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mesoblast
the regenerative medicine company

MEMORANDUM OF UNDERSTANDING FOR CONFIRMATORY TRIAL TO SUPPORT MARKETING APPROVAL OF REVASCOR FOR REDUCTION OF GASTROINTESTINAL BLEEDING IN LVAD PATIENTS

New York, USA; March 26 and Melbourne, Australia; March 27, 2019: Mesoblast Limited (ASX:MSB, Nasdaq:MESO), global leader in cellular medicines for inflammatory diseases, today announced that the International Center for Health Outcomes and Innovation Research (InCHOIR) at the Icahn School of Medicine at Mount Sinai and Mesoblast have entered into a Memorandum of Understanding (MOU) to conduct a confirmatory clinical trial using Mesoblast's product candidate Revascor (MPC-150-IM) for reduction of gastrointestinal (GI) bleeding in end-stage heart failure patients implanted with a left ventricular assist device (LVAD).

Dr Frank Pagani, Professor, Department of Cardiac Surgery at the University of Michigan, and co-principal investigator of the recently completed 159-patient study for which InCHOIR served as the central coordinating and data management arm, said: "Gastrointestinal bleeding episodes are a major life-threatening complication of LVAD implants that occur in 20-40% of recipients in the first six months, resulting in recurrent hospitalizations and compromising quality of life. Confirmation of our previous observations that Mesoblast's cell therapy reduced major bleeding episodes and related hospitalizations would identify a therapeutic approach that could greatly benefit these patients."

In a 30-patient pilot trial, Mesoblast's allogenic mesenchymal precursor cell (MPC) therapy Revascor showed a 70% reduction in GI bleeding events. This formed the basis for the successful Regenerative Medicine Advanced Therapy (RMAT) submission by Mesoblast to the United States Food and Drug Administration (FDA) for Revascor in 2017. Moreover, a 76% reduction in GI bleeding events was observed in the recent 159-patient trial ($p<0.001$). This was further associated with a 65% reduction in hospitalizations due to GI bleeding ($p<0.001$).

Mesoblast plans to meet with the FDA in the upcoming quarter to discuss an approval pathway for Revascor under its existing RMAT designation, which provides eligibility for priority review and accelerated approval. Mesoblast has received guidance from the FDA that reduction in GI bleeding and associated hospitalizations are a clinically meaningful outcome that can support marketing approval. Mesoblast will present the concordant results from the prior two trials, together with the plan for a confirmatory trial powered for the primary endpoint of reduction in GI bleeding.

Annetine C. Gelijns, PhD; Chair, Department of Population Health Science & Policy, Edmond A. Guggenheim Professor of Health Policy and Co-Director, InCHOIR, said: "The commitment to work on a new trial demonstrates our shared vision to confirm our observations of a reduction in major gastrointestinal bleeding episodes and associated hospitalizations in LVAD patients as part of the pathway of introducing this therapy into real world clinical practice."

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 technology platform to establish a broad portfolio of late-stage 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 Nasdaq (MESO). www.mesoblast.com

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Forward-Looking Statements

This announcement includes forward-looking statements that relate to future events or our future clinical development and 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 and its collaborators' preclinical and clinical studies; Mesoblast and its collaborators' 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.

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