/3 randomized, placebo-controlled trial to rigorously confirm whether its allogeneic mesenchymal stem cell therapy remestemcel-L provides a survival benefit in moderate/severe acute respiratory distress syndrome (ARDS) due to COVID-19 has commenced enrollment.

More than 20 medical centers across the United States will participate in the trial which is expected to complete enrollment within three to four months, with interim analyses planned which could result in stopping the trial early for efficacy or futility.

Mesoblast Chief Executive Dr Silviu Itescu stated: “There are limited treatment options for ventilator-dependent patients with acute respiratory distress syndrome, the principal cause of mortality in COVID-19 infection. Based on the encouraging initial results of remestemcel-L treatment under emergency compassionate use in New York, there is an urgent need to execute this robust randomized placebo-controlled trial in order to definitively determine whether this cell therapy can reduce the mortality of patients with COVID-19 ARDS on ventilators.”

The specific clinical protocol for use of remestemcel-L in patients in this trial was informed by the previously reported positive results from the emergency compassionate use protocol patients with COVID-19 ARDS. In line with specific guidance provided by the FDA for robust statistical analysis, the placebo-controlled trial will enroll up to 300 ventilator-dependent patients in intensive care units with moderate to severe COVID-19 ARDS randomized (1:1) to receive either two intravenous infusions of remestemcel-L within five days or placebo on top of maximal care. The primary endpoint is all-cause mortality within 30 days of randomization, with the key secondary endpoint being the number of days off mechanical ventilator support.

Mesoblast Chief Medical Officer Dr Fred Grossman said: “The promising initial results using remestemcel-L in the emergency compassionate use protocol create an imperative for an appropriately-sized definitive randomized controlled trial. We believe the central mechanism by which remestemcel-L modulates the inflammatory process provides a compelling rationale between these results in COVID-19 ARDS and other inflammatory conditions where the cell therapy has shown clinical benefits.”

The trial will be conducted in collaboration with the Cardiothoracic Surgical Trials Network, which was established by the United States National Institutes of Health’s National Heart, Lung and Blood Institute as a flexible platform for conducting collaborative trials. Mesoblast holds an Investigational New Drug (IND) application cleared by the United States Food and Drug Administration (FDA) for use of remestemcel-L in the treatment of patients with COVID-19 ARDS, and will provide investigational product of remestemcel-L for the trial.

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.

Mesoblast Limited
ABN 68 109 431 870
www.mesoblast.com

Corporate Headquarters
Level 38
55 Collins Street
Melbourne 3000
Victoria Australia

T +61 3 9639 6036
F +61 3 9639 6030

United States Operations
505 Fifth Avenue
Third Floor
New York, NY 10017
USA

T +1 212 880 2060
F +1 212 880 2061

Asia
21 Biopolis Road
#01-22 Nucleos (South
Tower)
SINGAPORE 138567

T +65 6570 0635
F +65 6570 0176

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.

For further information, please contact:

Media

Julie Meldrum
T: +61 3 9639 6036
E: julie.meldrum@mesoblast.com

Kristen Bothwell
T: +1 917 613 5434
E: kbothwell@rubenstein.com

Investors

Schond Greenway
+212 880 2060
E: schond.greenway@mesoblast.com

Paul Hughes
T: +61 3 9639 6036
E: paul.hughes@mesoblast.com

Mesoblast Limited
ABN 68 109 431 870
www.mesoblast.com

Corporate Headquarters
Level 38
55 Collins Street
Melbourne 3000
Victoria Australia

T +61 3 9639 6036
F +61 3 9639 6030

United States Operations
505 Fifth Avenue
Third Floor
New York, NY 10017
USA

T +1 212 880 2060
F +1 212 880 2061

Asia
21 Biopolis Road
#01-22 Nucleos (South
Tower)
SINGAPORE 138567

T +65 6570 0635
F +65 6570 0176