

REMESTEMCEL-L TO BE EVALUATED AS TREATMENT FOR CHRONIC GRAFT VERSUS HOST DISEASE IN PLANNED INVESTIGATOR-INITIATED TRIAL

Melbourne, Australia, August 14, 2019 and New York, USA, August 13, 2019: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in cellular medicines for inflammatory diseases, today announced that it intends to provide its allogeneic cell therapy product candidate remestemcel-L for evaluation under an investigator-initiated Investigational New Drug (IND) submission as a potential treatment in children with steroid-refractory *chronic* graft-versus-host disease (GVHD). The lead investigator will be Dr Joanne Kurtzberg, Jerome Harris Distinguished Professor of Pediatrics and Professor of Pathology, and Director, Pediatric Blood and Marrow Transplant Program at Duke University Medical Center.

In both *acute* and *chronic* forms of GVHD, the donated bone marrow stem cells view the recipient's body as foreign, and attack the body causing significant morbidity and mortality. *Acute* GVHD usually manifests within 100 days following a transplant while *chronic* GVHD generally manifests later (>100 days), and the two may occur separately or within the same patient.

The incidence of *chronic* GVHD is increasing and occurs in 30-70% of recipients of both related and unrelated bone marrow transplants.^{1,2} There are no therapies approved by the United States Food and Drug Administration (FDA) in the 50% of children with *chronic* GVHD who fail steroids. Mesenchymal stem cells have been used successfully in patients with steroid-refractory *chronic* GVHD and have been reported to result in durable responses in up to 75% of patients.³⁻⁵

Dr Kurtzberg said: "Given my experience with achieving successful outcomes with remestemcel-L in children with steroid-refractory *acute* GVHD, I look forward to evaluating the treatment's potential as salvage therapy in *chronic* GVHD, where there remains a significant unmet need."

Earlier this year, Mesoblast initiated filing of a rolling submission for a Biologics License Application (BLA) to the FDA for the use of remestemcel-L in children with steroid-refractory *acute* GVHD. This BLA submission is based on a successful Phase 3 trial in 55 children with steroid-refractory *acute* GVHD and supporting results from an Expanded Access Program (EAP) in 241 children. Dr Kurtzberg was the Principal Investigator in both trials.

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 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). www.mesoblast.com

1. Arai et al. Biol Blood Marrow Transplant. 2015; 21(2): 266–274.
2. Grube et al. Biol Blood Marrow Transplant: 2016; 22 (11): 1781-179
3. Went et al. Bone Marrow Transplantation 2010; 45:1732-1740.
4. Shai et al. Blood 2013; 122:3294.
5. von Bahr et al. Blood 2015; 126:3138.

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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. 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 in aGVHD; Mesoblast's ability to advance its aGVHD product candidate into, enroll and successfully complete, clinical studies; the timing or likelihood of regulatory filings and approvals for aGVHD; 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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