asx announcement

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the regenerative medicine company

CIRCULATION RESEARCH SPECIAL ARTICLE HIGHLIGHTS POTENTIAL OF MESOBLAST CELL THERAPY IN TREATMENT OF ADVANCED HEART FAILURE

New York, USA; and Melbourne, Australia; July 25, 2019: Mesoblast Limited (ASX: MSB; Nasdaq: MESO) today announced that premier cardiovascular journal Circulation Research has published a Special Article highlighting the important potential clinical benefits of Mesoblast's allogeneic mesenchymal precursor cell (MPC) technology platform as immunotherapy in patients with advanced chronic heart failure.

The Special Article highlighted that cardiac inflammation drives heart failure progression, and concluded that based on preclinical and Phase 2 clinical data there is a biologic rationale for the use of Mesoblast's MPCs in targeting this inflammatory process in order to improve heart failure outcomes.

The manuscript, titled *'Phase 3 DREAM-HF Trial of Mesenchymal Precursor Cells in Chronic Heart Failure; A Review of Biological Plausibility and Implementation of Flexible Clinical Trial Design,'* was requested by the journal's Editor-in-Chief. Its authors include the Phase 3 trial's co-principal investigators, Dr Emerson Perin, Texas Heart Institute, and Dr Barry Greenberg, University of California, San Diego Healthcare System. The article can be accessed at https://doi.org/10.1161/CIRCRESAHA.119.314951.

The ongoing, placebo-controlled double-blind Phase 3 trial of Mesoblast's heart failure cellular medicine Revascor, comprising 150 million MPCs, is evaluating the immunotherapy for reduction of heart failure-related hospitalizations and terminal cardiac events in patients with advanced heart failure. The events-driven trial completed enrollment of 566 patients in February 2019, and was previously successful in a pre-specified interim futility analysis of the primary efficacy endpoint in the first 270 patients.

Revascor is also being evaluated to prevent mucosal bleeding in end-stage chronic heart failure patients with a Left Ventricular Assist Device (LVAD) and recently received Orphan Drug Designation from the United States Food and Drug Administration (FDA) for this indication. Mesoblast is in discussions with the FDA regarding a potential approval pathway under the product's existing Regenerative Medicine Advanced Therapy (RMAT) designation for this life-threatening condition.

About Mesoblast

Mesoblast Limited (ASX:MSB; Nasdaq:MESO) has leveraged its proprietary technology platform to establish a broad portfolio of late-stage allogeneic (off-the-shelf) product candidates with three product candidates in Phase 3 trials – acute graft versus host disease, chronic heart failure and chronic low back pain due to degenerative disc disease. Through a proprietary process, Mesoblast selects rare mesenchymal lineage precursor and stem cells from the bone marrow of healthy adults and creates master cell banks, which can be industrially expanded to produce thousands of doses from each donor that meet stringent release criteria, have lot to lot consistency, and can be used off-the-shelf without the need for tissue matching. Mesoblast has facilities in Melbourne, New York, Singapore and Texas and is listed on the Australian Securities Exchange (MSB) and on the Nasdaq (MESO). For more information about Mesoblast, visit www.mesoblast.com.

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

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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, including Revascor, 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.

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