asx announcement

mesoblast
the regenerative medicine company

83% SURVIVAL IN COVID-19 PATIENTS WITH MODERATE/SEVERE ACUTE RESPIRATORY DISTRESS SYNDROME TREATED IN NEW YORK WITH MESOBLAST'S CELL THERAPY REMESTEMCEL-L

Key points:

• 83% survival in ventilator-dependent COVID-19 patients (10/12) with moderate/severe acute respiratory distress syndrome (ARDS) treated with two infusions of Mesoblast's allogeneic cell therapy remestemcel-L within the first five days under emergency compassionate use at New York City's Mt Sinai hospital during the period March-April 2020

• 75% (9/12) have successfully come off ventilator support within a median of 10 days

• These results contrast with only 9% of ventilator-dependent COVID-19 patients being able to come off ventilators with standard of care treatment and only 12% survival in ventilator-dependent COVID-19 patients at two major referral hospital networks in New York during the same time period[1,2]

• This compassionate use treatment experience has informed the design of the clinical protocol for the randomized, placebo-controlled Phase 2/3 trial of remestemcel-L in ventilator-dependent COVID-19 moderate/severe ARDS patients across North America

Melbourne, Australia; April 24, 2020; and New York, USA; April 23, 2020: Mesoblast Limited (ASX:MSB; Nasdaq: MESO) today announced 83% survival in ventilator-dependent COVID-19 patients (10/12) with moderate/severe acute respiratory distress syndrome (ARDS) treated during the period March-April 2020 with two intravenous infusions of Mesoblast's allogeneic mesenchymal stem cell product candidate remestemcel-L within the first five days. 75% (9/12) have successfully come off ventilator support at a median of 10 days. At this time, seven have been discharged from the hospital. Patients received a variety of experimental agents prior to remestemcel-L. All patients were treated under an emergency Investigational New Drug (IND) application or expanded access protocol at New York City's Mt Sinai hospital.

In contrast, only 9% (38/445) of ventilator-dependent COVID-19 patients at a major referral hospital network in New York City were able to come off ventilator support when treated with standard of care during March/April 2020.[1] Moreover, there was 88% mortality with only 12% survival (38/320) among ventilator-dependent COVID-19 patients at a second major referral hospital network in New York City during the same period.[2] These poor outcomes are consistent with earlier published data from China where mortality rates of over 80% were reported in patients with COVID-19 and moderate/severe ARDS.[3]

Mesoblast Chief Executive Dr Silviu Itescu stated: "The remarkable clinical outcomes in these critically ill patients continue to underscore the potential benefits of remestemcel-L as an anti-inflammatory agent in cytokine release syndromes associated with high mortality, including acute graft versus host disease and COVID-19 ARDS. We intend to rapidly complete the randomized, placebo-controlled Phase 2/3 trial in COVID-19 ARDS patients to rigorously confirm that remestemcel-L improves survival in these critically ill patients."

Mesoblast Chief Medical Officer Dr Fred Grossman said: "There is a significant need to improve the dismal survival outcomes in COVID-19 patients who progress to ARDS and require ventilators. We have implemented robust statistical analyses in our Phase 2/3 trial as recommended by the US Food and Drug Administration (FDA) in order to maximize our ability to evaluate whether remestemcel-L provides a survival benefit in moderate/severe COVID-19 ARDS."

References

[1] Petrilli CM et al. Factors associated with hospitalization and critical illness among 4,103 patients with Covid-19 disease in New York City. MedRxiv 2020 doi: https://www.medrxiv.org/content/10.1101/2020.04.08.20057794v1.full.pdf

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

[2] Richardson S et al. Presenting characteristics, comorbidities, and outcomes among 5700 patients hospitalized with COVID-19 in the New York City area. JAMA 2020. doi:10.1001/jama.2020.6775

[3] Liu Y et al. Clinical features and progression of acute respiratory distress syndrome in coronavirus disease 2019. Medrxiv 2020; https://www.medrxiv.org/content/10.1101/2020.04.08.20057794v1.full.pdf

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.

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

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