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MESOBLAST PROVIDES TOPLINE RESULTS FROM PHASE 3 TRIAL OF REXLEMESTROCEL-L FOR ADVANCED CHRONIC HEART FAILURE

Melbourne, Australia; December 15, and New York, USA; December 14, 2020: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today announced top-line results from the landmark DREAM-HF Phase 3 randomized controlled trial of its allogeneic cell therapy rexlemestrocel-L (REVASCOR®) in 537 patients with advanced chronic heart failure[1].

Over a mean 30 months of follow-up, patients with advanced chronic heart failure who received a single endomyocardial treatment with rexlemestrocel-L on top of maximal therapies had 60% reduction in incidence of heart attacks or strokes and 60% reduction in death from cardiac causes when treated at an earlier stage in the progressive disease process. Despite significant reduction in the pre-specified endpoint of cardiac death, there was no reduction in recurrent non-fatal decompensated heart failure events, which was the trial's primary endpoint. This suggests that rexlemestrocel-L reduces mortality by mechanisms that are distinct from those of existing drugs that reduce hospitalization rates but do not significantly impact cardiac mortality.

"There is an urgent need for new therapies that can reduce the high death rates in heart failure patients by different modes of action from existing drugs which reduce hospitalization rates but have not significantly reduced mortality rates," said Mesoblast Chief Executive Dr Silviu Itescu. "The reduction in mortality seen with rexlemestrocel-L in advanced chronic heart failure underlines the power of this technology and the commitment of Mesoblast to address diseases in patients with high unmet need which are refractory to existing therapies."

Key highlights were that a single injection of rexlemestrocel-L, on top of maximal therapy, resulted in the following pre-specified outcomes over a 30-month mean follow-up period:

- Significant reduction in the incidence of non-fatal ischemic major adverse cardiac events (MACE) due to a heart attack (myocardial infarction, MI) or stroke (cerebrovascular accident, CVA) by 60% relative to controls in the total population of 537 patients (p=0.002); reduction in MACE was seen consistently across both New York Heart Association (NYHA) class II or III populations and irrespective of whether the underlying cause of heart failure was ischemic or non-ischemic

- Significant reduction in death from all cardiac causes (CV death) in the 206 heart failure patients with NYHA class II disease by 60% relative to controls (p=0.037), which was evident in both ischemic and non-ischemic subgroups

- Prevention of NYHA class II patients progressing to CV death rates of NYHA class III patients (p=0.004); in contrast, NYHA class II patients on maximal therapy in the control group progressed to CV death rates of NYHA class III patients after a mean period of 20 months of disease stability

- Significant reduction in the composite of the pre-specified CV death or ischemic MACE outcomes in heart failure patients with NYHA class II disease by 55% relative to controls (p=0.009)

"The trial results show that rexlemestrocel-L significantly reduces cardiovascular mortality when used early in heart failure patients at risk of disease progression, and provides durable protection from heart attacks or strokes in these vulnerable patients," said the trial's co-principal investigator Dr Emerson Perin, Director of the Center for Clinical Research, Medical Director of Texas Heart Institute, and Clinical Professor, Baylor College of Medicine. "New therapies have not materially reduced the

high death rates from cardiovascular disease which is why these data have the potential to change the treatment paradigm for patients with advanced chronic heart failure."

Mesoblast Chief Medical Officer Dr Fred Grossman said: "We expect the mortality benefit observed in this seminal Phase 3 trial will support a potential path for approval of rexlemestrocel-L in patients with advanced chronic heart failure. We are planning to meet and discuss potential pathways to approval based on mortality reduction with the United States Food and Drug Administration."

Conference Call
There will be a webcast today beginning at 9.00am AEDT (Tuesday, December 15); 5.00pm EST (Monday, December 14, 2020). It can be accessed via https://webcast.boardroom.media/mesoblast-limited/20201214/NaN5fd6e483de11ae0019f60917

The archived webcast will be available on the Investor page of the Company's website: www.mesoblast.com

About the DREAM HF Phase 3 Trial
Clinical outcomes were evaluated in 537 advanced heart failure patients (206 with New York Heart Association, NYHA, class II disease and 331 with NYHA class III disease) randomized 1:1 to either a sham 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 nine months or a N-terminal pro–B-type natriuretic peptide (NT-proBNP) level of at least 1000 pg/ml. All patients were continued on maximal oral agents for heart failure, and were followed for at least twelve months post-procedure.

Baseline characteristics showed that both patient groups with 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 2568 pg/ml for NYHA class III vs 1842 pg/ml for NYHA class II, p=0.001).

Recurrent non-fatal heart failure MACE, incidence of ischemic MACE due to a heart attack or stroke, and death from cardiovascular causes (CV death), were evaluated over a mean follow-up period of 30 months.

About Mesoblast
Mesoblast 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 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

References
[1]There were 565 patients randomized of which 537 met the criteria which allowed for treatment to occur on a 1:1 randomization basis between rexlemestrocel-L and sham control

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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. 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 provide for an accelerated pathway to potential approval; 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.

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