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U.S. FDA ADVISORY COMMITTEE VOTES NINE TO ONE IN FAVOR OF REMESTEMCEL-L (RYONCIL™) FOR EFFICACY IN CHILDREN WITH STEROID-REFRACTORY ACUTE GRAFT VERSUS HOST DISEASE

Melbourne, Australia; August 14, 2020; and New York, USA; August 13, 2020: Mesoblast Limited (ASX:MSB; Nasdaq: MESO), global leader in cellular medicines for inflammatory diseases, today announced that the Oncologic Drugs Advisory Committee (ODAC) of the United States Food and Drug Administration (FDA) voted overwhelmingly in favor that the available data support the efficacy of remestemcel-L (RYONCIL™) in pediatric patients with steroid-refractory acute graft versus host disease (SR-aGVHD).

Mesoblast Chief Medical Officer Dr Fred Grossman said: "Steroid-refractory acute graft versus host disease is an area of extreme need, especially in vulnerable children under 12 years old where there is no approved therapy. We are very encouraged by today's outcome and are committed to working closely with the FDA as they complete their review of our submission regarding approval of RYONCIL for this life-threatening complication of an allogeneic bone marrow transplant."

The ODAC is an independent panel of experts that evaluates efficacy and safety of data and makes appropriate recommendations to the FDA. Although the FDA will consider the recommendation of the panel, the final decision regarding the approval of the product is made solely by the FDA, and the recommendations by the panel are non-binding. RYONCIL has been accepted for Priority Review by the FDA with an action date of September 30, 2020, under the Prescription Drug User Fee Act (PDUFA). If approved by the PDUFA date, Mesoblast plans to launch RYONCIL in the United States in 2020.

Pediatric transplant physician Dr Joanne Kurtzberg, the Jerome Harris Distinguished Professor of Pediatrics and Professor of Pathology, and Director, Pediatric Blood and Marrow Transplant Program at Duke University Medical Center, said: "This devastating condition has an extremely poor prognosis and there are no FDA-approved options for children under the age of 12. The clinical studies I have directed have demonstrated the potential for this treatment to fill a significant unmet medical need."

Conference Call
An audio webcast will begin at 10.30am AEST Friday August 14; 8.30pm EDT Thursday, August 13, 2020. The webcast can be accessed via https://webcast.boardroom.media/mesoblast-limited/20200813/NaN5f3237e85300840019de909d

The archived webcast will be available on the Investor page of the Company's website www.mesoblast.com

About Acute Graft Versus Host Disease
Acute GVHD occurs in approximately 50% of patients who receive an allogeneic bone marrow transplant (BMT). Over 30,000 patients worldwide undergo an allogeneic BMT annually, primarily during treatment for blood cancers, and these numbers are increasing.[1] In patients with the most severe form of acute GVHD (Grade C/D or III/IV) mortality is as high as 90% despite optimal institutional standard of care.[2,3] There are currently no FDA-approved treatments in the United States for children under 12 with SR-aGVHD, a potentially life-threatening complication of an allogeneic bone marrow transplant for blood cancer.

About RYONCIL™
Mesoblast's lead product candidate, RYONCIL (remestemcel-L), is an investigational therapy comprising culture-expanded mesenchymal stem cells derived from the bone marrow of an unrelated

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donor. It is administered to patients in a series of intravenous infusions. RYONCIL is believed to have immunomodulatory properties to counteract the inflammatory processes that are implicated in steroid-refractory acute graft versus host disease by down-regulating the production of pro-inflammatory cytokines, increasing production of anti-inflammatory cytokines, and enabling recruitment of naturally occurring anti-inflammatory cells to involved tissues.

1. Niederwieser D, Baldomero H, Szer J. Hematopoietic stem cell transplantation activity worldwide in 2012 and a SWOT analysis of the Worldwide Network for Blood and Marrow Transplantation Group including the global survey. Bone Marrow Transplant 2016; 51(6):778-85.
2. Westin, J., Saliba, RM., Lima, M. (2011) Steroid-refractory acute GVHD: predictors and outcomes. Advances in Hematology 2011;2011:601953.
3. Axt L, Naumann A, Toennies J (2019) Retrospective single center analysis of outcome, risk factors and therapy in steroid refractory graft-versus-host disease after allogeneic hematopoietic cell transplantation. Bone Marrow Transplantation 2019;54(11):1805-1814

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 mesenchymal lineage cell therapy technology platform to establish a broad portfolio of commercial products and late-stage product candidates. Mesoblast has a strong and extensive global intellectual property (IP) portfolio with protection extending through to at least 2040 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's Biologics License Application to seek approval of its product candidate RYONCIL™ (remestemcel-L) for pediatric steroid-refractory acute graft versus host disease (acute GVHD) has been accepted for priority review by the United States Food and Drug Administration (FDA), and if approved, product launch in the United States is expected in 2020. Remestemcel-L is also being developed for other inflammatory diseases in children and adults including moderate to severe acute respiratory distress syndrome. Mesoblast is completing Phase 3 trials for its product candidates for advanced 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 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 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 any decision that the FDA may make based upon the recommendation of the ODAC in relation to the efficacy of remestemcel-L), manufacturing activities

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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; 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 authorized by the Chief Executive.

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