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mesoblast

UPDATE ON SCHEDULED FDA ADVISORY COMMITTEE MEETING

Melbourne, Australia; August 11, 2020; and New York, USA; August 10, 2020: Mesoblast Limited (ASX:MSB; Nasdaq:MESO) today provided an update on the scheduled meeting of the Oncologic Drugs Advisory Committee (ODAC) of the United States Food and Drug Administration (FDA) which will review data supporting the Company's Biologics License Application (BLA) for approval of RYONCIL™ (remestemcel-L) in the treatment of steroid-refractory acute graft versus host disease (SR-aGVHD) in children. 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.

The meeting is scheduled to take place on August 13, 2020 from 8am to 5pm ET. The ODAC will vote in the afternoon session on whether the available data support the efficacy of remestemcel-L in pediatric patients with SR-aGVHD. This session will discuss the Phase 3 trial results and supporting clinical data included in the BLA. The morning session will be non-voting and will discuss issues related to the characterization and critical quality attributes of remestemcel-L.

Mesoblast has extensively prepared for this meeting and has provided a publicly available briefing book. Briefing materials and webcast information have been made publicly available and can be found on the FDA website at: https://www.fda.gov/advisory-committees/advisory-committee-calendar/august-13-2020-meeting-oncologic-drugs-advisory-committee-meeting-announcement-08132020-08132020#event-materials

The ODAC is an independent panel of experts that provides advice and appropriate recommendations to the FDA based on potential issues highlighted by the FDA during their review of the efficacy and safety of marketed and investigational products for use in the treatment of cancer. Although the FDA will consider the recommendation of the advisory committee, the final decision regarding the approval of the product is made by the FDA solely, and the recommendations by the panel are non-binding.

RYONCIL is under Priority Review by the FDA with an action date of September 30, 2020, under the Prescription Drug User Fee Act (PDUFA).

About RYONCIL™ (remestemcel-L)
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 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.

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 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 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, if approved; 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. 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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