asx announcement

mesoblast

MESOBLAST PRESENTS HEART FAILURE PHASE 3 TRIAL RESULTS AT INVESTOR HEALTHCARE CONFERENCE

Melbourne, Australia; January 12, and New York, USA; January 11, 2021: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, announced that its Chief Executive Officer, Dr Silviu Itescu, today presented additional data from the landmark DREAM-HF Phase 3 trial in patients with chronic heart failure. The presentation materials have been lodged with the ASX, and Mesoblast's presentation at the H.C. Wainwright Virtual BioConnect 2021 Conference can be accessed at https://journey.ct.events/view/f353f7fd-772e-43aa-aab0-e959da38254d. An archived webcast of the conference presentation will be available for 90 days on the Company's website at www.mesoblast.com.

The randomized controlled Phase 3 trial compared clinical outcomes between rexlemestrocel-L and sham control in 537 treated patients with chronic heart failure and reduced left ventricular ejection fraction (HFrEF).

Key Conclusions of the Presentation

Rexlemestrocel-L may provide a major breakthrough in reducing heart failure progression and mortality when used early (New York Heart Association, NYHA, class II disease), and may provide durable protection from heart attacks or strokes in high-risk patients. The specific data supporting these conclusions include:

- 60% reduction in incidence of Major Adverse Cardiac Events (MACE) due to heart attacks or strokes across entire 537 patient study population, irrespective of NYHA class II or III, ischemic or non-ischemic etiology (p=0.002);
- 68% reduction in the rate of recurrent hospitalizations from non-fatal heart attacks or strokes, with a hospitalization rate of 1.90 per 100 patient-years of follow-up in the rexlemestrocel-L arm versus 5.95 per 100 patient-years of follow-up in the control arm (p=0.0002);
- 60% reduction in cardiac death in NYHA class II patients (p=0.037) and prevention of progression to NYHA class III rate of cardiac death (p=0.004);
- Covariate regression analyses showed that elevated baseline levels of CRP, an important biomarker of systemic inflammation, predicted rexlemestrocel-L treatment effect on both MACE in all patients and cardiac death in NYHA class II patients, consistent with the proposed anti-inflammatory mechanism of action of the agent;
- 30% reduction in incidence of three-point MACE (cardiac death, heart attack or stroke) across entire 537 patient study population (p=0.027); and
- 55% reduction in incidence of three-point MACE (cardiac death, heart attack or stroke) in NYHA class II patients (n=206) (p=0.009).

Based on the observed reduction in mortality and morbidity in this Phase 3 trial, Mesoblast intends to meet with the United States Food and Drug Administration (FDA) to discuss a potential approval pathway.

About Chronic Heart Failure

Heart failure affects approximately 6.5 million people in the US and 26 million people globally, with increasing prevalence and incidence. Chronic heart failure is a progressive disease associated with cardiac and systemic inflammation and a high mortality rate that approaches 50% at 5 years as patients progress beyond NYHA class II disease. In addition, these patients are at high risk of recurrent heart attacks and strokes, reflecting the high degree of systemic inflammation and progressive atherosclerosis associated with chronic heart failure. The high rate of cardiac death, heart attacks and strokes accompanying disease progression continues to be the most significant unmet

need in this patient population since new therapies that have reduced recurrent hospitalizations due to cardiac decompensation have not materially impacted these MACE outcomes.

About the DREAM HF Phase 3 Trial
Clinical outcomes were evaluated in 537 treated advanced HFEF patients (206 with NYHA class II disease and 331 with NYHA class III disease) randomized 1:1 to either a sham-control procedure or a transendocardial injection by catheter of rexlemestrocel-L (150 million cells). Inclusion criteria enriched the trial for patients with advanced disease by requiring a prior heart failure hospitalization over the past one-to-nine months and/or a N-terminal pro–B-type natriuretic peptide (NT-proBNP) level of at least 1000 pg/ml (at least 1200 pg/mL in patients with atrial fibrillation). All patients were continued on maximal oral agents for heart failure and were followed for at least twelve months post the index cath lab-procedure. At the end of the trial, vital status (alive or dead) was established in 100% of the randomized patients.

Baseline characteristics for the 537 treated patient population showed that patient groups with baseline NYHA class II or NYHA class III clinical grades had advanced disease, but those with NYHA class III disease had significantly greater severity (mean NT-proBNP 2390 pg/ml for NYHA class III vs 1809 pg/ml for NYHA class II; p=0.001).

Recurrent non-fatal decompensated heart failure hospitalization events, incidence of heart attacks, strokes, and death from cardiac causes, and recurrent hospitalizations from these outcomes were evaluated for the 537 HFrEF patients over a median follow-up period of approximately 30 months.

About Mesoblast
Mesoblast is a world leader in developing allogeneic (off-the-shelf) cellular medicines for the treatment of severe and life-threatening inflammatory conditions. The Company has leveraged its proprietary mesenchymal lineage cell therapy technology platform to establish a broad portfolio of late-stage product candidates which respond to severe inflammation by releasing anti-inflammatory factors that counter and modulate multiple effector arms of the immune system, resulting in significant reduction of the damaging inflammatory process.

Mesoblast has a strong and extensive global intellectual property portfolio with protection extending through to at least 2040 in all major markets. The Company'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.

Remestemcel-L is being developed for inflammatory diseases in children and adults including steroid refractory acute graft versus host disease and moderate to severe acute respiratory distress syndrome. Mesoblast has completed Phase 3 trials of rexlemestrocel-L for advanced chronic heart failure and chronic low back pain. 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 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. All statements other than statements of historical fact, including our intention to discuss potential pathways to potential approval with the FDA, are forward-looking statements, which are often indicated by terms such as "anticipate," "believe," "could," "estimate," "expect," "goal," "intend," "likely," "look forward to," "may," "plan," "potential," "predict," "project," "should," "will," "would" and similar expressions and variations thereof. 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. The risks, uncertainties and other factors that may impact our forward-looking statements include, but are not limited to: 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; whether the FDA agrees to a potential approval pathway; 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. Unless required by law, 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 more information, please contact:

Corporate Communications / Investors
Schond Greenway
T: +1 212 880 2060
E: schond.greenway@mesoblast.com

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

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