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the regenerative medicine company

MESOBLAST'S PHASE 3 TRIAL OF REVASCOR IN ADVANCED CHRONIC HEART FAILURE SURPASSES THE NUMBER OF PRIMARY ENDPOINT EVENTS FOR TRIAL COMPLETION

Melbourne, Australia; December 17, 2019 and New York, USA; December 16, 2019: Mesoblast Limited (ASX: MSB; Nasdaq: MESO) today announced that its Phase 3 trial of Revascor for advanced chronic heart failure has surpassed the number of primary endpoint events required for trial completion. This cardiovascular outcomes trial has now initiated final study visits for all surviving patients with a target of last patient/last visit at the end of January 2020.

Once the last patient has completed their last visit, final data collection and entry processes will be performed and the database locked. All surviving patients will have been followed for at least 12 months, with a mean follow up period of approximately 30 months. The results from this pivotal trial are expected to be read out by mid-2020.

The double-blind, randomized, sham procedure-controlled Phase 3 trial is evaluating Revascor as an add-on treatment to standard-of-care for reduction of recurrent non-fatal heart failure-related major adverse cardiac events (HF-MACE) and terminal cardiac events (TCEs) in 566 patients with advanced chronic heart failure and reduced ejection fraction. The trial was designed to accrue more than 531 total primary endpoint events (HF-MACE) based on expected rates of HF-MACE in similarly advanced populations of heart failure patients and on treatment benefits seen with Revascor in earlier Phase 2 trial results. In April 2017, the Company reported that a pre-specified interim futility analysis of the primary efficacy endpoint in the Phase 3 trial's first 270 patients was successful.

In the United States alone, there are more than 6.5 million patients with heart failure[1]. Approximately 15% of this patient population has advanced chronic heart failure and is at high-risk for recurrent HF-MACE and TCEs. This high-risk group makes up the predominant patient population in the Revascor Phase 3 trial.

Mesoblast Chief Executive Dr Silviu Itescu stated: "We are very pleased to have achieved this important milestone in the largest trial of cell-based therapy for patients with advanced heart failure. These patients have exhausted other treatment alternatives, and have the highest burden of disease, recurrent hospitalizations and mortality."

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 cell therapy technology platform to establish a broad portfolio of commercial products and late-stage product candidates. Two products have been commercialized in Japan and Europe by its licensees, and it has established commercial partnerships in Europe and China for certain Phase 3 assets. In the United States, Mesoblast completed submission of a rolling Biologics License Application to the FDA to seek approval of its product candidate for acute graft versus host disease following a successful Phase 3 trial and is completing Phase 3 trials for its advanced heart failure and chronic low back pain product candidates. Mesoblast's proprietary manufacturing process yields industrial-scale, frozen, off-the-shelf, cellular medicines based on its mesenchymal lineage cell platform technology. These cell therapies, with defined pharmaceutical release criteria, are planned to be readily available to patients worldwide. Mesoblast has locations in Melbourne, New York, Singapore and Texas 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

1.Benjamin EJ, Virani SS, Callaway CW et al. American Heart Association Council on Epidemiology and Prevention Statistics Committee and Stroke Statistics Subcommittee. Heart Disease and Stroke Statistics-2018 Update: A report from the American Heart Association. Circulation. 2018;137:e67–e4922016;133:e38–e360.

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Mesoblast's 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 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. Forward-looking statements include, but are not limited to, statements about 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; and the pricing and reimbursement of Mesoblast's product candidates, if approved. 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 authorised by the Chief Executive.

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