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MESOBLAST MAINTAINS MOMENTUM WITH FDA ON ACCELERATED APPROVAL PATHWAY FOR REVASCOR® IN ISCHEMIC HEART FAILURE AND LABEL EXTENSION FOR RYONCIL® IN ADULTS WITH GVHD

Melbourne, Australia; June 12 and New York, USA; June 11, 2025: Mesoblast (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today provided an update on continued momentum with United States Food and Drug Administration (FDA) regarding both accelerated approval pathway for Revascor® (rexlemestrocel-L) in the treatment of patients with ischemic chronic heart failure with reduced ejection fraction (HFrEF) and inflammation, and label extension for Ryoncil® (remestemcel-L-rknd) in adults with steroid refractory acute graft versus host disease (SR-aGvHD).

In the first week of June, Mesoblast held a Type B meeting with FDA under its Regenerative Medicines Advanced Therapy (RMAT) designation for REVASCOR to discuss components of a potential filing for a Biologics License Application (BLA). There was general alignment on items regarding chemistry, manufacturing & controls (CMC), potency assays for commercial product release, and proposed design and primary endpoint for the confirmatory trial post-approval. The Company will await the final minutes from FDA in order to provide detailed feedback and timelines for potential filing.

In early July, Mesoblast has an upcoming meeting with FDA to discuss a pivotal trial of Ryoncil® in adults with SR-aGvHD. This trial will be conducted with the NIH-funded Bone Marrow Transplant Clinical Trials Network (BMT-CTN), the objective being to extend the product's label from children to adults with SR-aGvHD. Ryoncil® is the first and only mesenchymal stromal cell product approved by the FDA for any indication.

Ryoncil® became commercially available for purchase in the United States on March 28, 2025, within one quarter of receiving FDA approval to treat children with SR-aGvHD. More than 20 transplant centers will have been onboarded by the end of the quarter, exceeding the company's expectations at product launch. Mesoblast has continued to expand coverage for Ryoncil® to over 220 million US lives insured by commercial and government payers. To date, 37 of the 51 States provide fee-for-service Medicaid coverage for Ryoncil® through Orphan Drug Lists or medical exception / prior authorization (PA) process. The remainder will come online July 1, 2025, with mandatory coverage for all 24 million lives.

"We are very pleased with the momentum of interactions with FDA on both our cardiac and GvHD programs," said Mesoblast Chief Executive Dr. Silviu Itescu. "We are also encouraged by the strength of the of the Ryoncil® commercial launch, the rate of hospital onboarding, physician adoption, and payor coverage exceeding our expectations in the ten weeks since commercial launch. We will be providing an update on sales of Ryoncil® in our quarterly activities report at the end of next month."

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 therapies from the Company's proprietary mesenchymal lineage cell therapy technology platform 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's RYONCIL® (remestemcel-L) for the treatment of steroid-refractory acute graft versus host disease (SR-aGvHD) in pediatric patients 2 months and older is the first FDA approved mesenchymal stromal cell (MSC) therapy. Please see the full Prescribing Information at www.ryoncil.com.

Mesoblast is committed to developing additional cell therapies for distinct indications based on its remestemcel-L and rexlemestrocel-L allogeneic stromal cell technology platforms. RYONCIL is being developed for additional inflammatory diseases including SR-aGvHD in adults and biologic-resistant

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inflammatory bowel disease. Rexlemestrocel-L is being developed for heart failure and chronic low back pain. The Company has established commercial partnerships in Japan, Europe and China.

About Mesoblast intellectual property: Mesoblast has a strong and extensive global intellectual property portfolio, with over 1,000 granted patents or patent applications covering mesenchymal stromal cell compositions of matter, methods of manufacturing and indications. These granted patents and patent applications are expected to provide commercial protection extending through to at least 2041 in major markets.

About Mesoblast manufacturing: 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 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 X: @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, manufacturing activities and product marketing activities, if any; the commercialization of Mesoblast's RYONCIL for pediatric SR-aGVHD and any other 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 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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