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KEY OUTCOMES FROM FDA TYPE A MEETING AND MESOBLAST NEXT STEPS TO ACHIEVE RYONCIL APPROVAL

Melbourne, Australia; September 21 and New York, USA; September 20, 2023: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today provided an update on the path to approval for its lead-product candidate remestemcel-L in the treatment of pediatric and adult steroid-refractory acute graft versus host disease (SR-aGvHD), following a Type A meeting held with the United States Food and Drug Administration (FDA). FDA clarified that the key remaining issue for pediatric approval is providing further evidence that the potency assay will assure the consistent efficacy of commercial product.

The key outcomes of the meeting and Mesoblast next steps are:

- Mesoblast summarised the large body of existing clinical data with the improved Ryoncil® product version of remestemcel-L, manufactured after 2008 using the current process inspected by FDA, for potential approval in children.
- Mesoblast presented clinical data indicating that RYONCIL was associated with much higher survival of children with SR-aGVHD in the Expanded Access Protocol (EAP) compared with the earlier Prochymal version manufactured before 2008.
- Mesoblast presented consistently high survival in patients treated in RYONCIL, in children with SR-aGVHD in the EAP between 2008-2015, in the Phase 3 trial MSB-GVHD001 between 2015-2018, and in the Emergency Investigational New Drug (EIND) protocol from 2015-2023.
- FDA noted that the lack of a suitable potency assay for the RYONCIL product used during the Phase 3 trial MSB-GVHD001 for the pediatric acute GVHD indication has prevented the trial from being considered an adequate study for the purpose of demonstrating substantial evidence of effectiveness required for a marketing approval.
- Mesoblast intends to generate in the coming months new potency assay data for RYONCIL showing that the product used during pediatric Phase 3 trial MSB-GVHD001 was standardized as to its identity, strength, quality, purity, and dosage form to give significance to the results of the investigation as described in the Code of Federal Regulations for adequate and well-controlled studies (21 CFR 314.126), and that commercial batches made for the pediatric indication will meet the same standard.
- Mesoblast believes these additional data will provide a link between the RYONCIL product that was used in the Phase 3 trial MSB-GVHD001 for the pediatric indication to the RYONCIL product which will be used in a future trial for the adult indication.
- To address the adult indication, Mesoblast proposed an externally controlled single-arm registration trial design in adults and children over age 12 with SR-aGVHD who have failed both steroids and a second line agent, such as ruxolitinib, to be underpinned by a suitable potency assay.
- Mesoblast intends to perform this trial in partnership with world-leading investigators at the Blood and Marrow Clinical Trials Network (BM CTN), a body responsible for approximately 80% of all US transplants, with the costs expected to be covered by previously announced reductions in operational spend.
- FDA indicated its willingness to consider Mesoblast's proposed registrational trial design in adults, subject to agreement on the suitability of the potency assay for the product to be used in adults.

Mesoblast expects to receive the formal minutes of the Type A meeting within three weeks.

Mesoblast Chief Executive Silviu Itescu said: "We had a very productive meeting with the FDA's review team, allowing us to establish the path forward for potential approval of remestemcel-L in SR-aGVHD. We are gathering the additional potency assay data required to demonstrate the ability of Mesoblast's potency assay to show both the product used in the Phase 3 trial in children and the product made for

commercial release are standardized. In parallel, we are focused on initiating a registration trial in adults in partnership with world-leading investigators at the Blood and Marrow Clinical Trials Network."

About Mesoblast

Mesoblast (the Company) is a world leader in developing allogeneic (off-the-shelf) cellular medicines for the treatment of severe and life-threatening inflammatory conditions. The Company has leveraged its proprietary mesenchymal lineage cell therapy technology platform to establish a broad portfolio of late-stage product candidates which respond to severe inflammation by releasing anti-inflammatory factors that counter and modulate multiple effector arms of the immune system, resulting in significant reduction of the damaging inflammatory process.

Mesoblast has a strong and extensive global intellectual property portfolio with protection extending through to at least 2041 in all major markets. The Company's proprietary manufacturing processes yield industrial-scale, cryopreserved, off-the-shelf, cellular medicines. These cell therapies, with defined pharmaceutical release criteria, are planned to be readily available to patients worldwide.

Mesoblast is developing product candidates for distinct indications based on its remestemcel-L and rexlemestrocel-L allogeneic stromal cell technology platforms. Remestemcel-L is being developed for inflammatory diseases in children and adults including steroid refractory acute graft versus host disease, biologic-resistant inflammatory bowel disease, and acute respiratory distress syndrome. Rexlemestrocel-L is in development for advanced chronic heart failure and chronic low back pain. Two products have been commercialized in Japan and Europe by Mesoblast's licensees, and the Company has established commercial partnerships in Europe and China for certain Phase 3 assets.

Mesoblast has locations in Australia, the United States and Singapore 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

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. Forward-looking statements include, but are not limited to, statements about: the initiation, timing, progress and results of Mesoblast's preclinical and clinical studies, and Mesoblast's research and development programs; Mesoblast's ability to advance product candidates into, enroll and successfully complete, clinical studies, including multi-national clinical trials; Mesoblast's ability to advance its manufacturing capabilities; the timing or likelihood of regulatory filings and approvals (including the definitive outcome of the Type A meeting with the FDA, and any future decision that the FDA may make on the BLA for remestemcel-L for pediatric patients with SR-aGVHD), manufacturing activities and product marketing activities, if any; the commercialization of Mesoblast's product candidates, if approved; regulatory or public perceptions and market acceptance surrounding the use of stem-cell based therapies; the potential for Mesoblast's product candidates, if any are approved, to be withdrawn from the market due to patient adverse events or deaths; the potential benefits of strategic collaboration agreements and Mesoblast's ability to enter into and maintain established strategic collaborations; Mesoblast's ability to establish and maintain intellectual property on its product candidates and Mesoblast's ability to successfully defend these in cases of alleged infringement; the scope of protection Mesoblast is able to establish and maintain for intellectual property rights covering its product candidates and technology; estimates of Mesoblast's expenses, future revenues, capital requirements and its needs for additional financing; Mesoblast's financial performance; developments relating to Mesoblast's competitors and industry; 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

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any forward-looking statements, whether as a result of new information, future developments or otherwise.

Release authorized by the Chief Executive.

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