

MESOBLAST PARTNERS WITH THE CARDIOTHORACIC SURGICAL TRIALS NETWORK ESTABLISHED BY THE U.S. NATIONAL INSTITUTES OF HEALTH'S NATIONAL HEART, LUNG AND BLOOD INSTITUTE TO CONDUCT RANDOMIZED CONTROLLED TRIAL OF REMESTEMCEL-L FOR PATIENTS WITH ACUTE RESPIRATORY DISTRESS SYNDROME DUE TO COVID-19

Melbourne, Australia; Thursday April 9, 2020; and New York, USA; Wednesday April 8, 2020: Mesoblast Limited (ASX:MSB; Nasdaq:MESO) today announced that its allogeneic mesenchymal stem cell (MSC) product candidate remestemcel-L will be formally evaluated in a randomized, placebo-controlled trial in 240 patients with acute respiratory distress syndrome (ARDS) caused by coronavirus infection (COVID-19). This multi-center Phase 2/3 trial will be conducted as a public-private partnership in a collaboration with the Cardiothoracic Surgical Trials Network (CTSN), which was established by the United States National Institutes of Health's National Heart, Lung and Blood Institute (NHLBI) as a flexible platform for conducting collaborative trials. Mesoblast holds an Investigational New Drug (IND) Application from 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 for the trial.

Mesoblast Chief Executive Dr Silviu Itescu stated: "This significant public-private partnership is a prime example of how the combined resources of industry and government can be leveraged to evaluate in a most efficient and rigorous manner the potential of innovative therapies to make a meaningful difference to patient outcomes."

CTSN Chairman Dr A. Marc Gillinov said: "We are excited to work with Mesoblast to make a real impact on the high mortality associated with COVID-19. This randomized controlled trial is in line with our mandate to rigorously evaluate novel therapies for public health imperatives."

Professor and System Chair of Population Health Science and Policy and the Edmond A. Guggenheim Professor of Health Policy at the Icahn School of Medicine at Mount Sinai, Dr Annetine Gelijns, said: "The COVID-19 pandemic has resulted in very large numbers of people suffering with ARDS requiring ventilation in hospital intensive care units, with dismal outcomes, placing an enormous burden on the United States health system. We are committed to evaluating whether Mesoblast's mesenchymal stem cell product candidate for ARDS has the potential to make an impact on this unprecedented health crisis."

ARDS occurs due to an excessive immune response against the COVID-19 virus in the lungs, with the inflammatory cytokines produced by the immune cells (cytokine storm) destroying the lung tissue. These inflammatory cytokines also can cause damage to other organs such as liver, kidney, and heart.

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.

Mesoblast Chief Medical Officer Dr Fred Grossman said: "The mortality rate in moderate to severe ARDS due to COVID-19 can be as high as 80%. Remestemcel-L has demonstrated safety, efficacy and significant survival benefit in aGVHD where inflammation is at the core, similar to ARDS from COVID-19. The mechanism of action of remestemcel-L demonstrated in aGVHD supports the evaluation of remestemcel-L to safely tame a similar cytokine storm in the lungs that leads to the high mortality in patients with COVID-19."

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