

SUCCESSFUL INTERIM ANALYSIS OF EFFICACY ENDPOINT IN MESOBLAST'S PHASE 3 TRIAL FOR CHRONIC HEART FAILURE

Melbourne, Australia; and New York, USA; April 10, 2017: Mesoblast Limited (ASX: MSB; Nasdaq: MESO) today announced that the Phase 3 trial of its allogeneic mesenchymal precursor cell (MPC) product candidate MPC-150-IM in patients with moderate to advanced chronic heart failure (CHF) was successful in the pre-specified interim futility analysis of the efficacy endpoint in the trial's first 270 patients. It is expected that the trial will enroll in total approximately 600 patients. After notifying the Company of the interim analysis results, the trial's Independent Data Monitoring Committee (IDMC) additionally stated that they had no safety concerns relating to MPC-150-IM and formally recommended that the trial should continue as planned.

Dr Emerson C. Perin, Director, Research in Cardiovascular Medicine and Medical Director, Stem Cell Center at the Texas Heart Institute, and a lead investigator on the ongoing Phase 3 trial said: "It is very pleasing to see that this large and rigorously conducted Phase 3 trial of Mesoblast's cell therapy was successful in the pre-specified interim futility analysis for the trial's efficacy endpoint in the first 270 patients. Advanced heart failure is a very serious and life-threatening disease, and there is an urgent need to develop a safe and effective new therapy for these patients that may halt or reverse disease progression and prevent the high associated mortality."

Mesoblast Chief Executive Silviu Itescu commented: "Passing this interim futility analysis for MPC-150-IM is an important milestone for Mesoblast and our cardiovascular disease program. This validates our strategy and our prioritization of this valuable program."

This ongoing double-blinded randomized (1:1) trial is currently being conducted across multiple study sites in the United States and Canada. It is evaluating MPC-150-IM in adult patients with moderate to advanced New York Heart Association (NYHA) Class II/III chronic heart failure with left ventricular systolic dysfunction. The trial's primary efficacy endpoint is a comparison of recurrent non-fatal heart failure-related major adverse cardiac events (HF-MACE) in moderate to advanced CHF patients receiving either MPC-150-IM by catheter injection into the damaged left ventricular heart muscle or sham control. A Joint Frailty Model is the statistical method that evaluates multiple non-fatal heart failure-related events per patient (such as repeated hospitalizations for decompensated heart failure) while accounting for increased likelihood of a terminal cardiac event (such as death, implantation of a mechanical heart assist device or a heart transplant) for patients with multiple non-fatal heart failure events. In line with best practice for blinded Phase 3 clinical trials, the interim analysis data are only reviewed by the IDMC. Mesoblast, the United States Food and Drug Administration (FDA), and trial investigators are blinded to grouped safety and efficacy data for the ongoing trial as well as the numerical results of this interim analysis.

About Mesoblast's MPC-150-IM Cardiovascular Program

MPC-150-IM is Mesoblast's lead allogeneic, cell-based product candidate for the treatment of moderate to advanced chronic heart failure (CHF) due to left ventricular systolic dysfunction.

In Phase 2 results, a single injection of MPC-150-IM into the myocardium of patients with moderate to advanced chronic heart failure prevented any HF related hospitalizations or cardiac deaths over three years of follow-up.¹ Nonclinical studies showed that intramyocardial administration of MPCs in animal models of heart failure improved cardiac function and attenuated pathological ventricular remodelling. These effects were attributable, at least in part, to MPC secretion of biomolecules that stimulate reparative processes in the failing heart including new blood vessel formation, cardiac muscle cell survival, and reduction in tissue fibrosis.

MPC-150-IM is also being studied in a Phase 2b trial in 159 patients with NYHA Class IV end-stage heart failure patients in conjunction with implantation of a left ventricular assist device (LVAD). A major objective of this trial, which is being sponsored by the United States National Institutes of

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Health (NIH), is to assess the ability of MPC-150-IM to help wean patients from a LVAD dependent existence for survival (so-called "bridge to recovery").

Additionally, the FDA recently cleared the commencement of a 24-patient trial which is being sponsored by Boston's Children's Hospital. This study combines Mesoblast's proprietary allogeneic MPC-150-IM product with corrective heart surgery in children under the age of 5 with hypoplastic left heart syndrome.

About Chronic Heart Failure

In 2016, more than 15 million patients in the seven major global pharmaceutical markets are estimated to have been diagnosed with CHF.² Prevalence is expected to grow 46% by 2030 in the United States alone, affecting more than 8 million Americans.³ CHF is a progressive disease and is classified in relation to the severity of the symptoms experienced by the patient. The most commonly used classification system was established by the NYHA and ranges from Class I (mild) to Class IV or end stage (severe). Approximately half of people who develop heart failure die within 5 years of diagnosis.⁴ Patients with late NYHA Class II or Class III CHF continue to represent a significant unmet medical need despite recent advances in new therapies. CHF causes severe economic, social, and personal costs. In the United States, it is estimated that CHF results in direct costs of \$60.2 billion annually when identified as a primary diagnosis and \$115 billion as part of a disease milieu.⁵

1.Perin EC, Borow KM, Silva GV, et al. A phase II dose-escalation study of allogeneic mesenchymal precursor cells in patients with ischemic or nonischemic heart failure. *Circ Res.* 2015; 117:576-84

2.GlobalData-PharmaPoint (2016): Heart Failure-Global Drug Forecast and Market Analysis to 2025

3.AHA Statistical Update – Heart Disease and Stroke Statistics-(2017). *Circulation.* 2017;131:00-00. DOI: 10.1161/CIR.0000000000000485

4.Mozzafarian D, Benjamin EJ, Go AS, et al. on behalf of the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Heart disease and stroke statistics—2016 update: a report from the American Heart Association. *Circulation.* 2016;133:e38-e360

5.A Re-Evaluation of the Costs of Heart Failure and its Implications for Allocation of Health Resources in the United States. *Voigt J. Clinl.Cardiol.* 37, 5, 312-321 (2014)

About Mesoblast

Mesoblast Limited (ASX:MSB; Nasdaq:MESO) is a global leader in developing innovative cell-based medicines. The Company has leveraged its proprietary technology platform, which is based on specialized cells known as mesenchymal lineage adult stem cells, to establish a broad portfolio of late-stage product candidates. Mesoblast's allogeneic, 'off-the-shelf' cell product candidates target advanced stages of diseases with high, unmet medical needs including cardiovascular conditions, orthopedic disorders, immunologic and inflammatory disorders and oncologic/hematologic conditions.

Forward-Looking Statements

This press release 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 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. 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.

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